Legal Issues Relating to the Disposal of Dispensed Controlled Substances

Brian T. Yeh
Legislative Attorney

June 23, 2009

Congressional Research Service
7-5700
www.crs.gov
R40548

CRS Report for Congress
Prepared for Members and Committees of Congress
c11173008

Summary

According to the White House Office of National Drug Control Policy, the intentional use of prescription drugs for non-medical purposes is the second most common form of illicit drug abuse among teenagers in the United States, behind marijuana use. Young adults and teens may find their parents' prescription drugs in unsecured medicine cabinets or other obvious locations in the home, or they may retrieve expired or unwanted medication from the trash. It is believed that properly disposing of unwanted medications would help prevent prescription drug abuse by reducing the accessibility and availability of such drugs. Yet throwing prescription medications into the trash or flushing them down the toilet may not be environmentally acceptable. In response, many local communities and states have implemented pharmaceutical disposal programs (often referred to as drug "take-back" programs) that collect unused and unwanted medications from patients for incineration or other method of destruction that complies with federal and state laws.

Prescription drugs may be categorized as either controlled substance medication or non-controlled substance medication. Pharmaceutical controlled substances, such as narcotic pain relievers OxyContin® and Vicodin®, are among the most commonly abused prescription drugs. However, community take-back programs usually only accept *non*-controlled substance medication, in compliance with the federal Controlled Substances Act. This statute comprehensively governs all distributions of controlled substances, and it currently does not allow for a patient to deliver a controlled substance to another entity for disposal purposes unless law enforcement is present to assume custody of the controlled substances. As a consequence, patients seeking to reduce the amount of unwanted controlled substances in their possession have few alternative disposal options beyond discarding or flushing them.

The 111th Congress has been interested in developing ways for patients to dispose of unused or unwanted pharmaceuticals that are efficient, secure, and environmentally friendly. Two pieces of legislation have been introduced, the Safe Drug Disposal Act of 2009 (H.R. 1191) and the Secure and Responsible Drug Disposal Act of 2009 (H.R. 1359, S. 1292), that would change the federal restrictions on disposal of controlled substances that have been dispensed to patients. This report describes the provisions of the Controlled Substances Act and its implementing regulations that relate to patient disposal of unwanted prescription medication, as well as provides an analysis of the pending legislation.

Contents

Contacts

Introduction

Prescription drug abuse[1] is the second most common form of illicit drug abuse among teenagers in the United States, trailing only marijuana use.[2] Controlled substances, such as the narcotic pain relievers OxyContin® and Vicodin®, are among the most often abused prescription drugs.[3] Young adults and teens may have easy access to prescription drugs via their parents' medicine cabinets, from their friends or relatives, or they may retrieve expired or unwanted medication from the trash.[4] A possible approach to addressing the prescription drug abuse problem is to reduce the availability of such drugs by patients disposing of unwanted medications that have been accumulating in their homes.[5] Yet throwing prescription medications into the trash, flushing them down the toilet, or pouring them down a sink or drain—such that they end up in solid waste landfills or wastewater treatment systems—may have undesirable environmental consequences.[6]

Many local and state government agencies have established drug disposal programs (often referred to as pharmaceutical "take-back" programs) to facilitate the collection of unused, unwanted, or expired medications for incineration or other method of destruction that complies with federal and state laws.[7] However, these take-back programs often *exclude* controlled substance medications because federal law currently does not allow for a patient to deliver a controlled substance to another entity for disposal purposes, unless law enforcement is present to directly receive the controlled substances.[8] As a consequence, those seeking to reduce the amount of unwanted controlled substances in their households have few alternative disposal options beyond discarding or flushing them.

---

[1] In this report, prescription drug abuse is defined as the "use of prescription medications without medical supervision for the intentional purpose of getting high, or for some reason other than what the medication was intended." White House Office of National Drug Control Policy (hereinafter ONDCP), *Teens and Prescription Drug*, February 2007, at 8, *available at* http://www.theantidrug.com/pdfs/TEENS_AND_PRESCRIPTION_DRUGS.pdf.

[2] ONDCP, *Prescription Drug Abuse Prevention, at* http://www.whitehousedrugpolicy.gov/drugfact/prescr_drg_abuse.html*; see also* Substance Abuse and Mental Health Services Administration, *Results from the 2007National Survey on Drug Use and Health: National Findings, available at* http://www.oas.samhsa.gov/NSDUH/2k7NSDUH/2k7results.cfm.

