Issues in Pharmacy Waste Disposal
The Problem:

- The disposal of pharmaceuticals poses a problem on several levels:
  - Environmental Impact: Studies are showing traces of prescription drugs found in water supplies.
  - Potential for abuse of improperly disposed prescriptions.
Environmental Issues

• Improperly Disposed of Pharmaceutical Wastes:
  • May contaminate soil or seep into the groundwater and contaminate drinking supplies.
  • May run off into the nearest body of water and harm wildlife.
  • Pose health risk to you, your family, and community.

* Source: FDEP, Hazardous Waste Compliance Assistance Program
Controlling Laws and Rules

- Currently, the United States does not have Federal regulations on proper handling of unwanted medicines. However, disposal advice has been developed by the Office of National Drug Control Policy.

“Do not flush drugs down the toilet or drain unless the label or accompanying patient information specifically instructs you to do so.”

According to the FDA, do not flush prescription drugs down the toilet unless this information specifically instructs you to do so.
“To dispose of prescription drugs not labeled to be flushed, you may be able to take advantage of community drug take-back programs or other programs, such as household hazardous waste collection events, that collect drugs at a central location for proper disposal.”

While there is no current Federal regulation on drug disposal, controlled substances are generally heavily regulated by the Federal Drug Enforcement Administration.

Title 21, CFR. Parts 1300-1399: “These regulations are designed to establish a framework for the legal distribution of controlled substances to deter their diversion to illegal purposes and to ensure that there is a sufficient supply of these drugs for legitimate medical, scientific, research industrial, and other purposes.
The FDA has approved the flushing of certain medications.

Some states and environmentalists do not agree with the federal government’s policy on flushing certain medications. The Florida Department of Environmental Protection states that, “Although this method of disposal prevents immediate accidental ingestion, it can cause contamination in our aquatic environment because wastewater treatment systems, including septic tanks, are not designed to remove many of these medications.”
Instead, the Florida agency outlines a step-by-step method for the safe disposal of all prescription and over-the-counter medications:

1. Keep the medicines in the original container. This will help identify the contents if they are accidentally ingested.
2. Remove your name and prescription number to safeguard your identity.
3. For pills, add some water or soda to start dissolving them.
What to Tell Your Patients (continued):

4. For liquids, add something inedible like cat litter, dirt or cayenne pepper.
5. Close the lid and secure with duct tape or packing tape.
6. Place the bottle(s) inside an opaque (non see-through) container like a coffee can or plastic laundry bottle. Tape that container closed.
7. Tape that container closed.
8. Hide the container in the trash. Do not put in the recycle bin.
What to Tell Your Patients (continued):

**DO NOT** give drugs to anyone else.

**DO NOT** flush drugs down the toilet.

**DO NOT** put drugs in the trash without disguising them; human or animal scavengers may find them and misuse them.
Florida Laws and Rules

64B16-28.303 Destruction of Controlled Substances All Permittees (excluding Nursing Homes).

(1) Controlled substances that cannot be retained as usable shall be securely stored in the prescription department of the permittee pharmacy until destroyed.

(2) Permittees are required to complete a legible D.E.A. Form 41. This form, at the time of destruction, shall be witnessed and signed by the pharmacist of record and D.E.A. inspector, or a Department of Health inspector, or a Health and Rehabilitative Services inspector. This method of destruction does not require prior approval from D.E.A., but does require that a copy of the completed and witnessed D.E.A. Form 41 be mailed to D.E.A. immediately after destruction.
(3) Another method of destruction requires the pharmacist of record for the permit, a licensed physician, pharmacist, mid-level practitioner, or nurse, and a sworn law enforcement officer to serve as the witnesses. A copy of the completed D.E.A. Form 41 and a letter providing the proposed date of destruction, the proposed method of destruction and the names and titles of the proposed witnesses must be received by D.E.A. at least two weeks prior to the proposed date of destruction which shall constitute a request for destruction. The drugs may not be destroyed until D.E.A. grants approval of the request for destruction. A copy of the completed and witnessed D.E.A. Form 41 shall be mailed to D.E.A. immediately after destruction.

