

NYSDEC GUIDANCE FOR PROPER PHARMACEUTICAL DISPOSAL
CP # 66

New York State Department of Environmental Conservation

DEC Policy

Issuing Authority: Division of Water and Materials Management

Date Issued: 5/2/2017

Latest Date Revised:

I. Summary:

This document describes the New York State Department of Environmental Conservation (DEC) policy regarding the proper disposal of unused, unwanted, or expired pharmaceuticals. It provides guidance on how the “Disposal of Controlled Substances” final rule issued by the federal Drug Enforcement Administration (DEA) in 2014 (“2014 DEA Rule”), and the 2015 amendments to the NYS Public Health Law §3343-b, expand options for proper disposal of unused, unwanted, or expired pharmaceuticals. These changes affect end users, including households and residents at long-term care facilities (LTCFs). This policy also restates existing requirements under NYS’s Drug Management and Disposal Act of 2008 which requires posting of notices, by pharmacies and all other businesses authorized to sell drugs, to contain information on proper storage and disposal of pharmaceuticals.

Contact: For questions on this policy, please contact DEC’s Bureau of Public Outreach at 518-402-8044, or Rx.takeback@dec.ny.gov

II. Policy:

The policy of the DEC is to promote and facilitate the proper disposal of unused, unwanted, or expired pharmaceuticals in order to protect the waters of New York State and the aquatic life that depends on them. This policy encourages: (i) end users to properly dispose of unused, unwanted or expired pharmaceuticals; (ii) pharmacies and other entities to become authorized collectors under the 2014 DEA Rule and to accept unused, unwanted or expired pharmaceuticals from end users; (iii) pharmacies that become authorized collectors to also partner with LTCFs to collect unused, unwanted or expired pharmaceuticals from residents; (iv) LTCFs to participate with the existing DEC collection program; and (v) pharmacies and all other businesses authorized to sell drugs to comply with the posting requirements of the NYS Drug Management and Disposal Act of 2008.

This policy takes precedence over previously existing DEC guidelines and policies. All applicable federal, state and local laws and regulations continue to apply.

Specific guidance for the following entities is provided as Appendices to this Policy:

Appendix A – Households

Appendix B -Pharmacies, Law Enforcement and Other Authorized Collectors which Accept Pharmaceuticals from End Users

Appendix C - Long-Term Care Facilities (LTCF) and Other Class 3A Facilities

Appendix D - Posting Requirements for Pharmacies and all other Businesses Authorized to Sell Drugs.

Definitions

Key terms as used in this document are defined below

“Authorized collector” means a manufacturer, reverse distributor, distributor, narcotic treatment program, hospital or clinic with an on-site pharmacy that has modified its DEA registration to receive controlled substances for the purpose of destruction.

“Class 3A Facility” or “Class 3A Institutional Dispenser, Limited Licensee” means nursing homes, convalescent homes, health-related facilities, adult care facilities subject to the provisions of Title 10 NYCRR Parts 487, 488 & 490, and dispensaries or clinics not qualifying as institutional dispensers in license Class 3. Class 3A licenses are issued by the New York State Department of Health (DOH).

“End user” means a person who has lawfully obtained and possesses pharmaceuticals. This term includes “ultimate users.”

“Long-term care facility (LTCF)” means a nursing home, retirement care, mental care, or other facility or institution which provides extended health care to resident patients.

“Pharmaceutical” means all prescription and over-the-counter (OTC) human and veterinary medicine. The terms “pharmaceutical,” “drug,” and “medication” are used interchangeably in this document.

“Pharmacies and other entities” means pharmacies, as well as manufacturers, distributors, reverse distributors, narcotic treatment programs, and hospitals/clinics with an on-site pharmacy.

“Ultimate user” means 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 a member of their household. This term is used by the Secure and Responsible Drug Control Act of 2010.

III. Purpose and Background:

The purpose of this policy is to reaffirm DEC's commitment to promoting and facilitating the proper disposal of unused, unwanted, or expired pharmaceuticals in order to protect the waters of New York State and the aquatic life that depends on them.

Disposal of unused, unwanted, or expired pharmaceuticals by flushing down a drain can cause harm to aquatic life in the receiving waters.

Some pharmaceuticals pass largely unaltered through wastewater treatment plants and enter rivers and other receiving waters. Additionally, pharmaceuticals from health care facilities, pharmaceutical manufacturing facilities, veterinarians' offices, and farms can reach the water. There is also a significant health risk associated with the abuse of prescription pharmaceuticals remaining in the home.

