UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 11, 2018

OFFICE OF THE
ADMINISTRATOR

Dear U.S. Law Enforcement Partner:

Thank you for your service to our country. We appreciate your dedicated efforts to combat illegal drug use and the opioid crisis. Your hard work is critical to keeping Americans safe and healthy.

The U.S. Environmental Protection Agency supports the work of the law enforcement community to collect unwanted drugs from households to keep them from being accessed for illicit purposes. At the federal level, twice a year, the Drug Enforcement Administration sponsors National Prescription Drug Take Back days. As you are likely already aware, on the most recent take back day on April 28, 2018, law enforcement established nearly 6,000 collection sites across the country and collected nearly 1 million pounds of unwanted drugs.

Given the volume of drugs collected, it is important that the collection and disposal of these drugs is done in a manner that protects human health and the environment. As such, the EPA coordinates regularly with the DEA, the U.S. Department of Transportation and the U.S. Postal Service to provide law enforcement agencies with specific information they can use on how best to manage household drugs collected in take-back programs. I thought you might be interested to see the attached memorandum my agency recently put together highlighting a menu of options law enforcement may use to transport already collected household drugs to incinerators in manners that comply with EPA, DEA, DOT and USPS regulations. I have directed my staff to share this memorandum with all ten EPA Regional Administrators and for their teams to reach out to law enforcement and share these options as well.

The EPA joins with other federal agencies and stands with law enforcement officials nationwide in fighting the opioid epidemic. We are grateful for your service.

Sincerely,

Andrew R. Wheeler
Acting Administrator

Attachment

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 11 2018

OFFICE OF
SOLID WASTE AND
EMERGENCY RESPONSE

NOW THE
OFFICE OF LAND AND
EMERGENCY MANAGEMENT

SUBJECT: Management of Household Pharmaceuticals Collected by Law Enforcement During Take-Back Events and Programs

FROM: Barnes Johnson, Director
Office of Resource Conservation and Recovery

TO: RCRA Division Directors
EPA Regions 1-10

1) Background and Purpose

Law enforcement offices across the country are working to combat the opioid crisis. One tool they are using is collecting unwanted drugs from households to keep them from being accessed for illicit purposes. Twice a year, the Drug Enforcement Administration (DEA) sponsors National Prescription Drug Take Back days. In the most recent take back day on April 28, 2018, law enforcement established nearly 6,000 collection sites across the country and collected nearly 1 million pounds of unwanted drugs. Since its inception in September 2010, DEA has collected a total of nearly 10 million pounds of unwanted drugs. We strongly encourage law enforcement to participate in the DEA National Prescription Drug Take Back days, because when they do, drugs are safely removed from households and ultimately destroyed while preserving local law enforcement resources.

Law enforcement may also choose to collect unwanted household drugs at other times. EPA supports these efforts and wants to ensure that they are conducted in a manner that is protective of public health and the environment. Therefore, EPA coordinated with DEA, Department of Transportation (DOT) and the U.S. Postal Service (USPS), to provide law enforcement agencies with specific information they can use on how best to manage household drugs collected in take-back programs, so that the public can benefit from these critical programs.

The purpose of this memorandum is to explain the various options law enforcement agencies can use to transport and destroy household pharmaceuticals collected in take-back programs in order to encourage law enforcement to continue to offer such programs to the public. EPA is clarifying that law enforcement agencies can send collected household pharmaceuticals for destruction in a hazardous waste combustor regulated under § 112 of the Clean Air Act, or one of the following types of solid waste incineration units regulated under § 129 of the Clean Air Act:

- large and small municipal waste combustors (MWCs)
- hospital, medical, and infectious waste incinerators (HMIWIs)
- commercial and industrial solid waste incinerators (CISWIs), and
- very small municipal waste combustors that are regulated as other solid waste incinerators (OSWIs)

Additionally, this memorandum explains the various options law enforcement has for shipping collected household pharmaceuticals to one of these facilities.