(4) In lieu of destruction on the premises, controlled substances may also be shipped to reverse distributors for destruction in conformity with federal guidelines.
The Hazardous Waste Compliance Management Assistance Program suggests the following steps to manage Pharmaceutical Wastes:

**Step One: Establish a Pharmacy Management Plan:**

- Conduct Random expired pharmaceutical audits and remove outdates products from inventory.
- Send only legitimate and potentially creditable outdated pharmaceuticals through reverse distribution.
- Designate a clearly marked outdated pharmaceutical quarantine area to accumulate outdate pharmaceuticals and/or products that cannot be sold.
- All pharmaceuticals discarded by the facility must be reviewed for hazardous waste status.
Establish a Pharmacy Management Plan (Continued)

- The pharmacy has two options for managing outdates pharmaceuticals for credit through the return process:
  1. Use a Reverse Distributor
  2. Process all returns and waste internally.
Step 2: Identify Your Hazardous and Non-Hazardous Wastes
Step 3: Implement Best Management Practices For:

1. Container Maintenance
2. Storage
3. Labels
4. Recordkeeping
5. Spills
Step 4: Determine Your Waste Generator Status:

You must determine how much hazardous waste you generate each month. The set of rules you must follow depends on how much waste you generate, how much you store, and how long you store it.

- Less than 220 pounds
- 220-2,200 pounds
- More than 2,200 pounds
The Hazardous Waste Compliance Management Assistance Program (Continued)

- Step 5: Comply with Guidelines for Transport and Disposal.
  - Federal Drug Enforcement Administration Regulations

Summary: In response to concerns raised by individuals, public and private organizations, the healthcare industry, and the law enforcement community, the Drug Enforcement Administration (DEA) is soliciting information on the disposal of controlled substances dispensed to individual patients, also defined as ultimate users, as well as long term care facilities. DEA is seeking options for the safe and responsible disposal of dispensed controlled substances in a manner consistent with the Controlled Substances Act and its implementing regulations.
H.R. 1191, The Safe Drug Disposal Act of 2009:

H.R. 1191 would amend the Controlled Substances Act to provide for disposal of controlled substances by ultimate users and care takers through State take-back disposal programs, to amend the Federal Food, Drug, and Cosmetic Act to prohibit recommendations on drug labels for disposal by flushing.

Last Action: March 16, 2009, House Judiciary
- Referred to the Subcommittee on Commercial and Administrative Law.
H. R. 1359, Secure and Responsible Drug Disposal Act of 2009:

- To amend the Controlled Substances Act to provide for take-back disposal of controlled substances in certain instances, and for other purposes.
- Last Action: March 5, 2009, Referred to House Judiciary.
Proposed 2009 Florida Legislation

- SB 2650 Pharmaceutical Take-back Programs:
  - Requires drug manufacturers who sell drugs in this state to establish a take-back program that accepts and disposes of pharmaceuticals turned in by consumers by a certain date. Requires retail pharmacies to post a sign informing consumers about the take-back program.
Proposed 2009 Florida Legislation

Related Bill:

- HB 1357 - Pharmaceutical Take-Back Program Pilot Project: Provides the manufacturer of a drug may not sell the drug or allow the drug to be sold in pilot project area unless the manufacturer operates a pharmaceutical take-back program approved by DOH.
  - Provides requirements for such programs.
  - Requires retail pharmacies to post sign to inform consumers of availability of pharmaceutical take-back programs.
Results of 2009 Florida Legislation

- As of May 4, 2009:
  - SB2650: 03/19/09 S Introduced -SJ 00211 on Friday, March 20, 2009 8:33 AM. No report of further action as of May 4, 2009.
  - HB1357: Indefinitely postponed and withdrawn from consideration on Saturday, May 02, 2009 12:00 AM.
Possible Upcoming Rule Changes

64B16-28.301 Destruction of Controlled Substances — Class I Institutional Pharmacies — Nursing Homes.

(1) No change.

(2) A document must be completed showing the name and quantity of the drug, strength and dosage form, patient’s name, prescription number and name of the institution nursing home. This documentation, at the time of destruction, shall be witnessed and signed by the consultant pharmacist, director of nursing, and the nursing home administrator or his designee, which may include a licensed physician, pharmacist, mid-level practitioner, or nurse excluding the above.
Thank you for your time and attention.

Contact Information:

Email for Edwin Bayó:
e.bayo@mgfblaw.com

Phone: (850) 385-1314
Fax: (850) 385-4240