[3] ONDCP, *Prescription for Danger, A Report on the Troubling Trend of Prescription and Over-the-Counter Drug Abuse Among the Nation's Teens*, January 2008, at 3, *available at* http://www.theantidrug.com/pdfs/prescription_report.pdf.

[4] *Id.* at 5.

[5] 155 CONG. REC. E386 (daily ed. Feb. 25, 2009) (statement of Rep. Jay Inslee) ("Family medicine cabinets all across America have turned into the drug dealers of today.").

[6] The environmental effects of disposal of prescription drugs by flushing them down the toilet are beyond the scope of this report. For information related to this issue, *see* CRS Report R40177, *Environmental Exposure to Endocrine Disruptors: What Are the Human Health Risks?*, by Linda-Jo Schierow and Eugene H. Buck, and *Pharmaceuticals in the Nation's Water: Assessing Potential Risks and Actions to Address the Issue*: *Hearing Before the Subcomm. on Transportation Safety, Infrastructure Security, and Water Quality of the S. Comm. on Environment and Public Works*, 110th Cong., 2nd sess. (2008).

[7] For a survey of these programs, *see* Illinois-Indiana Sea Grant College Program, *Unwanted Medicine Take-back Programs: Case Studies*, April 2, 2009, *available at* http://www.iisgcp.org/UnwantedMeds/toolkit/2.0CaseStudies.pdf.

[8] Drug Enforcement Administration (hereinafter DEA), *Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration*, 74 Fed. Reg. 3480, 3483 (Jan. 21, 2009).

Current Federal Guidelines on Proper Disposal of Prescription Drugs

The White House Office of National Drug Control Policy (ONDCP) has issued the following recommendations regarding disposing of expired or unused prescription medications in such a way that makes it difficult for the drugs to be easily retrieved:[9]

Federal Guidelines for Proper Disposal of Prescription Drugs

- Do not flush prescription drugs down the toilet or drain unless the label or accompanying patient information specifically instructs the patient to do so.
- Take advantage of community pharmaceutical drug take-back programs or other programs, such as household hazardous waste collection events, that collect drugs at a central location for proper disposal.
- *In the event a drug take-back or collection program is not available:*
  1. Take the prescription drugs out of their original containers.
  2. Mix drugs with an undesirable substance, such as used coffee grounds or kitty litter.
  3. Put this mixture into disposable containers with a lid, such as an empty margarine tub, or into a sealable bag.
  4. Conceal or remove any personal information, including the Rx number, on the empty containers by covering it with black permanent marker or duct tape, or by scratching it off.
  5. Place the sealed container with the mixture, and the empty drug containers, into the trash.

This consumer guidance was developed in collaboration with the U.S. Food and Drug Administration (FDA).[10] In addition, a public-private collaboration between the U.S. Fish and Wildlife Service, the American Pharmacists Association, and the Pharmaceutical Research and Manufacturers of America has produced a national campaign called "SMARxT DISPOSAL™," to provide information regarding the safe disposal of medication and to raise public awareness about the possible environmental impacts from improper disposal of drugs.[11] The advice disseminated under the SMARxT DISPOSAL™ campaign regarding unused medication disposal is substantially similar to that offered by the ONDCP and FDA.

[9] ONDCP, *Proper Disposal of Prescription Drugs*, February 2009, *available at* http://www.whitehousedrugpolicy.gov/publications/pdf/prescrip_disposal.pdf.

[10] Food and Drug Administration, *How to Dispose of Unused Medicines*, June 23, 2008, *available at* http://www.fda.gov/consumer/updates/drug_disposal062308.pdf.

[11] U.S. Fish & Wildlife Service, *News Release: Medicine Disposal Partnership Will Encourage Public to Flush Less, Crush More*, March 17, 2008, *available at* http://www.fws.gov/news/newsreleases/showNews.cfm?newsId=BD972725-A176-1841-9F1266DD535BE6B1; *see also* the public awareness campaign's website *at* http://www.smarxtdisposal.net/.

However, while the federal guidelines encourage consumers to utilize community pharmaceutical drug take-back programs, the current legal restrictions on collecting controlled substances necessarily limit many programs. In January 2009, in response to the concerns raised about these impediments, the Drug Enforcement Administration (DEA), an agency within the U.S. Department of Justice, requested public comments in advance of a proposed rulemaking to permit the disposal of dispensed controlled substances in a manner that is consistent with the federal Controlled Substances Act.[12] As of the date of this report, the DEA has not yet promulgated a regulation concerning this matter.