History of New York State's Proactive Approach to Reducing Pharmaceuticals in Water

Historically, best management practices for disposal of unused, unwanted, or expired pharmaceuticals included flushing. In 2008, DEC formed a multidisciplinary Pharmaceutical Work Group, led by the Division of Water, with an initial focus on reducing the flushing of unused, unwanted, or expired pharmaceuticals. Other involved New York State agencies include the DOH, Office of the Attorney General, Division of Criminal Justice Services, Office of Mental Health, and Department of Corrections and Community Supervision.

Working with these other agencies, DEC developed and conducted an extensive "Don't Flush Your Drugs" campaign and developed guidance for alternative disposal methods. DEC encouraged collection events and provided information on alternatives to flushing. To implement New York's Drug Management and Disposal Act of 2008, DEC, with the New York State Education Department, established a notice containing information on the proper disposal of unused, unwanted or expired pharmaceuticals to be posted in pharmacies and other locations that sold pharmaceuticals across the state.

Complementary to DEC's efforts, a limited network of pharmaceutical collection options were developed and implemented across New York State. By 2014, many law enforcement stations established permanent collection receptacles for households to dispose of their unused, unwanted, or expired pharmaceuticals. Various municipalities hold collection events for members of their communities to dispose of unwanted, unused or expired pharmaceuticals. Twice a year, the DEA conducts nationwide collection days, with more than 200 sites just in New York State, collecting unwanted, unused or expired pharmaceuticals from households, as well as from long-term care facilities. DEC's own law enforcement personnel also picks up unwanted, unused or expired pharmaceuticals from health care facilities in the NYC Watershed, and on Long Island.

Environmental Impacts of Pharmaceuticals in the Water

A nationwide study done in 1999 and 2000 by the United States Geological Survey (USGS) found low levels of drugs such as antibiotics, hormones, contraceptives and steroids in 80% of the rivers and streams tested. Numerous studies since then confirm this growing problem. Low levels of pharmaceuticals were found in New York State waters and were found to be adversely affecting **fish and other aquatic wildlife**. Male fish can be feminized (produce eggs) when exposed to hormones (e.g., estrogen from birth control pills). Other pharmaceuticals, such as anti-depressants and beta-blockers, reduce fertility or affect spawning in certain aquatic organisms. Even *expired* pharmaceuticals can cause adverse effects in fish and other aquatic wildlife.

Health Risk in the Home from Unused, Unwanted, or Expired Pharmaceuticals

In addition to concerns for aquatic life in our waters, there is a significant threat of rising pharmaceutical abuse related to improper storage or disposal of unwanted, unused or expired pharmaceuticals in households.

Pharmaceuticals in the home present an easy opportunity for abuse. According to the Office of National Drug Control Policy, Executive Office of the President, as noted in the publication “Epidemic: Response to America’s Prescription Drug Abuse Crisis”:

Prescription drug abuse is the Nation’s fastest-growing drug problem. . . data from the National Survey on Drug Use and Health (NSDUH) show that nearly one-third of people aged 12 and over who used drugs for the first time in 2009 began by using a prescription drug non-medically. The same survey found that over 70 percent of people who abused prescription pain relievers got them from friends or relatives, while approximately 5 percent got them from a drug dealer or from the Internet. Additionally, the latest Monitoring the Future study—the Nation’s largest survey of drug use among young people—showed that prescription drugs are the second most-abused category of drugs after marijuana.” [internal citations omitted]

The number of prescriptions filled for opioid pain relievers—some of the most powerful medications available—has increased dramatically in recent years. From 1997 to 2007, the milligram per person use of prescription opioids in the U.S. . . . [showed] . . . an increase of 402 percent...Further, opiate overdoses, once almost always due to heroin use, are now increasingly due to abuse of prescription painkillers. [internal citations omitted].

