



February 19, 2013

Drug Enforcement Administration
Attention: DEA Office of Diversion Control
(OD/DX)
8701 Morrissette Drive
Springfield, Virginia 22152

Comment on FR Doc # 2012-30699
Document ID DEA-2012-0008-0001

RE: Docket No. DEA – 316

To Whom It May Concern,

The National Hospice and Palliative Care Organization (“NHPCO”) is the largest nonprofit membership organization representing hospice and palliative care programs and professionals in the United States. We represent over 2,400 hospices in the United States, and our members care for the vast majority of the nation’s hospice patients. The organization is committed to improving end-of-life care and expanding access to hospice care with the goal of creating an environment in which individuals and families facing serious illness, death, and grief will experience the best that humankind can offer.

The National Hospice and Palliative Care Organization (“NHPCO”) appreciates the opportunity to provide comments in response to the Drug Enforcement Administration (DEA) proposed rule regarding the secure disposal of controlled substances. Hospice plays a key role in facilitating the disposal of controlled substances for patients and families. With the patient population we serve, we are in patients’ homes every day, and while we recognize that the end user – the patient – is the owner of the drugs, hospice nurses regularly provide instruction to patients and families on how to dispose of no longer needed medications.

The Medicare Hospice Conditions of Participation require hospices to have a drug disposal policy, as printed below.

§ 418.106 Condition of participation: Drugs and biologicals, medical supplies, and durable medical equipment.

Medical supplies and appliances, as described in § 410.36 of this chapter; durable medical equipment, as described in § 410.38 of this chapter; and drugs and biologicals related to the palliation and management of the terminal illness and related conditions, as identified in the hospice plan of care, must be provided by the hospice while the patient is under hospice care.

(e) Standard: Labeling, disposing, and storing of drugs and biologicals.

- (1) Labeling. Drugs and biologicals must be labeled in accordance with currently accepted professional practice and must include appropriate usage and cautionary instructions, as well as an expiration date (if applicable).
- (2) Disposing.
 - (i) Safe use and disposal of controlled drugs in the patient's home. The hospice must have written policies and procedures for the management and disposal of controlled drugs in the patient's home. At the time when controlled drugs are first ordered the hospice must:
 - (A) Provide a copy of the hospice written policies and procedures on the management and disposal of controlled drugs to the patient or patient representative and family;
 - (B) Discuss the hospice policies and procedures for managing the safe use and disposal of controlled drugs with the patient or representative and the family in a language and manner that they understand to ensure that these parties are educated regarding the safe use and disposal of controlled drugs; and
 - (C) Document in the patient's clinical record that the written policies and procedures for managing controlled drugs was provided and discussed.
 - (ii) Disposal of controlled drugs in hospices that provide inpatient care directly. The hospice that provides inpatient care directly in its own facility must dispose of controlled drugs in compliance with the hospice policy and in accordance with State and Federal requirements. The hospice must maintain current and accurate records of the receipt and disposition of all controlled drugs.
- (3) Storing. The hospice that provides inpatient care directly in its own facility must comply with the following additional requirements—
 - (i) All drugs and biologicals must be stored in secure areas. All controlled drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1976 must be stored in locked compartments within such secure storage areas. Only personnel authorized to administer controlled drugs as noted in paragraph (d)(2) of this section may have access to the locked compartments; and
 - (ii) Discrepancies in the acquisition, storage, dispensing, administration, disposal, or return of controlled drugs must be investigated immediately by the pharmacist and hospice administrator and where required reported to the appropriate State authority. A written account of the investigation must be made available to State and Federal officials if required by law or regulation.

The comments are separated by the location of the patient and how this proposed rule may impact the hospice in caring for those patients.

Hospice patients in their own homes

1. We believe that the proposed rule is unclear about how unused controlled substances can be appropriately disposed of when a hospice patient has controlled substances that are no longer needed or that remain after a patient dies at home. The proposed rule states that the currently used practices of flushing or mixing with kitty litter or coffee grounds do not meet the new destruction standard of making the drug “non-retrievable.” One suggestion in the proposed rule, for incineration, is not possible in the home setting. A second suggestion, chemical digestion may be possible if common household products, such as bleach, laundry detergent, or acetone could be used for the digestion process. We request that in the final rule you provide more guidance regarding drug destruction for the health care professional who is working with a patient in the home setting. Are such professionals limited to advising end users about the availability of mail back and take back programs, and the location of authorized collection receptacles?
2. Some hospice providers use the product "Liqui-Loc" to render controlled substances non-retrievable and have asked whether use of this product will be acceptable as the proposed rule becomes final.
3. Upon the death of the patient, the final rule should address the opportunity for surviving spouses, legally recognized partners or caregivers to dispose of the unused controlled substances. Hospices work with these survivors around the many tasks that must be completed in the home after the death of a patient, including instruction on the proper disposal of unused medications.
4. Wider availability of mail back programs could be very useful, and hospices could play a role in facilitating this method of drug disposal by providing patients and families with a mail-back envelope for their use. We hope that hospices could deliver the mail back envelopes and explain to patients and families how to use that method of drug disposal, but there is significant concern about the cost to patients and families of the mail-back supplies, and whether that would be a barrier to use. We ask that the DEA include a recommendation for inexpensive or non-burdensome solutions for this method of drug disposal in the final rule, as well as commenting on the appropriate role of hospices in instructing patients and families on mail back and take back programs.

Hospice patients in a hospice inpatient facility

1. Hospices with their own hospice inpatient facilities may already be DEA registrants and can waste controlled substances on site without a DEA agent present. Current hospice practice is to comply with applicable federal, state and local laws regarding destruction.
2. If the hospice inpatient facility also has an in-house pharmacy (some but not all do), the pharmacy registration and the DEA license would govern destruction of the floor stock.

3. Some patients enter the hospice inpatient facility with controlled substances dispensed to the patient prior to their inpatient admission and brought with the patient to the facility from home. Hospice policy would dictate that those drugs are destroyed in compliance with the rules for hospice home care patients.

Hospice patients in long term care facilities

Hospices also provide care to terminally ill patients whose residence is a long term care facility. Many hospice patients in these settings require high doses of controlled substances to control pain and other difficult symptoms. NHPCO does not want to inadvertently discourage access to hospice services because of the extra burden of drug disposal in the long term care facility setting. We hope that the option of establishing disposal receptacles in these facilities will make disposal easier and safer.

Thank you for the opportunity to comment. We look forward to continuing to be part of the ongoing dialogue.

Sincerely,

A handwritten signature in cursive script, appearing to read "J. Donald Schumacher".

J. Donald Schumacher, PsyD
President and CEO
National Hospice and Palliative Care Organization