This report presents an overview of the Controlled Substances Act and its implementing regulations that relate to patient disposal of unwanted prescription medication, as well as describes legislation introduced in the 111th Congress that would amend federal law to provide for more accessible methods of secure and environmentally responsible disposal of dispensed controlled substances.

Overview of the Controlled Substances Act

Most prescription drugs are not controlled substances[13] and therefore are not regulated under the Comprehensive Drug Abuse Prevention and Control Act of 1970, commonly referred to as the Controlled Substances Act (CSA).[14] However, some prescription drugs—in particular those most susceptible to abuse such as narcotics and opiates that are often used in the treatment of pain[15]—come within the purview of the CSA because they have a greater potential for abuse than other prescription drugs and may lead to physical and psychological dependence. Enacted in 1970, the CSA is designed to regulate and facilitate the use of controlled substances for legitimate medical, scientific, research, and industrial purposes and to prevent these substances from being diverted for illegal purposes. By delegation from the U.S. Attorney General, the DEA is responsible for administering and enforcing the CSA and its implementing regulations. [16]

The CSA assigns various plants, drugs, and chemicals to one of five schedules, ranging from Schedule I, which contains substances that have no currently accepted medical use in treatment and cannot safely be made available under prescription (such as heroin), to Schedules II, III, IV, and V, which include substances that have recognized medical uses and may be manufactured, distributed, and used in accordance with the CSA.[17] The order of the schedules reflects substances that are progressively less dangerous and addictive.[18] Schedule II narcotics include the drugs

[12] DEA, *Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration*, 74 Fed. Reg. 3480 (Jan. 21, 2009).

[13] By one estimate, between 10%-11% of all drug prescriptions written in the United States are for pharmaceutical controlled substances. *Electronic Prescribing of Controlled Substances: Addressing Health Care and Law Enforcement Priorities: Hearing Before the S. Comm. on the Judiciary*, 110th Cong. (2007) (statement of Joseph T. Rannazzisi, DEA).

[14] The Federal Food, Drug, and Cosmetic Act, enforced by the Food and Drug Administration, governs the safety and efficacy of all kinds of prescription medications (controlled and non-controlled substances), including the approval, manufacturing, and distribution of such drugs.

[15] *Generation Rx: The Abuse of Prescription and Over-the-Counter Drugs: Hearing Before the S. Comm. On the Judiciary*, 110th Cong. (2008) (statement of Dr. Leonard J. Paulozzi, Centers for Disease Control and Prevention).

[16] 21 U.S.C. § 871(a); 28 C.F.R. § 0.100(b).

[17] *See* 21 U.S.C. § 812. The list of controlled substances may be found in 21 C.F.R. § 1308.11-15.

[18] For a more comprehensive description of the CSA, *see* CRS Report RL34635, *The Controlled Substances Act:* (continued...)

morphine, codeine, and OxyContin®. Schedule III substances include Vicodin® and anabolic steroids, while Schedule IV includes Xanax® and Valium®. Schedule V contains, among other things, cough medicines that contain a limited amount of codeine (Robitussin AC®).[19]

Prescriptions for Controlled Substances

It is unlawful for any person to prescribe or dispense controlled substances without first registering with the DEA Administrator.[20] No controlled substance that is a prescription drug (as determined under § 503(b) of the Federal Food, Drug, and Cosmetic Act) assigned to Schedules II, III, IV, and V may be dispensed without a prescription.[21] A prescription for a controlled substance may be issued only for a "legitimate medical purpose" by a physician "acting in the usual course of his professional practice."[22] The CSA authorizes the DEA Administrator to suspend or revoke a physician's prescription privileges upon a finding that the physician has "committed such acts as would render his registration ... inconsistent with the public interest."[23] In determining the public interest, the DEA Administrator is required to consider the following factors:[24]

- the recommendation of the appropriate state licensing board or professional disciplinary authority
- the applicant's experience in dispensing, or conducting research with respect to controlled substances
- the applicant's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances
- compliance with applicable state, federal, or local laws relating to controlled substances
- such other conduct which may threaten the public health and safety

CSA Regulatory Scheme

The regulatory structure of the CSA creates a "closed system" in which distribution of controlled substances may lawfully occur among registered handlers.[25] The CSA places several regulatory requirements upon legitimate handlers of controlled substances, including registration, providing effective security, recordkeeping, and reporting.[26] Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance, or who proposes to engage in the

(...continued)

Regulatory Requirements, by James E. Nichols and Brian T. Yeh.

