DEA Responds to NAHC Questions Regarding Disposal of Controlled Substances
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The Drug Enforcement Administration (DEA) issued a Final Rule implementing the Disposal of Controlled Substances Act (Disposal Act) on September 9, 2014, that became effective on October 9, 2014. The Disposal Act provides that, “if a person dies while lawfully in possession of a controlled substance for personal use, any person lawfully entitled to dispose of the decedent’s property may deliver the controlled substance to another person for the purpose of disposal under the same conditions as provided” for ultimate users (21 U.S.C. 822(g)(4)). The Disposal Act and its implementing rule from the DEA have significant application in hospice and home care where controlled substances are in widespread use. The restrictions in the Disposal Act mean that hospice and home care staff can only take possession of the drugs for disposal purposes if that staff person is legally authorized to receive it and dispose of it, such as through a state law or rule. Otherwise, home hospice and home care personnel are not authorized to receive pharmaceutical controlled substances from patients or their family/caregiver for the purpose of disposal.

On December 10, 2014, NAHC and its affiliate, the Hospice Association of America (HAA), wrote to the DEA seeking clarification of the impact of the Disposal Act on hospice and home care programs. The topic was also covered in NAHC Report in its September 30, 2014, October 29, 2014, and January 4, 2015 editions. The DEA responded this week.

The DEA's response confirms NAHC and HAA’s interpretation of the Disposal Act and the new rules that staff can dispose of controlled substances in certain circumstances, but that staff is otherwise limited to assisting patients and other individuals in possession of the drugs with proper disposal. “Possession of a drug” means having the drug under a person’s control including activities such as handling them for purposes of disposal or taking the container and putting it in a mail-back envelope.

The DEA explained that a hospice or home care staff member can dispose of controlled substances where:

1. specifically authorized under state law to do so;
2. the drugs are considered “abandoned” such as when the patient dies or leaves them in a hospice residential facility and there is no authorized person available to take custody of the drugs;
3. the hospice pharmacy or inpatient unit meets the standards to qualify to become a “collector” or maintains authorized collection receptacles at the facility;
4. the disposal involves controlled substance waste; or
5. the hospice or home care provider supplies compliant mail-back packages to the patient or person with authority to possess the drugs and the staff deposits the sealed package in the mail.

The full text of the DEA responses is reproduced below.

“Q: When a hospice patient dies while under the care of a hospice, is it permissible for a person who had the authority to dispose of the personal property of the decedent to transfer possession of any controlled substances used in the care of the decedent to hospice personnel for purposes of proper disposal?

A: NO.

Q: Is it permissible for a hospice patient or household member of a hospice patient who is still alive to transfer possession of controlled substances to hospice personnel for purposes of proper disposal?

A: NO.
Q: If a state law provides that a member of the family or household of a deceased hospice patient is permitted or must transfer possession of controlled substances used by the decedent to hospice personnel for purposes of disposal under a prescribed disposal process, are the hospice personnel permitted to take possession of the controlled substances under the Disposal Act and the DEA’s implementing regulations?

A: **YES, if the state allows.** If so, is there a prescribed disposal method to be followed by the hospice? **Again, if the state allows, the authorized employee can insert the controlled substances into a mail-back package; transfer to law enforcement; or contact the local DEA for guidance on proper disposal procedures.**

Q: Can a hospice provide a compliant mail-back package to the ultimate user or a person with authority to dispose of a decedent’s personal property and take possession of the package for purposes of mailing it in accord with the process for mail-backs under Title 21, Code of Federal Regulations, Section 1317.70(b) (21 C.F.R. § 1317.70(b))?

A: **YES,** hospice can provide a compliant mail-back package to the patient or person with authority to dispose of the decedent’s property.

After the controlled substances are placed in the mail-back package and the package is sealed; the staff member can deposit it into the facility’s outgoing mail system in instances where the ultimate user or person with authority to dispose of the decedent’s property does not have access to the mailing system/room.

Please note, the ultimate user or the person with authority to dispose of a decedent’s personal property are not required to transfer the mail-back package to hospice staff for the purpose of mailing.

Q: Can hospice personnel directly dispose of controlled substance waste such as trace elements left in a syringe, pump bag, or cassette that was used in the administration of the drugs?

A: **YES,** and this holds true regardless as to whether or not the patient is deceased or alive.

