

REGULATION OF REVERSE DISTRIBUTION OF CONTROLLED SUBSTANCES IN UNITED STATES

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ABSTRACT

Opioid analgesics are an important component of pain management for many patients. Though the patients use opioids properly under the direction of their physicians, the abuse and diversion of these medications is a major problem. In the United States, approximately 11 million people used opioids in 2002 for nonmedical purposes. The US Drug Enforcement Administration (DEA) defines the diversion of medications as “the redirection of narcotic drugs and psychotropic substances from the legitimate distribution chain of medical and scientific use into illicit channels.” There are more than 1 million potential sources for drug diversion, including theft, fraud, and illegal sales involving physicians, pharmacies, hospitals, and nursing homes. Collection and Proper disposal of these medications are crucial in countering this illegal activity.

KEYWORDS: Opioids, Reverse Distribution, Controlled Substances.

INTRODUCTION

The supply of prescription opioids remains high in the U.S. An estimated 1 out of 5 patients with non-cancer pain or pain-related diagnoses are prescribed opioids in office-based settings. From 2007 – 2012, the rate of opioid prescribing has steadily increased among specialists more likely to manage acute and chronic pain. Prescribing rates are highest among pain medicine (49%), surgery (37%), and physical medicine/rehabilitation (36%). However, primary care providers account for about half of opioid pain relievers dispensed. There are more than 1 million potential sources for drug diversion, including theft, fraud, and illegal sales involving physicians, pharmacies, hospitals, and nursing homes. Among the most

common narcotics included in drug diversion are codeine, hydrocodone, hydromorphone, methadone, and oxycodone. The collection and proper disposal of these medications is crucial in countering this illegal activity.^[1]

Current Guidelines and Regulations for the disposal of Controlled Substances.

The WHO has published the following statement regarding the proper disposal of controlled substances: Controlled substances must be destroyed under supervision of a pharmacist or the police depending on national regulations. Such substances must not be allowed into the public domain as they may be abused. They should either be rendered unusable, by encapsulation or inertization, and then dispersed among the municipal solid waste in a landfill, or incinerated.

Great Britain's Environmental Protection Act of 1990 mandates that controlled substances not be disposed into wastewater systems, but the legislation provides little further guidance.

Australia's National Health and Medical Research Council considers incineration, when possible, to be the most appropriate method of disposal.¹² Pharmacies in Australia are able to return unsold or expired medications to some pharmaceutical companies through a system of reverse distributors. Australia and Canada have implemented measures to assist consumers in proper disposal of unused medications: the Return Unwanted Medications Program and the Medications Return Program, respectively. In Canada, the National Association of Pharmacy Regulatory Authorities guides pharmacists on proper ways to accept expired, unused, and discontinued medications—including controlled substances—from consumers. These guidelines facilitate proper disposal of these substances and prevent their illegal diversion. Health Canada issued detailed guidelines for that nation's citizens and similar information and guidelines have been released in several European nations. Many countries in Latin America have regulations for the public regarding the disposal of unused opioid medications.

For example, Argentina, Colombia, Cuba, Mexico and Peru allow—or, in some cases, require—patients to dispose of unused opioid medications by returning them to such healthcare institutions as hospitals, pharmacies and government health agencies.^[2]

The Controlled Substances Act forms the backbone of US drug policy. It established the scheduling system, which places legal and illegal drugs with potential for abuse into five categories - from Schedule V, the least dangerous, to Schedule I, the most dangerous.

Substances in Schedule I are considered to have "no currently accepted medical use" and are completely prohibited. Drugs in the Schedule II to V classification are considered to all have some amount of medical use and therefore undergo varying amounts of regulation. Opioid analgesics are an important component of pain management for many patients.^[3]

Table. 1.

Drug Scheduling Guide United States	
Schedule I	Most potential for abuse and dependence No medicinal qualities Heroin, LSD, Marijuana, Ecstasy, Peyote
Schedule II	High potential for abuse and dependence Some medicinal qualities Vicodin, Cocaine, Meth, OxyContin, Adderall
Schedule III	Moderate potential for abuse/dependence Acceptable medicinal qualities Doctor's prescription required Tylenol with Codeine, Ketamine, Steroids, Testosterone
Schedule IV	Low potential for abuse and dependence Acceptable medicinal qualities Prescription required - fewer refill regulations Xanax, Darvon, Valium, Ativan, Ambien, Tramadol
Schedule V	Lowest potential for abuse/dependence Acceptable medicinal qualities Prescription required - fewest refill regulations Robitussin AC, Lomotil, Motofen, Lyrica
Source: United States Drug Enforcement Agency	

Drug Enforcement Administration (DEA) – Mission and Organization

The Drug Enforcement Administration is a United States federal law enforcement agency under the U.S. Department of Justice.