2) Introduction

Prescription pharmaceutical abuse is a fast-growing problem in the United States and has been described as an epidemic by the U.S. Center for Disease Control and Prevention (CDC).[1] In October 2017, the U.S. Department of Health and Human Services declared the opioid epidemic a national public health emergency.[2] According to CDC data, most people who begin abusing prescription pharmaceuticals obtain them from friends and family for the first time, often from household medicine cabinets.[3] Households tend to accumulate old, expired, or simply unwanted prescription and over-the counter pharmaceuticals, increasing the potential for abuse and diversion. Many law enforcement agencies have established take-back events and programs to collect prescription and over-the-counter pharmaceuticals from households. These take-back programs for household pharmaceuticals help reduce the misuse and abuse of drugs and the number of accidental poisonings, while at the same time reducing the practice of flushing household pharmaceuticals which may result in their entry into the environment.

EPA encourages the public to take advantage of household pharmaceutical take-back collection programs that accept prescription and over-the-counter pharmaceuticals, as these programs offer a safe and environmentally-conscious way to dispose of unwanted pharmaceuticals. The Agency recommends incineration rather than landfilling as the preferred disposal method for household pharmaceuticals collected during take-back programs and events. Although it is not required, EPA has historically recommended combustion in a permitted hazardous waste incinerator, a large municipal waste combustor, or a small municipal waste combustor for the destruction of collected household pharmaceuticals. The purpose of this memorandum is to explain the various options that law enforcement agencies can use for the transportation and destruction of collected household

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[1] *See* Seth et al., "Quantifying the Epidemic of Prescription Opioid Overdose Deaths" American Journal of Public Health. 2018 April; 108(4) 500-502.

[2] *See* press release dated October 26, 2017, "HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis," *available at* https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html

[3] *See* press release dated January 12, 2015, "2013 Drug Overdose Mortality Data Announced." *available at* https://www.cdc.gov/media/releases/2015/p0114-drug-overdose.html

pharmaceuticals in order to encourage law enforcement to continue to offer pharmaceutical take-back programs to the public.

3) Background – RCRA Regulations

Pharmaceuticals that are unwanted (e.g., expired or unused) by consumers (households) are not regulated federally as hazardous wastes and are generally handled through municipal solid waste collection and disposal systems. Although many pharmaceutical wastes meet the definition of hazardous waste under the Resource Conservation and Recovery Act (RCRA), the federal RCRA hazardous waste regulations include an exemption for all hazardous waste generated by households.[4] Thus, household pharmaceutical wastes, like other household hazardous wastes, are not subject to the federal RCRA hazardous waste regulations, even when collected at a take-back event or program.[5]

4) Background – Controlled Substances Act[6]

A portion of household pharmaceuticals that are collected through take-back events and programs are controlled substances. Controlled substances are drugs or other substances that have the potential for abuse and dependence and are controlled by the Drug Enforcement Administration (DEA) to protect public health and safety. In addition to federal, state, tribal and/or local environmental regulatory requirements, collection of pharmaceutical controlled substances through take-back events and programs must be conducted in compliance with the requirements of the Controlled Substances Act (CSA) and its implementing regulations published by DEA (21 U.S.C. 801–971; 21 CFR parts 1300 - 1321). In general, only persons registered with DEA are permitted to possess controlled substances as authorized by their registration and must comply with the applicable requirements associated with their registration. There are exceptions however. For example, when carrying out their official duties law enforcement personnel are not required to register with DEA in order to receive and possess controlled substances. Additionally, a patient who receives a controlled substance pursuant to a lawful prescription – also known as an ultimate user – is not required to register with DEA in order to receive and possess that controlled substance.

