On-Demand Clinical News

Proper Disposal of Medicine: A Review of the Disposal Act of 2010 and the Final Rule of 2014

Brett Gillis, PharmD

"In 2014, the Drug Enforcement Administration (DEA) issued a final rule for the disposal of pharmaceutical controlled substances by ultimate users in accordance with the Secure and Responsible Drug Act (Disposal Act) that was enacted in 2010. Policies and regulations related to each element of the disposal process, including the transfer, delivery, collection, destruction, return, and recall of controlled substances, by both registrants and non-registrants were reviewed. The intent is to discourage diversion and protect the environment."

An ultimate user is defined as a "person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household." All of the recommended collection methods (take-back events, mail-back programs, and collection receptacles) are voluntary and no one is required to establish or operate a disposal program, and no ultimate user is required to utilize any of these three methods. Although these three methods seek to protect the environment and discourage diversion, this rule does not prohibit ultimate users from using existing lawful methods (such as mixing the medication with an undesirable substance such as kitty litter or coffee grounds, sealing this mixture in a sealable bag, and throwing it out in the household trash; or flushing medications that appear on the FDA "Medicines Recommended for Disposal by Flushing" list). State and local laws may be more stringent than the federal regulations, so it is important to verify applicable state and local laws. Sec. 418.106 Condition of Participation also promulgates additional requirements for hospices.

The DEA appreciates the difficulties facing home hospice staff with regard to the disposal of controlled substances. Individuals lawfully entitled to dispose of an ultimate user decedent's property are authorized to dispose of the ultimate user's pharmaceutical controlled substances by using any of the three aforementioned recommended disposal options.

Upcoming Lunch and Learn Presentations

July

"Anticoagulation at End of Life"

Presenter: Joelle Potts, PharmD, CGP Tuesday, July 14, 2015 at 3:00pm ET; Wednesday, July 15, 2015 at 12:00pm ET

August

"Terminal Restlessness and Agitation in the Dying"

Presenter: Priya Narula, PharmD, CGP

Tuesday, August 11, 2015 at 3:00pm ET; Wednesday, August 12, 2015 at 12:00pm ET

RSVP by contacting Suzanne Stewart, Lunch and Learn Coordinator, at: 1-800-662-0586 ext. 3303 or <u>sstewart@procarerx.com.</u>

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Proper Disposal of Medicine continued from page 1

Accordingly, a member of the hospice patient's household may dispose of the patient's 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.

Furthermore, "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." The rule does *not* specifically authorize home hospice and homecare personnel to personally receive controlled substances from ultimate users for the purpose of disposal unless otherwise authorized by law (for example, under state law). Healthcare agencies have been encouraged to partner with authorized collectors to promote or jointly conduct mail-back programs.

Long-term care facilities (LTCFs) may dispose of controlled substances on behalf of an ultimate user who resides or has resided at that LTCF through a collection receptacle that is maintained by an authorized hospital/clinic or retail pharmacy at that LTCF. This allowance does *not* extend to other persons (for example, a hospice nurse) who are also attending to a person who is a resident of a LTCF unless authorized to do so under the Controlled Substances Act (CSA).

> Hospices are encouraged to partner with disposal programs and should continue to assist patients and families with the proper disposal of medications.

In summary, the Final Rule does *not* provide any new authorization for hospices or hospice employees related to controlled substances. Instead, it expands the entities to which ultimate users may transfer controlled substances and the methods by which such controlled substances may be collected, and goes on to clarify the recently expanded collection methods (take-back events, mail-back programs, and collection receptacles) as voluntary (the Final Rule does *not* prohibit ultimate users from using other existing lawful disposal methods). Hospices are encouraged to partner with disposal programs and should continue to assist patients and families with the proper disposal of medications as permitted by federal, state, and local law.

Resources

FOR HEALTHCARE PROFESSIONALS:

Information regarding drug disposal from the Office of Diversion Control (U.S. Department of Justice, DEA) is available online at: http://www.deadiversion.usdoj.gov/drug_disposal/

The Final Rule is available in the Federal Register or by accessing the DEA's website or PDF link at: <u>http://www.gpo.gov/fdsys/pkg/FR-2014-09-09/pdf/2014-20926.pdf</u>

The FDA provides additional information and a list of medications that should be flushed online at: <u>http://www.fda.gov/Drugs/ResourcesForYou/Consumers/Bu</u> <u>yingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeD</u> <u>isposalofMedicines/ucm186187.htm</u>

FOR THE PUBLIC:

Information and help sheets for the general public are available online under the Non-DEA Registrant (General Public) Drug Disposal heading from the Office of Diversion Control (U.S. Department of Justice, DEA) at: <u>http://www.deadiversion.usdoj.gov/drug_disposal/</u>

The public may also contact the Office of Diversion Control Call Center at 1-800-882-9539 or use their search engine at: <u>https://www.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s1</u> to locate a disposal location.





