DEA Questions and Answers on Policy Issues
From the ASCP Annual Meeting 2018

ASCP provided a forum for the discussion of certain controlled substance compliance questions and the issues below were verbally clarified by Loren Miller, DEA Section Chief for Policy, at the Chat with the DEA session during the ASCP Annual Meeting on Sunday, November 4, 2018.

**Question #1: What are the requirements of a prescription for a product that is to be dispensed out of the emergency kit?**

**Answer:** In order to remove a controlled substance product from the emergency kit, there must be a valid prescription just as there would be if the product was being dispensed from the pharmacy. Every prescription for a controlled substance must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her profession. See 21 CFR §1306.04(a). In order to be a valid prescription, it must have all of the elements in 21 CFR §1306.11 if it is a Schedule II controlled substance, or all of the elements in 21 CFR §1306.21 if it is a Schedule III-V controlled substance. Prescriptions may be (i) delivered to the pharmacy in hardy copy form; (ii) sent to the pharmacy as an electronic prescription in accordance with 21 CFR §1306.08; (iii) faxed to the pharmacy in accordance 21 CFR §1306.21(c) or 21 CFR §1306.11(f); or (iv) communicated to the pharmacy verbally in accordance with 21 CFR §1306.11(d).

**Question #2: May a pharmacy use a single prescription from an authorized practitioner to dispense the initial dose from the emergency kit and any additional quantity for continuation of medication from the pharmacy?**

**Answer:** Yes, provided that certain conditions are met. First, the prescription must be a valid prescription for a controlled substance that was issued by the practitioner for a legitimate medical purpose. See 21 CFR §1306.04(a). Secondly, the valid prescription must have all of the elements required by law. See 21 CFR §1306.11 and 21 CFR §1306.21. Thirdly, the prescription must be eligible to be partially filled under 21 CFR §1306.13(b) or 21 CFR §1306.23. Lastly, the emergency kit must be utilized in accordance with DEA’s Statement of Policy titled Controlled Substances in Emergency Kits for Long Term Care Facilities and applicable state law.

**Question 3: May a pharmacy place a controlled substance which is packaged in a multi-dose container (i.e., morphine sulfate liquid - Roxanol®) into the emergency kit at the long-term care facility?**

**Answer:** Yes, so long as the product is the smallest commercially available container. For example, if morphine sulfate is available in 15mL, 30mL and 100mL bottles; the pharmacy should utilize the 15mL container for placement in their emergency kits.

These questions will be posted to the ASCP DEA Practice Resource Center (PRC) on our website. When ASCP receives written responses on these issues, that information will also be posted on the PRC. Contact: Arnie Clayman at ASCP – aclayman@ascp.com