In October 2010, the Secure and Responsible Drug Disposal Act of 2010 was enacted; DEA finalized the regulations implementing this Act in 2014.[7] The Act and implementing regulations provide the basic framework to allow the public (i.e., the ultimate users) to dispose of their unwanted or expired controlled substance pharmaceuticals in a secure and responsible manner. Until DEA finalized the implementing regulations for the Act, ultimate users could not deliver their controlled substance pharmaceuticals to any other person for the purpose of disposal other than by surrender to law enforcement (including to DEA) such as at a take-back event with law enforcement present. Since DEA finalized the implementing regulations there are now additional options for ultimate users, including collection receptacles at retail and hospital pharmacies as well as mail-back envelopes. Ultimate users

[4] *See* the "household waste" exclusion at 40 CFR 261.4(b)(1), which is often referred to as the household hazardous waste exclusion.
[5] *See* memorandum dated October 2, 2015, from Johnson to RCRA Division Directors, RCRA Online #14853.
[6] EPA conferred with DEA during the development of this memorandum in order to ensure accuracy when summarizing the DEA regulations.
[7] *See* 79 FR 53520; September 9, 2014.

still have the option to surrender their controlled substances to law enforcement, including DEA. In fact, for several years DEA has sponsored the National Prescription Drug Take Back Day twice a year (on the last Saturday in April and October), collecting and ensuring the proper destruction of millions of pounds of unwanted pharmaceuticals.

The DEA regulations require that the controlled substances collected by DEA registrants that are authorized collectors of ultimate user pharmaceuticals (e.g., in take-back programs) must be destroyed so that they are non-retrievable.[8] Although law enforcement is not required to meet the DEA regulations that apply to DEA registrants, the DEA regulations state, "Any controlled substances collected by law enforcement through a take-back event, mail-back program, or collection receptacle should be transferred to a destruction location in a manner that prevents the diversion of controlled substances."[9] As a result, the remainder of this memorandum assumes that law enforcement will choose to meet the non-retrievable standard like the DEA registrants. Currently, most, if not all, controlled substances that are collected in take-back events and programs are destroyed by incineration in order to meet DEA's non-retrievable standard. In addition to the DEA regulations, incineration (or other destruction methods used to meet DEA's non-retrievable standard) must be done in accordance with all applicable federal, state, tribal and local environmental regulations. This memorandum explains the incinerators that can be used by law enforcement agencies for the destruction of collected household pharmaceuticals that comply with EPA regulations.

5) Options Available to Law Enforcement for Destruction of Pharmaceuticals from Take-Back Events or Programs

a) Available Incineration Units for the Destruction of Pharmaceuticals from Take-Back Events or Programs

There are a number of types of solid waste and hazardous waste combustion units that law enforcement can use to destroy household pharmaceuticals collected through take-back events or programs. Because the collected household pharmaceuticals are solid waste, they must be sent for disposal/destruction in a hazardous waste combustor regulated under § 112 of the Clean Air Act, or one of the following solid waste incineration units regulated under § 129 of the Clean Air Act:

- large and small municipal waste combustors (MWCs)
- hospital, medical, and infectious waste incinerators (HMIWIs)
- commercial and industrial solid waste incinerators (CISWIs), and
- very small municipal waste combustors that are regulated as other solid waste incinerators (OSWIs)

[8] *See* 21 CFR 1300.01: "Non-retrievable means, for the purpose of destruction, the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the controlled substance unavailable and unusable for all practical purposes. The process to achieve a non-retrievable condition or state may be unique to a substance's chemical or physical properties. A controlled substance is considered "non-retrievable" when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes."

[9] *See* 21 CFR 1317.35 Collection by law enforcement.

Thus, law enforcement has a variety of options for disposing and destroying of collected household pharmaceuticals that meet EPA's mandate of protecting human health and the environment.[10] Although EPA encourages the owners/operators of these incinerators to consider accepting the collected household pharmaceuticals and a number have recognized the unique services they offer and role they can play in helping to mitigate the national opioid epidemic, we note that these incinerators are not obligated to accept collected household pharmaceuticals for destruction.

b) Options Available to Law Enforcement for Transporting Pharmaceuticals from Take-Back Events and Programs to DEA Registered Reverse Distributors[11]