[19] U.S. DEP'T OF JUSTICE, DEA, PRACTITIONER'S MANUAL (2006 ed.), at 5-6.

[20] 21 U.S.C. §§ 822, 841(a)(1).

[21] 21 U.S.C. § 829.

[22] 21 C.F.R. § 1306.04(a); United States v. Moore, 423 U.S. 122 (1975).

[23] 21 U.S.C. § 824(a)(4); 21 C.F.R. § 1301.36.

[24] 21 U.S.C. § 823(f).

[25] DEA, *Electronic Prescriptions for Controlled Substances*, 73 Fed. Reg. 36722 (proposed June 27, 2008).

[26] For more details about these requirements, *see* CRS Report RL34635, *The Controlled Substances Act: Regulatory Requirements*, by James E. Nichols and Brian T. Yeh.

manufacture, distribution, dispensing, importation, or exportation of any controlled substance, must obtain a registration issued by the DEA (unless exempt).[27] Manufacturers and distributers of controlled substances must register annually, and those who dispense controlled substances must obtain registrations that may not be issued for less than one year or more than three years.[28] Registrations specify the extent to which registrants are authorized to manufacture, possess, distribute, or dispense controlled substances. All registrants must provide "effective controls and procedures" to prevent the theft or diversion of the controlled substances in their possession.[29] In addition, the CSA imposes accountability requirements on all registered handlers of controlled substances. Registrants must keep strict records and maintain inventories in compliance with federal law and rules adopted by the relevant state.[30] For example, a registrant must maintain a complete and accurate record of each substance manufactured, received, sold, delivered, or otherwise disposed of by the registrant.[31] Registrants must also complete and submit to the DEA periodic reports of every sale, delivery, or other disposal of any controlled substance.[32]

The DEA has described the movement of a controlled substance from manufacture to the patient as follows:

> [A] controlled substance, after being manufactured by a DEA-registered manufacturer, may be transferred to a DEA-registered distributor for subsequent distribution to a DEA-registered retail pharmacy. After a DEA-registered practitioner, such as a physician or a dentist, issues a prescription for a controlled substance to a patient (i.e., the ultimate user), that patient can fill that prescription at a retail pharmacy to obtain that controlled substance. In this system, the manufacturer, the distributor, the practitioner, and the retail pharmacy are all required to be DEA registrants, or to be exempted from the requirement of registration, to participate in the process.[33]

This "closed system" of distribution guarantees that a particular controlled substance is always under the control of a DEA-registered person until it reaches the patient or is destroyed, and the CSA's regulatory requirements "ensure that all controlled substances are accounted for from their creation until their dispensing or destruction."[34]

CSA Civil and Criminal Penalties

For persons who lawfully handle controlled substances, failure to comply with the regulatory requirements of the CSA may result in civil penalties involving fines.[35] Examples of violations include the distribution or dispensing of a controlled substance not authorized by the person's registration with the DEA, as well as the refusal or failure to make, keep, or furnish any record or

[27] 21 U.S.C. § 822; 21 C.F.R. §§ 1301.22-1301.26 (exempting agents of registrants, certain military personnel, and law enforcement officials from DEA registration requirements).

[28] 21 U.S.C. § 822(a).

[29] 21 C.F.R. § 1301.71.

[30] 21 U.S.C. § 827.

[31] 21 U.S.C. § 827.

[32] 21 U.S.C. § 827(d).

[33] DEA, *Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration*, 74 Fed. Reg. 3480, 3481 (Jan. 21, 2009).

[34] DEA, *Definition and Registration of Reverse Distributors*, 70 Fed. Reg. 22591 (May 2, 2005).

