NAHC Resource: Hospice Disposal of Controlled Substances
November, 2018

Public Law 115-271—Support for Patients and Communities Act -- Opens Door for Hospice Disposal of Controlled Substances

BACKGROUND:
In September 2014 the Drug Enforcement Administration (DEA) issued final regulations implementing the Controlled Substances Act in which the agency clarified (for the first time) that hospices were prohibited from disposing or assisting in the disposal of controlled substances for hospice patients unless there was a state law granting authority to the hospice to do so. On October 24, 2018, a new law – the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (P.L. 115-271) – was enacted. Section 3222 of the SUPPORT for Patients and Communities Act provides authority for certain hospice staff in qualified hospices to dispose of controlled substances if those substances were lawfully dispensed to the person receiving hospice care.

The regulation governing the Controlled Substances Act created a significant stir in the hospice community; prior to the rule’s issuance nearly all hospices were either assisting with disposal or disposing of patient’s unused medications in an attempt to prevent diversion. Following publication of the regulations hospices were conflicted as many still felt an obligation to prevent diversion of the medications as much as possible. One positive aspect, though, was that hospices had an opportunity to revisit their role in the disposal of controlled substances. Some determined that they really did not want the risk of inserting their staff into the cycle of controlled substance possession and opted for education of patients or their caregivers on safe disposal without direct involvement of staff in disposal of the medications. On the other hand, as a result of lobbying by hospices and state homecare and hospice associations, some states passed laws giving hospice staff the authority to assist with or to dispose of controlled substances. Only in those states with such laws were hospice staff permitted to assist with disposal/dispose of controlled substances.

PROVISIONS OF THE SUPPORT FOR PATIENTS AND COMMUNITIES ACT:
Section 3222 of the SUPPORT for Patients and Communities Act authorizes specific hospice staff employed by or working under arrangement for qualified hospices to dispose of controlled substances following the patient’s death or upon expiration of the medication if those substances were lawfully dispensed to the person receiving hospice care. Hospices should review this section of the Act carefully and consider the following:
1. The SUPPORT for Patients and Communities Act (hereinafter referred to as the Act) must be considered alongside any state or local laws pertaining to the handling and disposal of controlled substances. Hospices must observe the most stringent requirement. Some of the expected variances between the Act and state or local laws include
   a. Types of staff that can dispose of the controlled substances. The Act allows only nurses (RN, LPN, NP), physicians, and physician assistants.
   b. When medications may be disposed of by hospice staff. The Act allows for this at the time of death, when the medication has expired, and when the patient no longer needs it due to modifications in the plan of care.
2. Hospices MAY follow the Act, but are not required to do so. Unless negated by state or local laws, hospices can still choose to not insert their staff into the disposal process. There are some good reasons a hospice may decide to go this route and it includes limiting risk of/accusations of hospice staff diversion.
3. The Act requires the hospice to train any nurses, physicians or physician assistants disposing of controlled substances in the disposal of controlled substances in a secure and responsible manner so as to discourage abuse, misuse, or diversion so this may require modifications to existing training or additional training topics. Also, evidence of this training should be maintained.
4. A hospice must have written policies and procedures regarding the disposal of controlled substances and must provide these policies and procedures to the patient*, patient representative and family at the time controlled substances are first ordered; discuss these with the patient and document the discussion.
5. After disposal by the hospice staff/assistance with disposal, the staff must document in the patient’s clinical record documents in the patient’s clinical record the type of controlled substance, dosage, route of administration, and quantity so disposed; and the time, date, and manner in which that disposal occurred.
6. For those hospices contracting with nurses (i.e. waiver for nursing shortage), review the contract to ensure that disposal of medications falls within the scope of the contract/arrangement.

*As of January 25, 2019 this requirement for policies and procedures is consistent with hospice conditions of participation at 418.106(e)(2). However, under the proposed rule Medicare and Medicaid Programs: Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction hospices would not have to provide policies and procedures but instead would have to provide information regarding the use, storage, and disposal of controlled drugs to the patient or patient representative, and family.

Applicable Federal Laws, Rules and Regulations

SUPPORT for Patients and Communities Act

SUPPORT Act, Sec. 3222, Disposal Of Controlled Substances Of A Hospice Patient By Employees Of A Qualified Hospice Program

Controlled Substances Act
Medicare and Medicaid Programs: Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction

Resources for Safe Storage and Disposal of Medications (can be used as part of an “admission packet”)

Disposal of Unused Medicines: What You Should Know (English with link to Spanish)

Where and How to Dispose of Unused Medications

Hospice and Palliative Nurses Association (HPNA) Recommendations for Safe Drug Disposal in the Home Setting

Suggested Content - Policies and Procedures

NAHC and its affiliate, the Hospice Association of America, recommend that hospices have policies and procedures encompass at least the following:

- Safe storage, management and disposal of controlled substances in the home – this typically would include
  - a statement that the hospice supports the safe storage, management and disposal of controlled substances and has procedures in place to educate the patient/representative/caregivers on methods of safe storage, management and disposal of controlled substances in the home
  - that these are explained verbally as well as in writing in a language and manner the patient/representative/caregiver understands
  - a description of the procedures the hospice follows to support safe storage, management and disposal of controlled substances (i.e. delivery methods, routine medication review and process of accounting for all medications, etc.)

- Process for identification and management of medication diversion/suspected diversion by patient/representative/caregivers, etc. as well as by hospice staff, volunteers or contractors.

- A procedure for training all current and new staff on safe storage, management and disposal of medications in the home as well as how controlled substances are handled, specifically the hospice staffs’ role in these areas, in facilities such as assisted living facilities and nursing homes.
  - Such training should be repeated any time there is a change in the policies/procedures and periodically, as needed
  - Documentation of training should be maintained by the hospice for each individual who may dispose of controlled substances

Please note: Hospices that provide inpatient care directly must observe the conditions of participation at §418.106(c), §418.106(d), §418.106(e), §418.106(e)(2)(C)(ii) and §418.106(e)(3), §418.106(e)(3)(ii).
Additional Resources:

**Applicable Federal Laws, Rules And Regulations**

**Controlled Substances Act**

**SUPPORT for Patients and Communities Act**

**Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction**

**Medicare Conditions of Participation for Hospices**

§418.106(e)(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:

§418.106(e)(2)(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;

§418.106(e)(2)(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

§418.106(e)(2)(C) - Document in the patient’s clinical record that the written policies and procedures for managing controlled drugs was provided and discussed.

**Resources for Safe Storage and Disposal of Medications**

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