Complex Symptoms: Focus on Pain

Sheri Irvine, PharmD

Pain is a complex symptom in hospice patients that can be difficult to treat; however, identifying a plan that individualizes patient care will allow for better management. Some strategies are: using routine and PRN orders, minimizing pill burden through selecting medications that treat multiple symptoms, and by planning ahead to make sure medications are on hand.

To successfully treat refractory pain, one crucial step is identifying the type of pain and selecting medications that target it.

Nociceptive: Somatic or Visceral	Neuropathic	Bone Pain
 Muscle, tissue or organ pain May or may not radiate Dull, aching, or throbbing Preferred Analgesics Morphine, Oxycodone, Hydromorphone 	 Shooting, stabbing, radiating, burning, tingling, numb, electrical Preferred Analgesics Methadone and Adjuvants (ex. Gabapentin) 	 Inflammatory process Pain with movement Preferred Analgesics Corticosteroids, NSAIDs

Collecting information on the individual patient will also determine the appropriate therapy. This includes: primary diagnosis, renal and liver function, age, PMH, and current disease processes. We then assess the pain complaint: OPQRST (Onset, Provocation/Palliation, Quality, Region/Radiation, Severity, Time) and identity causes that can be eliminated. A step that is often forgotten is assessing caregivers, dosing, and formulation. For example, if a patient is unable to swallow a tablet, we need to provide an alternate formulation. Also, if a patient does not have adequate caregiver assistance, can we expect them to receive medications that are dosed frequently? Once the type of pain and appropriate medications are identified, we question whether or not current medication doses are optimized. Doses should be titrated to adequately control pain but minimize side effects.

Why not Methadone?	Methadone Monitoring
 One of the preferred long-acting opioids in end of life care Multiple routes of administration-PO, SL, PR, PV, SQ, IV, IM Unique receptor affinity The most effective opioid for neuropathic pain Less cognitive impairment and euphoria than other opioids Appropriate option for patients with renal or hepatic impairment Consider for patients with a morphine allergy/intolerance Preferred with > 7 day prognosis 	 Daily Methadone Checks x 5-7 days We DO expect: The patient to need more BTP medication in the first 1-3 days, while methadone reaches SS Increased sleepiness (especially if patient has not had pain control in a long time!) We DON'T expect: A pain crisis (10/10) Over-sedation or lethargy



Complex Symptoms: Focus on Pain continued from page 3

Oral Corticosteroids	Monitoring
 Multiple indications in end of life care including: Breathing Bone pain Inflammation from cancer Mood Appetite 	 Monitor for adverse effects Titrate up as needed to achieve pain relief If dosed BID, give 2nd dose prior to 2pm
 Which steroid to pick? Prednisone (Deltasone[®]) generally 1st Line Dexamethasone (Decadron[®]) preferred with: Brain involvement Patients with or at risk for clinically significant 	fluid retention/edema

References

 Symptom Management at End of Life. Care Search Palliative Care Knowledge Network. Available online from: <u>http://www.caresearch.com.au/caresearch/ClinicalPractice/Physical/EndofLifeCare/SymptomManagementattheEndofLife/tabid/</u> <u>741/Default.aspx</u>

- 2. Palliative Pharmacy Care. JM Strickland. Agitation and Delirium. Pgs. 77-89. American Society of Health-System Pharmacists. Bethesda, MD. 2009.
- 3. Lexi-Comp Drug Database. Available by subscription only from: online.lexi.com.

Take Care of Yourself and Your Patients this Summer...

Decoding Sunscreen Labels

As seen in Consumer Reports on Health, Volume 21 Number 8

Many people aren't sure what to look for on a sunscreen label, according to an April 2009 survey of 1,000 U.S. adults conducted by the Consumer Reports National Research Center. Here is a guide to some of the confusing terms.

SPF: A product's sun protection factor indicates how well it blocks harmful ultraviolet B radiation. While many sunscreens boast SPFs of 75 or higher, proposed labeling rules from the Food and Drug Administration would cut off SPF numbers at 50. But you don't want a product with an SPF under 30, either.

Broad Spectrum: That implies that a product also protects against UVA rays, a more deeply penetrating form of radiation, but it doesn't say how much protection you'll get.

Nanoparticles: Research has raised health concerns about those tiny particles, but sunscreen makers don't have a say whether their products contain them. If you're concerned, avoid those with titanium dioxide or zinc oxide, both of which are often nanosized.

PABA-free: Many sunscreen labels make this claim, though it doesn't mean much. PABA (para-aminobenzoic acid) can cause allergic reactions and possibly other problems, but few if any sunscreens sold in the U.S. still include it.

Vitamin D: Nearly 75 percent of the sunscreen users in our survey said they wanted a product with vitamin D. Sunscreen might interfere with the body's ability to make the nutrient from sunlight. But rubbing vitamin D on your skin probably won't raise blood levels of the nutrient, experts say. Instead, use sunscreen and get vitamin D from foods, such as fatty fish and fortified milk, or pills.

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