



WikiLeaks Document Release

<http://wikileaks.org/wiki/CRS-RS22491>

February 2, 2009

Congressional Research Service

Report RS22491

Legal Constraints Potentially Affecting Medication Recycling

Emily M. Cowley, American Law Division

August 8, 2006

Abstract. In recent years, the rising costs of prescription drugs have motivated various policymakers to implement cost-saving measures. In some cases, states have pursued programs to collect and redistribute unused medications that would otherwise be discarded. However, the ability to implement these so-called drug recycling programs may be constrained by federal or state law or both. For example, medications classified as controlled substances are regulated by the Controlled Substances Act (CSA). Furthermore, drugs that require prescriptions, as many controlled substances do, are regulated by the Federal Food, Drug, and Cosmetics Act (FFDCA). Additionally, programs may encounter logistical problems related to billing under the Health Insurance Portability and Accountability Act (HIPAA), which is not designed to accommodate drug recycling. Despite these hurdles, states have begun to implement drug recycling programs. Although the details of the laws vary among states, most contain strict rules to ensure the safety of the medications. This report provides an overview of the federal laws that may affect state drug recycling programs, as well as examples of these state programs.

WikiLeaks

CRS Report for Congress

Received through the CRS Web

Legal Constraints Potentially Affecting Medication Recycling

Emily M. Cowley
Law Clerk
American Law Division

Summary

In recent years, the rising costs of prescription drugs have motivated various policymakers to implement cost-saving measures. In some cases, states have pursued programs to collect and redistribute unused medications that would otherwise be discarded. However, the ability to implement these so-called drug recycling programs may be constrained by federal or state law or both. For example, medications classified as controlled substances are regulated by the Controlled Substances Act (CSA). Furthermore, drugs that require prescriptions, as many controlled substances do, are regulated by the Federal Food, Drug, and Cosmetics Act (FFDCA). Additionally, programs may encounter logistical problems related to billing under the Health Insurance Portability and Accountability Act (HIPAA), which is not designed to accommodate drug recycling. Despite these hurdles, states have begun to implement drug recycling programs. Although the details of the laws vary among states, most contain strict rules to ensure the safety of the medications. This report provides an overview of the federal laws that may affect state drug recycling programs, as well as examples of these state programs.¹

Introduction

Problems for patients associated with dramatic increases in the cost of prescription medications have generated a great deal of interest among the media, interest groups, and legislators alike.² Although no broad consensus exists regarding the causes of — and thus solutions to — the rapid increase in many pharmaceutical prices, policymakers have explored a number of options, including the recycling of unadulterated surplus drugs.

¹ This report was prepared under the general supervision of Jody Feder, Legislative Attorney.

² See, e.g., Andy Miller, *Drug Recycling Gets a Fresh Debate*, ATLANTA J.-CONST., Dec. 15, 2005, at 1A.

Currently, many health care institutions, especially long-term care facilities (LTCFs), routinely dispose of medications that otherwise have a useful life. This practice typically occurs when drugs are dispensed to patients but remain unused because the patient switches medication, is discharged, or dies. Studies have estimated that more than one billion dollars worth of drugs are discarded each year in the United States.³ One way to counter this costly practice is to recycle the unused medications. However, the ability to implement recycling programs may be constrained by federal and/or state law.

Current regulation of pharmaceuticals and those who dispense them consists of a complex system of federal and state laws. There are three federal laws discussed below that may impede the practice of recycling medications. At the state level, state controlled substances laws, pharmacy laws, and other rules promulgated by state boards of pharmacy govern practices relating to the manufacture, distribution, and possession of medicines. Nevertheless, state legislatures that have implemented drug recycling programs appear to tailor them to conform to existing regulations. State laws vary greatly regarding who may return and accept the medications, which medications may be recycled, and the procedures in place to safeguard against adulteration or unlawful possession of the medications.