Q: May the inpatient unit (IPU) qualify as any entity with authority to dispose of controlled substances under the applicable conditions for a hospital or skilled nursing facility?

A: **YES,** with regards to disposing of pharmaceutical wastage, the controlled substances can be disposed of in accordance with applicable Federal, State, tribal, and local laws and regulations (e.g., environmental, hazardous/biohazard, and other safety-related laws and regulations). For example, after a pre-filled syringe or a single-dose vial or syringe is administered to a patient, any remaining substance in the syringe or vial is not required to be destroyed in accordance with new Part 1317.

Q: Can the in-house pharmacy be used to lawfully collect and/or dispose of controlled substances?

A: **Only a DEA-registered pharmacy or hospital/clinic with an onsite pharmacy, who voluntarily modify its registration to become a collector, can collect controlled substances from ultimate users for the purpose of disposal.**

A DEA-registered pharmacy, who modifies its registration, can maintain receptacle(s) at long term care facilities.

Also the pharmacy, without modifying its registration, can partner with a DEA-registered mail-back collector for the purpose of providing packages to patients or authorized persons of the decedent’s property for the purpose of disposal.

Q: May the hospice staff and/or residential unit staff dispose of controlled substances under the same authority applicable to the “ultimate user” or otherwise when the patient dies or leaves the residential unit?
A:  If the patient dies or leaves the hospice facility and there isn’t an authorized person of the decedent’s property available to take custody of the controlled substances, the staff should treat the controlled substances as “abandoned” and insert into a mail-back package and mail; transfer them to law enforcement; or contact the local DEA for guidance on proper disposal procedures.”

The DEA went on to comment in its response, stating:

“The DEA appreciates the difficulties facing home hospice staff with regard to the disposal of pharmaceutical controlled substances. The Disposal Act provides that “if a person dies while lawfully in possession of a controlled substance for personal use, any person lawfully entitled to dispose of the decedent’s property may deliver the controlled substance to another person for the purpose of disposal under the same conditions as provided” for ultimate users. Title 21, United States Code, Section 822(g)(4) (21 U.S.C. § 822(g)(4)). Otherwise, home hospice and homecare personnel are not authorized to receive pharmaceutical controlled substances from ultimate users for the purpose of disposal. In addition, an ultimate user includes “a person who has lawfully obtained, and possesses, a controlled substance for his own use or for the use of a member of his household.”


Accordingly, a member of the hospice patient's household may dispose of the patient’s pharmaceutical controlled substances, but the home hospice or homecare provider cannot do so unless otherwise authorized by law (for example, under state law) to dispose of the decedent’s personal property. The rule provides a number of options for ultimate users and persons lawfully entitled to dispose of a deceased ultimate user’s property to safely and securely dispose of pharmaceutical controlled substances, yet the DEA does not require ultimate users to utilize these options.

However it is unlawful for ultimate users to transfer pharmaceutical controlled substances to unauthorized persons, and it is unlawful for unauthorized persons to receive such substances. It is also unlawful for an person to possess a controlled substance unless authorized to do so under the CSA (i.e., an ultimate user, an entity registered with the DEA, or an entity exempted from registration with the DEA). 21 U.S.C. § 844(a). Home hospice and other homecare providers are encouraged to assist their patients, and their patients’ families, in disposing of pharmaceutical controlled substances in accordance with the CSA and its implementing regulations. While education is paramount, home healthcare agencies are also encouraged to partner with authorized collectors to promote or jointly conduct mail-back programs.

The DEA understands that there may be circumstances where there is no authorized person to dispose of the controlled substances, such as when controlled substances are abandoned at a school or summer camp, and return to the ultimate user is not feasible. In such instances, the affected entities should contact local law enforcement or their local DEA office for guidance on proper disposal procedures.”

NAHC and its affiliate, Hospice Association of America, will continue to monitor the application of the DEA rules. We specifically recommend that hospice or home care providers check their state law and, if desired, through the state association seek to secure state law authorization to take possession of controlled substances upon the death of a patient. This will create a clear path to proper disposal of controlled substances in such circumstances. Otherwise, providers are encouraged to assist patients and their families/caregivers in the proper disposal of unused drugs through the use of compliant mail-back packages or other disposal methods where the provider staff do not take possession of the drugs.