This memorandum describes cost-effective options that comply with the EPA, DEA, and DOT or USPS regulations that law enforcement can use to transport collected household pharmaceuticals to incinerators. For example, Law enforcement can choose to ship the collected household pharmaceuticals in the liners placed into outer packaging and ship the package using a carrier such as UPS, FedEx, or the US Postal Service. If law enforcement chooses this option, DEA regulations state that law enforcement should keep records, including the date of transfer and, if utilized, the identifying information of the unique identification number of the sealed inner liner, size of the sealed inner liner, and the name, address, and registration number of the DEA registered reverse distributor to which the package is shipped.[12] When using a commercial carrier such as UPS or FedEx, there are several vendors that sell receptacle liners and outer packaging systems that have been granted MMS (manufacture, mark, sell and use) special permits by DOT. Anyone, including law enforcement, that uses these receptacle liners and outer packaging systems is considered compliant with the DOT hazardous materials shipping standards.[13] Additionally, when using the US Postal Service as the carrier, law enforcement personnel are allowed to ship controlled substances to a DEA registered reverse distributor.[14]

There are currently approximately 35 DEA-registered reverse distributors that are authorized by DEA to accept shipments of collected household pharmaceuticals.[15] While some DEA registered reverse distributors operate incinerators, most do not. Those that do not operate incinerators must deliver the collected household pharmaceuticals that they receive at their DEA registered address to an incinerator and witness their destruction on behalf of law enforcement. Reverse distributors and incinerators may be willing to provide service to law enforcement at reduced rates. We encourage law enforcement to contact multiple vendors and compare pricing for liners/outer packaging and for handling and destruction. We also note that law enforcement should look for a vendor that is compliant with the DOT hazardous material regulations (HMR) for shipping the collected household pharmaceuticals. Additionally, to help minimize costs, law enforcement is encouraged to participate in the twice-a-year

[10] Note that this list does not include human or pet crematoria. Human and pet remains are not considered solid wastes and therefore crematoria are not regulated as solid waste incineration units under § 129 of the Clean Air Act. However, if the crematoria are used to burn solid wastes, such as collected household pharmaceuticals, they would be subject to § 129 of the Clean Air Act.

[11] EPA conferred with DOT and USPS during the development of this memorandum in order to ensure accuracy when summarizing the DOT and USPS regulations.

[12] DEA defines the term "reverse distribute" in 21 CFR 1300.01 as "to acquire controlled substances from another registrant or law enforcement for the purpose of (1) Return to the registered manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf; or (2) Destruction.

[13] Alternatively, law enforcement agencies can file a one-page application with DOT to become a party to DOT special permit 20255, which waives the DOT hazardous materials regulations provided certain types of inner and outer packaging are used.

[14] *See* USPS Publication 52, § 453.31

[15] The list of DEA registered reverse distributors varies over time. Contact the DEA at ODLP@dea.usdoj.gov for an up-to-date list of DEA registered reverse distributors.

DEA-sponsored National Prescription Drug Take Back Days. The DEA pays for the transportation and destruction of the household pharmaceuticals collected during those events.

Another option available to law enforcement is to purchase mail-back envelopes that meet Federal and State law and regulation and then hand these out to individuals in their communities. Individuals can place their controlled substances in the pre-addressed, postage-paid envelopes and then mail them to the DEA registered location where the envelopes will be destroyed on-site by incineration to meet DEA's non-retrievable standard.

Law enforcement agencies also have the option of transporting collected household pharmaceuticals to an incinerator. However, law enforcement representatives have expressed concern that the transportation of collected household pharmaceuticals to incinerators is expensive, especially in states where law enforcement may have to travel long distances to an incinerator. This concern has been based on the assumption that law enforcement is required to have two officers drive the collected household pharmaceuticals to a permitted incinerator and witness their destruction. Although this method of transportation is available to law enforcement, as described above it is not the only option available.

