Dear Mr. Clayman:

This is in response to a request made to the Drug Enforcement Administration (DEA) by the American Society of Consultant Pharmacists (ASCP) during a meeting on August 22, 2018, and subsequent conversations that have taken place between the ASCP and the DEA. The DEA apologizes for the delay in this response and appreciates the opportunity to address the ASCP’s request.

The ASCP noted there are times when a retail pharmacy servicing a patient in a Long Term Care Facility (LTCF) has in the pharmacy’s physical possession a prescription for a controlled substance for that patient. However, due to issues such as distance between the pharmacy and LTCF, or inclement weather, the pharmacy is unable to deliver the controlled substance to the LTCF within a timeframe which best meets the patient’s medical needs. If the pharmacy has placed a DEA registered Automated Dispensing System (ADS) in the LTCF then no issue should exist, as the pharmacy can release the needed dosage to the patient through this system. Unfortunately, not all retail pharmacies servicing patients in LTCFs are utilizing the ADS option. The ASCP advised that, as an alternative, if a retail pharmacy placed an Emergency Kit (E-Kit) in the LTCF, then in the interest of patient care, the pharmacy could instruct the LTCF staff to withdraw the initial dose of this prescription from the E-Kit with all subsequent doses physically delivered to the LTCF by the retail pharmacy. However, in exploring this alternative the ASCP membership had received conflicting information from the DEA’s field offices as to whether the DEA agreed with the use of the E-Kit in this fashion. Further, the ASCP was aware the DEA’s Diversion Control Division took the position in 2017 that such an alternative seemed to be in conflict with existing regulations. The ASCP asked the DEA to reconsider its position on this subject. The DEA has reviewed the information the ASCP has provided and is in agreement with the ASCP that the alternative as outlined above does not conflict with the CSA or its implementing regulations, and may contribute toward good patient care.

As background, on April 9, 1980, the DEA published in the Federal Register a Statement of Policy (45 FR 24128) which addressed the storage of controlled substances in E-Kits for LTCFs. According to this Statement of Policy, “the placement of emergency kits containing controlled substances in non-federal registered LTCFs shall be deemed to be in compliance with the
Comprehensive Drug Abuse Prevention and Control Act of 1970, if the appropriate state agency or regulatory authority specifically approves such placement and promulgates procedures which delineate. . . . One item that the states were to delineate is found in part (D) of the Statement of Policy. "The emergency medical conditions under which the controlled substances may be administered to patients in the LTCF to include the requirement that medication be administered by authorized personnel only as expressly authorized by an individual practitioner and in compliance with the provisions of Title 21, Code of Federal Regulations, Section 1306.11 (21 C.F.R. § 1306.11) and 21 C.F.R. § 1306.21."

It is also important to note 21 C.F.R. § 1306.11(d) deals with the issuance by a practitioner of an oral prescription for a schedule II controlled substance in an emergency, as defined by the Secretary of the Department of Health and Human Services in 21 C.F.R. § 290.10.

Unfortunately, it has become clear that over time some confusion has arisen on whether LTCF staff can access an E-Kit in an LTCFs only when all of the criteria in 21 C.F.R. 1306.11(d) are met. It is true that 21 C.F.R. § 1306.11(d) is one condition under which controlled substances can be dispensed from an E-Kit in an LTCF, but it is not the only condition. The DEA issued the 1980 Statement of Policy so that state licensing and regulatory boards could promulgate specific rules on the use and handling of controlled substances in E-Kits in LTCFs. Thus, it falls to each state to determine if, in addition to 21 C.F.R. § 1306.11(d), there are any other conditions under which a pharmacy may dispense a controlled substance from an E-Kit at an LTCF.

The DEA takes this opportunity to reiterate that a pharmacy may only dispense controlled substances in compliance with Federal law and regulation. One of the most important principles underlying the CSA and its implementing regulations is that to be valid every prescription for a controlled substance must be based on a determination by an individual practitioner that the dispensing of the controlled substance is for a legitimate medical purpose in the usual course of professional practice. United States v. Moore, 423 U.S. 122 (1975) and 21 C.F.R. § 1306.04(a). A DEA registered retail pharmacy that plans to dispense a controlled substance to a patient in an LTCF first will need to have in its physical possession the valid prescription before any dispensing takes place. Further, each such prescription will contain all of the specific information as outlined in 21 C.F.R. § 1306.11(d) and 21 C.F.R. § 1306.13(b) prior to dispensing.

The DEA, in an effort to help registrants remain compliant with the CSA and its implementing regulations, takes this opportunity to underscore some potential hazards existing when a retail pharmacy authorizes the withdrawal of the initial dose of a controlled substance from an E-Kit. The DEA does not intend this to be an all-inclusive list of potential hazards:

- As discussed earlier, this letter addresses the ASCP’s request to allow a retail pharmacy servicing a patient in an LTCF, and possessing a valid prescription for the patient, to instruct the LTCF staff to withdraw the initial dose of the patient’s prescription from the E-Kit with all subsequent doses physically delivered to the LTCF by the retail pharmacy. This letter does not, and should not, be considered approval by the retail pharmacy for any pharmacy to use the E-Kit for general dispensing to the LTCF patient. Such general dispensing is addressed through the use of an ADS.
A DEA registered retail pharmacy is required to maintain complete and accurate records of its handling of controlled substances at all times. Title 21, United States Code, Section 827 (21 U.S.C § 827) and 21 C.F.R. § 1304.21(a). This includes the retail pharmacy generating and maintaining a record of the dispensing of this initial dose, at the time of the dispensing. This record could be on the prescription itself or in the electronic records, the pharmacy maintains regarding this prescription. 21 U.S.C. § 827 and 21 C.F.R. § 1304.03. However, the DEA has previously encountered situations where retail pharmacies, dispensing controlled substances from E-Kits, have failed to generate or maintain such records. The pharmacy is then in the position of having incomplete or inaccurate records, which may result in administrative, civil, or criminal penalties.

As referenced earlier, a DEA registered retail pharmacy is required to maintain complete and accurate records of its handling of controlled substances at all times. This is reiterated in part C of the 1980 Statement of Policy. However, the DEA has encountered situations where retail pharmacies, dispensing controlled substances from E-Kits in an emergency, have failed to generate or maintain the records necessary to appropriately document and account for the restocking of these kits.

There are times when a patient in an LTCF has a controlled substance prescription that expires, and the patient’s practitioner has not yet communicated a subsequent follow up prescription to the servicing pharmacy. The pharmacy has no authority to dispense a controlled substance from the E-Kit in expectation of receiving a future prescription. As mentioned earlier, the pharmacy will have the prescription in its physical possession prior to the pharmacy authorizing any dispensing of controlled substances from the E-Kit.

The DEA has concluded in consultation with the ASCP, and in the interest of patient care, a pharmacy that has in its physical possession a prescription for a controlled substance, and has placed an E-Kit in an LTCF, could instruct the LTCF staff to withdraw the initial dose of this prescription from that E-Kit, with all subsequent doses not being dispensed from the E-Kit but physically delivered to the LTCF by the retail pharmacy. However, such activity can only take place if the appropriate state authority (state licensing or regulatory board) has first promulgated rules authorizing such activity. The DEA communicated this information to the ASCP at their annual meeting on November 4, 2018.

I trust this letter adequately addresses the concerns raised by the ASCP. 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 Policy Section at (202) 307-7297.

Sincerely,

John J. Martin
Assistant Administrator
Diversion Control Division