Federal and State Laws and Regulations to Address Pharmaceuticals

Recent state and national actions represent major steps forward by allowing pharmacies and other authorized collectors to accept unused, unwanted, or expired pharmaceuticals for proper disposal. Additionally, New York’s Drug Management and Disposal Act of 2008 requires that all pharmacies and other retailers in the state that sell pharmaceuticals to post a notice on the proper disposal of drugs. On September 9, 2014, the DEA published the 2014 DEA Rule in accordance with the Controlled Substances Act, as amended by the Secure and Responsible Drug Disposal Act of 2010 (“Disposal Act”). This rule authorizes households to transfer unused, unwanted, or expired pharmaceutical controlled substances to entities authorized by the DEA for safe, secure and responsible disposal. Furthermore it allows retail pharmacies and other entities, with authorization from the DEA, to

voluntarily administer mail-back programs and maintain pharmaceutical collection receptacles (i.e., to become “authorized collectors”). However, under the 2014 DEA Rule authorized collectors are not allowed to conduct take-back events. Law enforcement may continue to conduct take-back events at any time, though. Any person or community group, registrant or non-registrant, may partner with law enforcement to conduct take back events.

Enacted in 2015, amendments to the Public Health Law §3343-b, expanded options for proper disposal of unused, unwanted, or expired pharmaceuticals from consumers (end users), which includes households, and patients at LTCFs.

IV. Responsibility:

The responsibility for maintaining, interpreting, and updating this policy lies with the Divisions of Water and Materials Management, in conjunction with the Office of General Counsel and other members of the Pharmaceuticals Work Group.

V. Related References:

10 NYCRR 80.51, Surrender and Disposal of Controlled Substances, November 26, 2008.

Public Health Law §3343-b, Safe Disposal of Unused Controlled Substances, amended September 27, 2014

Environmental Conservation Law, Article 27, Title 27, Drug Management Disposal Act, March 24, 2009

Education Law, Article 137, Pharmacy, Section 6808(2), Registered and Operating Establishments
21 CFR- Title 21 of the Code of Federal Regulations (Drug Enforcement Administration), Volume 9,
Chapter II, April 1, 2015:

(i) Part 1300 Definitions

(ii) Part 1301 Registration of Manufacturers, Distributors, and Dispensers of Controlled
Substances

(iii) Part 1304 Records and Reports of Registrants

(iv) Part 1305 Orders for Schedule I and II Controlled Substances

(v) Part 1307 Miscellaneous

Part 1317 Disposal

Executive Office of the President of the United States (2011). Epidemic: Responding to America’s
Prescription Drug Crisis. Retrieved from

https://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/rx_abuse_plan.pdf

Secure and Responsible Drug Disposal Act of 2010, 21 USC §801 *et seq.*, as added by Pub.L. 111-273,
124 US Stat. 2858

APPENDICES

Appendix A. Guidance for Households

Households are strongly encouraged to dispose of any unused, unwanted, or expired pharmaceuticals through take-back program options as described below.

Caution: Keep all pharmaceuticals in a safe place, secure from children, pets, and abuse, until disposing of them. Avoid crushing pharmaceuticals as some can be harmful in powder form.

With limited exception (below), DEC recommends that no pharmaceuticals be flushed.

Households may dispose of any unused, unwanted, or expired pharmaceuticals in several ways other than flushing:

1. **At those pharmacies that have a collection receptacle.**
 - Contact your pharmacy to find out if it has a collection receptacle, or search for a nearby pharmacy that does, on the DEA website:
<https://www.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s1>
 - Call the DEA Registration Call Center at 1-800-882-9539 to find a collection receptacle near you.
2. **At a local collection receptacle or event other than at a pharmacy.**
 - Some county and local law enforcement offices offer collection receptacles inside their stations. Contact your local law enforcement office to find out whether they provide a collection receptacle at their location and the hours that it may be used.

New York State Police Troop Headquarters offer 24 hour/7 day a week collection receptacles in their offices. For a listing, by county, of New York State Police Troop Headquarters and other law enforcement agencies, that maintain collection receptacles, visit the following webpage:

http://health.ny.gov/professionals/narcotic/medication_drop_boxes/

- Some municipalities offer household pharmaceutical collection events, in partnership with law enforcement. Contact your local municipality to find such events. **Note: Most Municipal Household Hazardous Waste Collections do NOT accept pharmaceuticals.**
3. Through programs that offer mail-back envelopes for consumers (free of charge or for a nominal fee). Consumers simply place their pharmaceuticals into the envelope, and drop it in the regular mail. Such envelopes are currently available at many pharmacies.