[35] 21 U.S.C. § 842.

report required under the CSA. The CSA provides that violations of its regulatory requirements generally do not constitute a crime,[36] unless the violation was committed *knowingly*, in which case imprisonment of up to one or two years is authorized.[37]

The CSA provides a variety of criminal sanctions for *unlawful* possession, manufacturing, distribution, or importation of controlled substances. The CSA outlaws simple possession of controlled substances regardless of intent, stating that, "It shall be unlawful for any person knowingly or intentionally to possess a controlled substance ... "[38] However, the CSA permits patients to possess a controlled substance that "was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice.... "[39] Any person who violates the simple possession offense may be sentenced to a term of imprisonment of not more than one year, and fined a minimum of $1,000, or both.[40] A second violation raises the minimum fine to $2,500 and a minimum imprisonment term of 15 days with a maximum of two years; a third offense carries a minimum fine of $5,000 and minimum imprisonment for 90 days, with a maximum term of three years.[41]

The CSA also prohibits any person from knowingly or intentionally acquiring or obtaining possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge.[42] A violation of this section may result in a term of imprisonment of not more than four years or a fine of up to $250,000, or both; second offenses involving this section increases the maximum imprisonment term to eight years.[43]

The CSA broadly defines "distribution" to include virtually every transfer of possession.[44] Dispensing a controlled substance means "to deliver a controlled substance to an ultimate user ... by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance."[45] The term "deliver" means "the actual, constructive, or attempted transfer of a controlled substance or a listed chemical, whether or not there exists an agency relationship."[46] It is unlawful for any person knowingly or intentionally to distribute or dispense, or to possess with intent to distribute or dispense, a controlled substance, *except* as authorized by law.[47] The criminal penalties for violating this prohibition on unlawful distribution of a controlled substance vary depending on whether the individual is a first-time offender or a repeat offender, the type of substance involved, and the quantity of the type of substance involved.[48] For example,

[36] 21 U.S.C. § 842(c)(3).

[37] 21 U.S.C. § 842(c)(2).

[38] 21 U.S.C. § 844(a).

[39] *Id.*

[40] The penalties are increased for possession of flunitrazepam (a kind of date-rape drug known by its slang term "roofie") or a mixture or substance which contains cocaine base. *See* 21 U.S.C. § 844(a).

[41] *Id.*

[42] 21 U.S.C. § 843(a)(3).

[43] 21 U.S.C. § 843(d)(1).

[44] 21 U.S.C. § 802(11) ("The term 'distribute' means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical.").

[45] 21 U.S.C. § 802(10).

[46] 21 U.S.C. § 802(8).

[47] 21 U.S.C. § 841(a)(1).

[48] For a complete list of criminal sanctions for all violations of the CSA, *see* CRS Report RL30722, *Drug Offenses:* (continued...)

a violation of § 841(a) by a first-time offender involving a schedule II substance such as codeine is punishable by a term of imprisonment of up to 20 years and a fine of up to $1,000,000.[49] For a second offense, the fine increases to $2,000,000 and the maximum imprisonment term increases to 30 years.

Disposal of Controlled Substances

Disposal By DEA Registrants

DEA registrants may need to dispose of controlled substances in their possession when they are expired, unusable, or unwanted. Under the CSA and DEA regulations, there are three different options for registrants to dispose of controlled substances:[50]

1. The distributor or dispenser may return the controlled substance to the pharmaceutical manufacturer who accepts returns of outdated or damaged controlled substances.
2. The distributor, dispenser, or manufacturer may itself dispose of the controlled substances under procedures specified by federal regulation, 13 C.F.R. § 1307.21.[51]
3. The distributor, dispenser, or manufacturer may transfer the controlled substances to a "reverse distributor" to take custody of the controlled substances for the purpose of returning them to the manufacturer or arranging for their disposal.[52]

Disposal By Ultimate Users

While disposal of controlled substances by DEA registrants is governed by the federal regulations described above (and also perhaps local, county, or state environmental and waste disposal laws), disposal of controlled substances by patients is left to their discretion. The CSA and DEA regulations are largely silent on the ways in which patients may discard controlled substances that have been dispensed to them.

(...continued)

Maximum Fines and Terms of Imprisonment for Violation of the Federal Controlled Substances Act and Related Laws, by Charles Doyle and Brian T. Yeh.

[49] 21 U.S.C. § 841(b)(1)(C).

[50] DEA, *Definition and Registration of Reverse Distributors*, 70 Fed. Reg. 22591, 22592 (May 2, 2005).