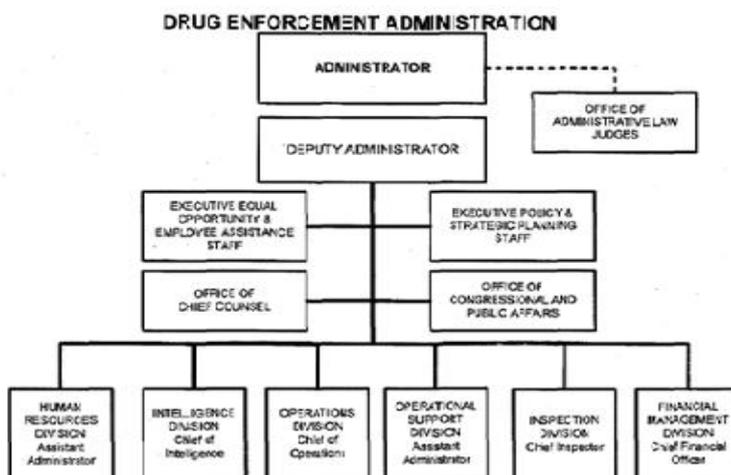
The Drug Enforcement Administration was created by President Richard Nixon through an Executive Order in July 1973 in order to establish a single unified command to combat "an all-out global war on the drug menace." At its outset, DEA had 1,470 special agents and a budget of less than \$75 million. Today, the DEA has nearly 5,000 special agents and a budget of \$2.03 billion.

The mission of the DEA is to enforce the controlled substances laws and regulations of the United States and bring to the criminal and civil justice system of the United States, or any other competent jurisdiction, those organizations and principal members of organizations, involved in the growing, manufacture, or distribution of controlled substances appearing in or destined for illicit traffic in the United States; and to recommend and support non-enforcement programs aimed at reducing the availability of illicit controlled substances on the domestic and international markets.^[4]

In carrying out its mission as the agency responsible for enforcing the controlled substances laws and regulations of the United States, the DEA's primary responsibilities include:

- Investigation and preparation for the prosecution of major violators of controlled substance laws operating at interstate and international levels.
- Investigation and preparation for prosecution of criminals and drug gangs who perpetrate violence in our communities and terrorize citizens through fear and intimidation.
- Management of a national drug intelligence program in cooperation with federal, state, local, and foreign officials to collect, analyze, and disseminate strategic and operational drug intelligence information.
- Seizure and forfeiture of assets derived from, traceable to, or intended to be used for illicit drug trafficking.
- Enforcement of the provisions of the Controlled Substances Act as they pertain to the manufacture, distribution, and dispensing of legally produced controlled substances.
- Coordination and cooperation with federal, state and local law enforcement officials on mutual drug enforcement efforts and enhancement of such efforts through exploitation of potential interstate and international investigations beyond local or limited federal jurisdictions and resources.
- Coordination and cooperation with federal, state, and local agencies, and with foreign governments, in programs designed to reduce the availability of illicit abuse-type drugs on the United States market through nonenforcement methods such as crop eradication, crop substitution, and training of foreign officials.
- Responsibility, under the policy guidance of the Secretary of State and U.S. Ambassadors, for all programs associated with drug law enforcement counterparts in foreign countries.
- Liaison with the United Nations, Interpol, and other organizations on matters relating to international drug control programs.

Chart. 1.



On September 9, 2014 DEA made available the public the final rule for the Disposal of Controlled Substances published in the Federal Register and became effective on October 9, 2014.

These regulations implement the Secure and Responsible Drug Disposal Act of 2010 (Disposal Act) to prevent drug abuse by authorizing regulations that outline methods for ultimate users to dispose of their unused or unwanted pharmaceutical controlled substances. The final rule authorizes ultimate users to transfer unwanted and unused pharmaceutical controlled substances in their lawful possession to an authorized collector for safe, secure, and responsible disposal.

The new rule also regulate each stage of the disposal process, including the transfer, delivery, collection, destruction, return, and recall of pharmaceutical controlled substances, by both registrants and non-registrants. These disposal regulations are incorporated into a new 21 C.F.R. part 1317.

Authorized collectors may collect pharmaceutical controlled substances from ultimate users either through **collection receptacles, or by mail-back programs.**

The new rule also outlines the security controls and other reporting and recordkeeping requirements associated with collection activities. Many of these requirements are contained in the new part 1317, and some requirements are contained in revised parts 1301, 1304, and 1305. The new rule does not require any registrant to become a collector. Becoming a collector is voluntary.

The new rule eliminates existing 21 C.F.R. 1307.12 and 1307.21, which outline requirements for registrant and non-registrant disposal, including return and recall. The new part 1317 contains the requirements on disposal procedure and security, collection of pharmaceutical controlled substances from ultimate users, return and recall, and destruction of controlled substances.

DEA Form 41 must be used to record the destruction of all controlled substance inventory, as well as the destruction of pharmaceutical controlled substances that are collected from ultimate users.

DEA Form 106 must be used by registrants to report the theft or loss of any controlled substance, including sealed inner liners and returned mail-back packages. It has been updated to include the collection of information relevant to lost or stolen sealed inner liners and returned mailback packages.

