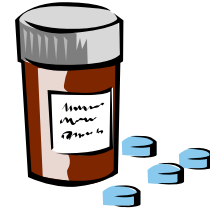

Requirements for a Pharmaceutical Collection in Ohio

DSIWM and DAPC Guidance Document #1000

DATE: Oct. 2009

Background

Studies conducted by U.S. EPA have shown that pharmaceuticals are present in our nation's waterbodies (see www.epa.gov/ppcp/basic2.html). Further research suggests that certain drugs may cause ecological harm. In the past few years, media has brought this problem to the attention of citizens and various governmental entities.



As a result, various entities and private companies have become interested in sponsoring collection events for unused and expired pharmaceuticals. However, there are no federal or Ohio laws specifically oriented to pharmaceutical take-back collections or disposal. Due to the lack of specific regulation, Ohio EPA has worked with relevant agencies to develop a consensus on how to properly collect and dispose of pharmaceuticals that are generated from Ohio residents. Therefore, Ohio EPA is providing the following information about how to properly plan and hold a residential pharmaceutical collection event, based on the legal requirements of the appropriate agencies.

Organizing a Residential Pharmaceutical Collection Event

If you wish to organize a collection event for pharmaceuticals, the Drug Enforcement Administration (DEA) requires that you first obtain written permission from one of the DEA offices in Ohio. The DEA offices by county are provided at the end of this document.

The request letter must include:

- names and addresses of all agencies involved;
- description, date, and time of event(s); and
- description of law enforcement officials to be present.

If your request is approved, the DEA office will respond with a formal letter of permission which expires one year after the date of issuance. Each event will be evaluated on a case-by-case basis.

Note: For the purposes of this document, a **controlled substance** is any drug or chemical that is regulated by the federal government, and can be obtained legally only with a valid prescription (i.e., OxyContin, Vicodin, Ritalin, Adderall).

DEA conditions for pharmaceutical collection

- A duly authorized and certified full-time law enforcement officer shall be responsible for supervising the collection.
- The law enforcement officer must have sole control of all controlled substances until they are turned over for destruction.
- Only pharmaceutical drugs may be accepted (no illegal drugs such as marijuana, heroin, methamphetamine, LSD, etc.).
- The law enforcement officer shall ensure the controlled substances are disposed of in accordance with his/her standard agency procedures.
- Destruction shall comply with federal, state and local regulations.

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Law Enforcement Requirement

According to DEA, a person cannot knowingly distribute or dispense a controlled substance unless they have a valid DEA registration. This means that the end user cannot give prescribed controlled substances to another person. However, a law enforcement exemption in Title 21 of the Code of Federal Regulations authorizes law enforcement to handle controlled substances when acting in the course of their official duties. In accordance with this exemption, DEA requires a law enforcement officer to be present to assume custody of controlled substances at any pharmaceutical collection event. While controlled substances only comprise a portion of all pharmaceuticals, a typical collection event would be expected to receive a mixture of controlled and non-controlled substances. Therefore, unless a pharmacist is present to identify controlled substances, the law enforcement officer would be responsible for all collected pharmaceuticals.

Note for Third Party Contractors:

An environmental contractor cannot collect controlled substances at a collection event without law enforcement assuming custody, regardless of whether the contractor holds DEA registration.

Ohio State Board of Pharmacy

The Ohio State Board of Pharmacy states that DEA's policy on pharmaceutical collection events complies with Ohio law. Additionally, the Board states that pharmacies (and other terminal distributors) cannot take back pharmaceuticals, according to the Ohio Administrative Code. There are few exceptions to this, such as the Drug Repository Program, a program in which non-controlled drugs are donated for re-use. For more details about this program, contact the Board of Pharmacy at (614) 466-4143.