In the event that take-back options 1, 2, or 3 are not available, or are overly inconvenient, follow all of these steps to dispose of unused, unwanted, or expired pharmaceuticals in the trash:

- Add water and then salt, ashes, dirt, cat litter, coffee grounds, or another undesirable substance, to unused, unwanted, or expired pharmaceuticals. This helps avoid accidental or intentional misuse and/or misdirection of unused, expired, or unwanted pharmaceuticals. To

- prevent consumption by scavenging humans, pets, or wildlife, do not conceal discarded pharmaceuticals in food.
- Place all unused, unwanted, or expired pharmaceuticals in an outer container, such as a sealable bag, box or plastic tub to prevent discovery and removal from the trash. Seal the container with strong tape.
- Place unused, unwanted, or expired pharmaceuticals in containers for household trash pickup as close to your trash collection day as possible to reduce the accidental or intentional risk of misuse and/or misdirection.

Exceptions

The federal Food and Drug Administration (FDA) notes that there are a small number of medicines that may be especially harmful and, in some cases, fatal with just one dose if they are used by someone other than the person for whom the medicine was prescribed. To prevent accidental ingestion of these potentially dangerous medicines by children, or pets, it is recommended that these medicines be disposed of quickly through a medicine take-back program or by transferring them to a DEA-authorized collector. If these disposal options are not readily available, these medicines may be flushed down the sink or toilet as soon as they are no longer needed. FDA's list of hazardous medications can be found at <http://www.fda.gov>.

Sharps

DEC *strongly recommends* disposing of medications with attached needles at hospital-based household sharps collection programs. All hospitals in New York State (except for federal facilities) are required to accept sharps from households. If this disposal option is not available, place syringes or IVs (including an attached needle) in a puncture proof container. Then seal the container with tape, label it as "sharps," and place the container in the garbage outside of the home. Sharps may **not** be placed in collection receptacles or in mail-back packages.

Appendix B. Guidance for Authorized Collectors and Law Enforcement to Accept Pharmaceuticals in Collection Receptacles from End Users

The 2014 DEA Rule allows retail pharmacies and other entities authorized by the DEA to collect pharmaceutical controlled substances from ultimate users by becoming an authorized collector and voluntarily administering mail-back programs or maintaining collection receptacles.

The 2014 DEA Rule also allows law enforcement to continue to conduct take-back events and maintain collection receptacles without becoming an authorized collector.

Controlled and non-controlled pharmaceuticals may be co-mingled in a single collection receptacle. To further encourage pharmacies and other entities to become authorized collectors, on June 23, 2016, the DEC announced that authorized collectors and law enforcement are allowed to collect pharmaceuticals without approval from the DEC as long as they remain in compliance with the requirements of 21 CFR Parts 1300, 1301, 1304, 1305, 1307, and 1317. If the final disposal of pharmaceutical waste occurs in

New York State, it must be destroyed in a municipal waste combustion facility or by another method approved by the DEC.

Law enforcement agencies that conduct take-back events and maintain collection receptacles must meet DOH requirements as set forth on the DOH Bureau of Narcotic Enforcement's (BNE) website:

<https://www.health.ny.gov/professionals/narcotic/>. Retail pharmacies, manufacturers, reverse distributors, distributors, narcotic treatment program, or hospitals or clinics with an on-site pharmacy may modify their existing DEA registration in order to become an authorized collector. Authorized collectors may collect pharmaceutical controlled substances from households using either collection receptacles or mail-back programs.

Retail pharmacies and hospitals/clinics with an on-site pharmacy may maintain collection receptacles at LTCFs licensed by the DOH BNE and in accordance with federal DEA regulations.

Consistent with the 2014 DEA Rule, DEC strongly encourages pharmacies and other DEA registrants to become authorized collectors to allow for the increased safe disposal of controlled pharmaceuticals in a safe and effective manner consistent with effective controls against diversion.

To become an authorized collector, DEA registrants must:

- Modify their registrations online at <http://www.DEAdiversion.usdoj.gov/>; and
- Follow all DEA requirements under 21 CFR Part 1300 *et seq.*

Commercial transporters of collected pharmaceuticals may be required to obtain a 6 NYCRR Part 364 Waste Transporter Permit if transport for the purpose of subsequent disposal occurs by vehicle. For questions or more information regarding the Part 364 Waste Transporter Permit program please contact DEC's Division of Materials Management at (518) 402-8611.

DEA fact sheets and information on registrant drug disposal may be found at:

http://www.deadiversion.usdoj.gov/drug_disposal/index.html.

Appendix C. Guidance for Long-Term Care Facilities (LTCFs) and Other Class 3A Facilities

The 2014 DEA Rule allows retail pharmacies, hospitals, and medical clinics to maintain collection receptacles at LTCFs on a voluntary basis.