Title 21 C.F.R. parts 1301 and 1304 have been revised to include security, inventory, recordkeeping, and other requirements and procedures pertinent to persons who reverse distribute. One important new requirement is that those entities who reverse distribute must destroy controlled substances received for the purpose of destruction within 30 calendar days of receipt. Day 1 is the day the substances are physically acquired through pick-up or delivery.

21 C.F.R. Part 1304 has been revised to include inventory and recordkeeping requirements pertinent to authorized collectors, reverse distributors, and any other person who reverse distributes.^[5]

Return and recall requirements, including recordkeeping, are outlined in 21 C.F.R. parts 1304, 1305, and 1317.

New part 1317 in Drug disposal rule provides the following requirements

- Collection of pharmaceutical controlled substances from ultimate users
- Return and recall
- Disposal procedures
- Destruction of controlled substances

Table. 2.

DEA REGISTRANTS AS ON 17/03/2016

Serial No	Registrants	Total No.
1	Importers	243
2	Manufacturers	548
3	Distributors	779
4	Pharmacies	71893
5	Hospitals	16858
6	Practitioners	1506344
7	Research analysis	9428
8	Patients	332,182,887
9	Narcotic treatment programs	1441

Collection receptacles for Controlled substances

Registrants authorized to collect controlled substances from ultimate users for the purpose of destruction (1317.40) are,

- Retail pharmacies
- Hospitals and clinics have onsite pharmacy
- Narcotic treatment programs
- Manufacturers
- Distributors
- Reverse distributors
- Longterm care facilities at which registered hospitals /clinics with onsite pharmacies or retail pharmacy.^[6]

Disposal refer generally to the wide range of activities that result in Controlled Substances being unavailable for further use or one entity ridding themselves of such substances (e.g., returns).

A controlled substance can be disposed of by destruction , return, recall, sale or through the manufacturing process.

Destruction procedures (1317.95)

The final rule implements a standard of destruction **non-retrievable**. The process utilized to render a substance "non-retrievable" shall permanently alter the substance's physical or chemical condition or state through irreversible means and thereby render the substance unavailable and unusable for all practical purposes. A 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 destruction of any controlled substance shall be in accordance with the following requirements.

(a) *Transfer to a person registered or authorized to accept controlled substances for the purpose of destruction.* If the controlled substances are transferred to a person registered or authorized to accept the controlled substances for the purpose of destruction, two employees of the transferring registrant shall load and unload or observe the loading and unloading of any controlled substances until transfer is complete.

(b) *Transport to a registered location.* If the controlled substances are transported by a registrant to a registered location for subsequent destruction, the following procedures shall be followed.

(1) Transportation shall be directly to the registered location (the substances shall be constantly moving towards their final location and unnecessary or unrelated stops and stops of an extended duration shall not occur).

(2) Two employees of the transporting registrant shall accompany the controlled substances to the registered location.

(3) Two employees of the transporting registrant shall load and unload or observe the loading and unloading of the controlled substances until transfer is complete.

(c) *Transport to a non-registered location.* If the controlled substances are transported by a registrant to a destruction location that is not a registered location, the following procedures shall be followed.

(1) Transportation shall be directly to the destruction location (the substances shall be constantly moving towards their final destruction location and unnecessary or unrelated stops and stops of an extended duration shall not occur).

(2) Two employees of the transporting registrant shall accompany the controlled substances to the destruction location.

(3) Two employees of the transporting registrant shall load and unload or observe the loading and unloading of the controlled substances.

(4) Two employees of the transporting registrant shall handle or observe the handling of any controlled substance until the substance is rendered non-retrievable; and

(5) Two employees of the transporting registrant shall personally witness the destruction of the controlled substance until it is rendered non-retrievable.

(d) *On-site destruction.* If the controlled substances are destroyed at a registrant's registered location utilizing an on-site method of destruction, the following procedures shall be followed

(1) Two employees of the registrant shall handle or observe the handling of any controlled substance until the substance is rendered non-retrievable; and

(2) Two employees of the registrant shall personally witness the destruction of the controlled substance until it is rendered non-retrievable. Additionally, the names and signatures of the two employees that witnessed the destruction must be recorded on DEA Form 41.

The ultimate users can dispose their unwanted pharmaceutical controlled substances safely and securely. It also limit the supply of controlled substances for misuse, abuse and diversion. Provides alternate disposal methods thereby protecting the environment from harmful contaminants.

Incineration is the ONLY method currently accepted by DEA. Sewering and landfill disposal (mixing with kitty litter, etc.) do not meet non-retrievable standard.

11th National Take back day was conducted by DEA on 30th September 2016 and collected a total weight of 893498 pounds (447 tons).^[11]

CONCLUSION

The disposal of unused prescription drugs and controlled substances in particular is a complicated issue. The Controlled Substances Act and Drug Enforcement Agency regulations provide a closed system of distribution of Controlled substances. Critical success factors for safe and effective Controlled substances disposal system are consumer convenience, legal and regulatory feasibility, program sustainability and effective outreach and education of stake holders involved in the system. DEA strongly encourages all practitioners to continue to adhere to security control and procedures that ensures pharmaceutical waste packages are not diverted to supply chain.

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