Destruction Options for Law Enforcement Collecting Pharmaceuticals

For the safe destruction of pharmaceutical waste from residents, an entity conducting a pharmaceutical take-back event may contact a local facility permitted by Ohio EPA's Division of Air Pollution Control (DAPC) to operate one of the following types of facilities or emission units:

- Hazardous Waste Incinerators and Solid Waste Incinerators
- Sewage Sludge Incinerators equipped with an afterburner operating at a temperature of at least 1800°F
- Basic Oxygen Furnaces
- Electric Arc Furnaces
- Blast Furnaces
- Cement Kilns, Lightweight Aggregate Kilns, Lime Kilns (no asphalt concrete plants)

Ohio EPA will not require additional approvals or permit modifications for these types of facilities prior to disposing of pharmaceuticals in the unit as long as no more than five percent of the fuel fed into the furnace consists of pharmaceutical waste. Entities should be cautioned that specific facilities may have further requirements before disposing of the waste. Contact the Ohio EPA District Office or local air agency for assistance with locating and contacting such facilities in your area. The Ohio EPA District Office or local air agency to contact is listed by county at

<http://www.epa.ohio.gov/dapc/general/dolaa.aspx>.

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Another potential destruction option

Third party hazardous waste or environmental service corporations may be able to provide on-site destruction of collected pharmaceuticals (for example, through dissolution). If this is the case, DEA may allow the resulting fluid to be transported and destroyed by the corporation. Entities interested in this destruction option should describe the intended method in the letter to DEA requesting permission to hold a pharmaceutical collection event.

What about pharmaceuticals that are not generated by households?

Pharmaceuticals generated from households are exempt from Ohio's hazardous waste rules. However, businesses including hospitals, veterinary clinics, nursing homes, prisons, doctor offices, pharmacies and pharmaceutical manufacturers must evaluate their discarded pharmaceuticals (and other wastes) to determine if they are a listed or characteristic hazardous waste. Pharmaceuticals that are hazardous must be managed in accordance with the applicable hazardous waste rules and cannot be collected, managed or disposed through a pharmaceutical collection event for residents. If you have any questions, contact the Ohio EPA Division of Hazardous Waste Management at (614) 644-2917.

Other Considerations When Planning a Collection Event

If volunteers will be used during a collection event, it is important to educate them about the requirement that the law enforcement officer must maintain sole control over the pharmaceuticals until they are destroyed.

Entities holding a collection event may want to consider suggesting that residents remove personal information from prescription containers prior to bringing them to the collection event.

Additionally, entities might consider recycling the plastic pill bottles. For assistance in locating a recycler, contact your solid waste management district or Ohio EPA's Division of Solid and Infectious Waste Management at (614) 728-5353. (For a listing of solid waste management districts, go to http://www.epa.ohio.gov/portals/34/document/general/swmd_chair_list.pdf.)



DEA Offices in Ohio, by county

COLUMBUS - phone: (614) 255-4200, fax: (614) 469-5788
500 South Front Street, Suite 612
Columbus, OH 43215

Athens	Franklin	Logan	Noble
Belmont	Gallia	Madison	Perry
Champaign	Greene	Meigs	Pickaway
Clark	Guernsey	Miami	Preble
Coshocton	Harrison	Monroe	Shelby
Darke	Hocking	Montgomery	Union
Delaware	Jefferson	Morgan	Vinton
Fairfield	Knox	Morrow	Washington
Fayette	Licking	Muskingum	

DETROIT - phone: (313) 234-4000
431 Howard Street
Detroit, MI 48226

Defiance	Henry	Williams
Fulton	Lucas	Wood

CINCINNATI - phone: (513) 684-3671
36 East 7th Street, Suite 1900
Cincinnati, OH 45202

Adams	Hamilton	Ross
Brown	Highland	Scioto
Butler	Jackson	Warren
Clermont	Lawrence	
Clinton	Pike	

CLEVELAND - phone: (216) 274-3600
1375 East 9th Street, Suite 700
Cleveland, OH 44114

Allen	Geauga	Medina	Stark
Ashland	Hancock	Mercer	Summit
Ashtabula	Hardin	Ottawa	Trumbull
Auglaize	Holmes	Paulding	Tuscarawas
Carroll	Huron	Portage	Van Wert
Columbiana	Lake	Putnam	Wayne
Crawford	Lorain	Richland	Wyandot
Cuyahoga	Mahoning	Sandusky	
Erie	Marion	Seneca	