DOH requires institutional facilities without the services of an on-site pharmacy to be licensed as a Class 3A Institutional Dispenser, Limited facility; however, **not every Class 3A licensee meets the qualifications required to be recognized by the DEA as a LTCF.**

There are several disposal methods available to LTCFs and other Class 3A facilities:

1. Disposal Options for LTCF residents: Mail-back programs and collection receptacles.

LTCF residents may participate in DEA-authorized collection mail-back programs and collection receptacles in accordance with federal DEA regulations.

- While LTCFs, themselves, may not use mail-back packages or administer a mail-back program, LTCF *residents* may use all disposal methods made available to ultimate users under the DEA rule, including participation in mail-back programs.
- On behalf of an LTCF resident, an LTCF employee may place the resident's unused, unwanted, or expired pharmaceuticals in a mail-back package, seal it, and deposit it into the LTCF's outgoing mail system.

- Retail pharmacies, as well as hospitals and medical clinics with an on-site pharmacy, may maintain DEA-authorized collection receptacles at LTCFs in accordance with federal DEA regulations. (21 CFR 1317.75) (21 CFR 1317.80)
 - An LTCF employee may place unused, unwanted, or expired pharmaceuticals that are lawfully possessed into an authorized collection receptacle located at that LTCF on behalf of an ultimate user who resides, or has resided, at such LTCF.
2. Class 3A facilities' staff with lawful temporary custody of unused, unwanted, or expired pharmaceutical controlled substances may surrender them to law enforcement for destruction ***pursuant to a DOH-approved Law Enforcement Take-Back Event.***
- Law enforcement may collect controlled substances from ultimate users and persons lawfully entitled to dispose of a deceased ultimate user's property.
 - Law enforcement agencies shall appoint a law enforcement officer employed by that agency to oversee the collection.
 - Control and chain of custody of the collected pharmaceuticals will be securely maintained by those law enforcement officers from the time of collection to transfer, storage, or destruction of the controlled pharmaceuticals.
 - Each Class 3A facility seeking to participate in a DOH-approved Law Enforcement Take-Back Event must complete and submit required documentation to the applicable DOH BNE regional office. Instructions and forms may be located on DOH's website (www.health.ny.gov).
 - All Class 3A Facilities, including LTCFs, may request pharmaceutical pick-ups by DEC Law Enforcement on an "as needed" basis. These pick-ups are dependent upon the availability of DEC resources. DEC Law Enforcement may also be able to conduct periodic pre-scheduled pickups. Contact DEC's Bureau of Public Outreach at 518-402-8044.
 - Once a Class 3A facility confirms its participation in the pick-up by DEC Law Enforcement, DEC Law Enforcement will contact the facility to schedule an approximate time and date for pickup. Law enforcement officers provide security, maintain chain of custody, witness the surrender to the incineration facility, and witness destruction via incineration of all waste pharmaceuticals collected.

Appendix D. Posting Requirements for Pharmacies and all other Businesses Authorized to Sell Drugs

Every pharmacy registered pursuant to NYS Education Law Section 6808(2), and other retailers that sell drugs, including veterinary offices, must conspicuously display the Department's "Proper Disposal of Pharmaceuticals" notice as required under New York's Drug Management and Disposal Act of 2008.

A printable/downloadable copy of the poster and guidance are available on the DEC website at www.dec.ny.gov

Where the notice should be posted:

DEC recommends that the notice be posted in the following manner:

In a pharmacy setting, the notice should be legible to a consumer at the pick-up counter. Options include posting on a wall visible from the counter, or on the counter itself. If a pharmacy is within a store, but the pharmacy closes for some portion of the store hours, the notice should also be visible in the pharmacy department during hours when the pharmacy is closed.

In a non-pharmacy retail setting, the notice should be posted at one of the following locations:

- At the checkout counter
- On/above/visible from aisles where drugs are displayed
- As a shelf-label or other in-aisle placement with the display of drugs

Size and Form of the Notice

DEC recommends that the notice be formatted as follows:

Print the notice in color. The notice should be at least 8.5 by 11 inches.

Stores are encouraged to frame, laminate, or otherwise ensure that the notice is durable.

Feel free to also reproduce a smaller size notice in black and white as a handout to consumers, for shelf displays, on shopping bags or medicine bags.