[51] Under 13 C.F.R. § 1307.21, any person may request permission from DEA to dispose of controlled substances without the need for a DEA or state government witness. If a registrant has a regular need to dispose of controlled substances, the DEA may grant blanket authorization for such disposal; however, "DEA normally requires that the registrant provide two designated responsible individuals to accompany the drugs to the disposal site and witness the destruction." DEA, *Definition and Registration of Reverse Distributors*, 70 Fed. Reg. 22591 (May 2, 2005).

[52] A "reverse distributor" is a DEA-registered entity "who receives controlled substances acquired from another DEA registrant for the purpose of—(1) returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent; or (2) where necessary, processing such substances or arranging for processing such substances for disposal." 21 C.F.R. 1300.01(b)(41).

The CSA refers to an individual patient as an "ultimate user," meaning "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 by a member of his household."[53] Ultimate users are not required to register with the DEA[54] because the controlled substances in their possession "are no longer part of the closed system of distribution and are no longer subject to DEA's system of corresponding accountability."[55] Therefore, an individual patient may dispose of a controlled substance prescription medication without prior approval from the DEA, or without notifying any legal authority beforehand or afterwards.

However, DEA regulations do permit any person in possession of any controlled substance, including both registrants and non-registrants, to request assistance with disposal of such substance from the DEA Special Agents in Charge (SAC) of the area where the person is located.[56] An ultimate user who seeks the help of the DEA in disposing of a controlled substance must submit a letter to the SAC that provides several pieces of information, including the following: (1) the user's name and address; (2) the name and quantity of the controlled substance to be disposed of; (3) how the applicant obtained the substance (if known); and (4) the name, address, and DEA registration number of the person who possessed the controlled substance before the user (if known).[57] Upon receipt of this letter, a SAC may authorize the ultimate user to dispose of the controlled substance by one of the following methods: (1) by transfer to a DEA registrant; (2) by delivery to a DEA agent or to the nearest DEA field office; (3) by destruction in the presence of a DEA agent; or (4) by "such other means as the Special Agent in Charge may determine to assure that the substance does not become available to unauthorized persons."[58] The DEA has conceded that ultimate users have very rarely utilized this procedure that is available to them.[59]

The DEA's website and the agency's comments published in the Federal Register have repeatedly asserted the DEA's view that the CSA prohibits consumers from returning unwanted or unused controlled substances to their pharmacies or giving them to other DEA-registered entities for disposal purposes.[60] The DEA has stated that the CSA has no provisions that allow a DEA registrant (such as a pharmacy) to accept and take custody of controlled substances from a non-registrant (individual patient).[61] The DEA has previously explained the following:

---

[53] 21 U.S.C. § 802(27).

[54] 21 U.S.C. § 822(c)(3).

[55] DEA, *Definition and Registration of Reverse Distributors*, 68 Fed. Reg. 41222, 41226 (proposed July 11, 2003).

[56] 13 C.F.R. § 1307.21(a).

[57] *Id.*

[58] 13 C.F.R. § 1307.21(b)(4).

[59] DEA, *Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration*, 74 Fed. Reg. 3480, 3483 (Jan. 21, 2009).

[60] *See* DEA, General Questions and Answers, *available at* http://www.deadiversion.usdoj.gov/faq/general.htm#rx-10 ("An individual patient may not return his/her unused controlled substance prescription medication to the pharmacy."); DEA, *Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration*, 74 Fed. Reg. 3480, 3482 (Jan. 21, 2009) ("[N]o provisions in the CSA or DEA regulations allow a DEA registrant to routinely acquire controlled substances from a non-registrant (i.e. individual patient).").

[61] DEA, Office of Diversion Control, General Questions and Answers, *available at* http://www.deadiversion.usdoj.gov/faq/general.htm#rx-10. However, an individual patient may return unused controlled substances to a pharmacy if the controlled substance was dispensed in error or if the controlled substance medication is subject to an FDA-supervised recall. *Id.*

> The Controlled Substances Act is unique among criminal laws in that it stipulates acts pertaining to controlled substances that are permissible. That is, if the CSA does not explicitly permit an action pertaining to a controlled substance, then by its lack of explicit permissibility the act is prohibited.[62]

Not only does the CSA lack provisions that permit the transfer of a controlled substance between non-registrants and DEA registrants, but the CSA expressly prohibits an ultimate user to engage in "distribution" of a controlled substance.[63] Because the CSA defines "distribute" to mean "deliver ... a controlled substance"[64] and further defines "deliver" to mean "the actual, constructive, or attempted transfer of a controlled substance,"[65] it is illegal for an ultimate user to give a controlled substance to another person (whether DEA-registered or not) for disposal purposes.[66]

Some state and community drug take-back programs accept controlled substances from patients because they have been granted "temporary allowances" from the DEA to do so—such programs involve the participation of law enforcement agencies that have sought authorization from the SAC to directly receive the controlled substances from ultimate users for disposal purposes.[67] In the absence of such DEA approval, however, community pharmaceutical take-back programs are not permitted to collect controlled substances from consumers.