6) Open Burning of Pharmaceuticals

EPA has received inquiries from law enforcement about whether open burning of pharmaceuticals collected in take-back events is allowed. Open burning[16] of residential, commercial, institutional, or industrial solid waste is prohibited under the RCRA Subtitle D regulations in 40 CFR 257.3-7(a).[17] Additionally, in many cases, state laws and local ordinances strictly limit or prohibit open burning of household waste.

Because emissions from open burning are generally not controlled, open burning of pharmaceuticals from take-back events may pose health risks to law enforcement officers and members of the surrounding communities. This is due to the potential formation, release and exposure to pollutants formed as byproducts during open burning of the pharmaceuticals and their plastic, glass, multi-laminate films, and cardboard packaging (see Figure 1). These pollutants, such as dioxins, furans, particulate matter, sulfur dioxide, lead, mercury, and hexachlorobenzene may cause immediate and long-term adverse health effects such as cancer, respiratory illness and reproductive disorders.[18] It is also possible that barrels with fans (sometimes referred to as burn barrels), may pose similar risks from emissions (see Figures 2 and 3). Further, given the comparatively low combustion temperature, and the difficulty in controlling the combustion temperature, it is not evident that open burning or burn barrels would achieve the DEA's non-retrievable standard for the destruction of controlled substances. Finally,

[16] *See* 40 CFR 257.3-7(c): Open burning "means the combustion of solid waste without (1) control of combustion air to maintain adequate temperature for efficient combustion, (2) containment of the combustion reaction in an enclosed device to provide sufficient residence time and mixing for complete combustion, and (3) control of the emission of the combustion products."

[17] Open burning of certain items is allowed by RCRA Subtitle D: infrequent burning of agricultural wastes in the field, silvicultural wastes for forest management purposes, land-clearing debris, diseased trees, debris from emergency clean-up operations, and ordnance. *See* 40 CFR 257.3-7(a).

[18] EPA does not have emissions data from the open burning of collected household pharmaceuticals specifically. But a study by EPA's National Risk Management Research Laboratory and others, concluded that "the emissions from open burning [household trash] are several orders of magnitude higher than for controlled combustion in a modern, clean-operating MWC [municipal waste combustor]." See Lemieux, Lutes, Abbott, and Aldous; Environ. Sci. Technol. 2000, 34, 377-384.

we caution that the ash residue from open burning can contain toxic metals, such as mercury, lead, chromium, and arsenic and must be managed in accordance with applicable solid and hazardous waste regulations.

7) Conclusion

There are various avenues available to law enforcement for environmentally responsible disposal of collected household pharmaceuticals. Additionally, based on input from stakeholders, EPA anticipates that these environmentally responsible disposal methods are also expected to be cost-effective methods for law enforcement. EPA encourages the law enforcement officials to closely work with state and federal agencies to determine the best available option for managing and disposing of the collected household pharmaceuticals.

8) State RCRA Regulations May Differ from the Federal RCRA Regulations

Please note that under Section 3006 of RCRA individual states can be authorized to administer and enforce their own hazardous waste programs in lieu of the federal program. States that are authorized to implement the RCRA program have authority to promulgate regulations that are more stringent than the federal program. Thus, some states may potentially regulate collected household pharmaceuticals as hazardous wastes under their state programs. You should consult with the appropriate authorized state agency for any site-specific guidance. If you have any questions about the federal hazardous waste regulations discussed in this memorandum, please contact Laura Stanley at (703) 308-7285 or Kristin Fitzgerald at (703) 308-8286, both with the EPA's Office of Resource Conservation and Recovery.

Figure 1: Collected household pharmaceuticals and their packaging prior to being burned in a burn barrel. Pharmaceutical packaging can include plastic, glass, multi-laminate films, cardboard, etc.

Photo used with permission of Forsyth Herald

Figure 2: Collected household pharmaceuticals and their packaging being loaded into a burn barrel with a fan.

Photo used with permission of Forsyth Herald

Figure 3: Collected household pharmaceuticals being burned in a burn barrel with a fan.

Photo used with permission of Forsyth Herald