Legislation in the 111th Congress

Several bills have been introduced in the 111th Congress that would change current law and make it easier for patients to dispose of unused controlled substances by participating in drug take-back programs or delivering them to entities authorized by law to dispose of them. Introduced on February 25, 2009, by Representative Inslee, the Safe Drug Disposal Act of 2009 (H.R. 1191) would amend the CSA to allow states to operate drug disposal programs that accept from patients unwanted or unused controlled substances without requiring the presence of law enforcement personnel.[68] Specifically, the bill would direct the Attorney General to promulgate regulations that describe five drug take-back program models from which states may choose and implement, to

---

[62] DEA, *Electronic Prescriptions for Controlled Substances*, 73 Fed. Reg. 36722, 36724 (proposed June 27, 2008). *See also, e.g.*, 21 U.S.C. § 841(a) ("*Except as authorized by this subchapter*, it shall be unlawful for any person knowingly or intentionally—(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or (2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance.") (emphasis added).

[63] 21 U.S.C. § 841(a)(1) ("Except as authorized by this title, it shall be unlawful for any person knowingly or intentionally to ... distribute ... a controlled substance"); DEA, *Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration*, 74 Fed. Reg. 3480, 3481 (Jan. 21, 2009) ("[T]he CSA and its implementing regulations do not contemplate a situation in which an ultimate user would distribute controlled substances.")

[64] 21 U.S.C. § 802(11).

[65] 21 U.S.C. § 802(8).

[66] DEA, *Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration*, 74 Fed. Reg. 3480, 3481 (Jan. 21, 2009).

[67] *Id.*

[68] 155 CONG. REC. E386 (daily ed. Feb. 25, 2009) (statement of Rep. Jay Inslee) ("[T]he Controlled Substances Act has inadvertently established a barrier between safe and unsafe disposal methods of unused or unwanted controlled substances. Without amending this law, controlled substance abuse on our streets and prescription drug pollution of our water ways will continue to rise.").

permit an ultimate user (or a care taker)[69] to dispose of unused or partially used controlled substances through delivery to a designated facility. Beyond these five model state programs, the regulations must also allow states to devise an alternative means of disposal that best suits the state and that receives the approval of the Attorney General. The bill requires that any approved state drug disposal program must, among other things, permit ultimate users to dispose of controlled substances through non-law-enforcement personnel and incorporate environmentally sound practices for disposal. Furthermore, the bill would amend Section 505 of the Federal Food, Drug, and Cosmetic Act[70] and Section 351 of the Public Health Service Act[71] to require the Secretary of Health and Human Services to ensure that the labeling for drugs or biological products does "not include any recommendation or direction to dispose of the drug by means of a public or private wastewater treatment system, such as by flushing down the toilet."[72]

The Secure and Responsible Drug Disposal Act of 2009 (H.R. 1359, S. 1292), introduced by Representative Stupak on March 5, 2009, and Senator Klobuchar on June 18, 2009, would amend the CSA to allow an ultimate user—without being registered—to deliver controlled substances to an entity that is authorized under the CSA to dispose of them, providing that such disposal occurs in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances. Also, the bill would grant the Attorney General discretion to promulgate regulations that authorize long-term care facilities to dispose of controlled substances on behalf of ultimate users.

Author Contact Information

Brian T. Yeh
Legislative Attorney
byeh@crs.loc.gov, 7-5182

[69] H.R. 1191 defines "care taker" to mean "a person responsible for taking care of one or more individuals or animals, including through provision of controlled substances; and may include a physician or other health care professional, a veterinarian, a long-term care facility, a nursing home, a hospital, a jail, or a school." H.R. 1191, § 2(a).

[70] 21 U.S.C. § 355.

[71] 42 U.S.C. § 262.

[72] H.R. 1191, §3(a).