Federal Laws Affecting Reuse of Drugs

Federal laws regulating pharmaceuticals pose potential obstacles to the implementation of drug recycling programs. Specifically, many of the medications covered by recycling programs are considered controlled substances and thus are subject to the requirements of the Controlled Substances Act (CSA).⁴ Furthermore, most, if not all, of the drugs in question also require a prescription in order to be dispensed, and therefore are regulated by the Federal Food, Drug, and Cosmetics Act (FFDCA)⁵ — thus adding another layer of federal statutory regulations. Additionally, programs to recycle medications may also encounter logistical problems relating to billing under the Health Insurance Accountability and Portability Act (HIPAA).⁶

Controlled Substances Act

One potential impediment to drug recycling programs is the CSA. Enacted in 1970 with the main objectives of combating drug abuse and controlling traffic in controlled

³ See Thomas M. Morgan, *The Economic Impact of Wasted Prescription Medication in an Outpatient Population of Older Adults*, 50 J. FAMILY PRACTICE 779, 780 (2001) (noting that one billion dollars per year is a conservative estimate of the lost due to drug waste).

⁴ 21 U.S.C. §§ 801 et seq.

⁵ Id. §§ 301 et seq.

⁶ Health Insurance Portability and Accountability Act of 1996, P.L. 104-191, 110 Stat. 1936 (1996). Issues related to billing difficulties may also implicate Medicaid and Medicare programs. See, e.g., *CMS: Nursing Homes Must Return Unused Meds*, UNITED PRESS INT'L, Mar. 27, 2006 (reporting that Medicaid requires nursing homes to return unused medications to pharmacies when patients leave or die). However, these issues are beyond of the scope of this report.

substances,⁷ the CSA created a regulatory regime criminalizing the unauthorized manufacture, distribution, dispensation, and possession of the substances covered by the act.⁸ Enforced by the federal Drug Enforcement Agency (DEA), the CSA establishes civil as well as criminal sanctions for its violation.

The CSA is relevant to drug recycling programs because most, if not all, of the costly medications the programs seek to recycle are considered controlled substances under the CSA.⁹ Practitioners who dispense or administer controlled substances listed on Schedules II through V, including substances that may not require a prescription, must register with the DEA.¹⁰ Entities that apply for federal registration to handle controlled substances and those so registered must provide effective controls and procedures to guard against theft and diversion of controlled substances in accordance with security requirements. These requirements vary depending on the type of activity and the substances.¹¹

However, unlike hospitals and pharmacies, most long-term care facilities (LTCFs) are not registrants.¹² Due to the stringent safety standards imposed on registrants, registration may not be feasible or cost-effective for many facilities to implement. Because of the prohibition against handling or possessing controlled substances without DEA registration, the CSA seems to preclude LTCFs — or any entity not registered with the DEA — from effectively participating in a drug recycling program. As a result, the DEA distribution system, which is designed to prevent diversion by establishing a closed distribution loop among registrants for purposes of tracking all entities that handle controlled substances prior to dispensing, often prevents LTCFs from returning such drugs to pharmacy stock and forces them to destroy any unused controlled substances.¹³

An alternative to recycling programs that LTCFs may wish to pursue is the installation of automated dispensing systems (ADS). Similar to a vending machine, an ADS is stocked with drugs by a pharmacy, which controls the device remotely and programs it to dispense drugs on a single-dose basis. The DEA recently promulgated a rule to allow this practice as a way to “mitigate the problem of excess stocks and

⁷ See 21 U.S.C. § 801.

⁸ See *id.* § 812 (establishing the five schedules of controlled substances). Substances included on Schedule I have a high potential for abuse, no currently accepted medical use in treatment, and lack of accepted safety for its use whereas substances on Schedule V have a relatively low potential for abuse, a currently accepted medical use, and limited physical or psychological dependence even if abused. *Id.* § 812(b).

⁹ For example, Hospice Atlanta listed morphine, oxycontin and percocet — each worth about \$70 — as medications they regret discarding. see Miller *supra* note 2.

¹⁰ See 21 U.S.C. § 822 (a)(2); see *also* §802 (defining practitioner as anyone who distributes, dispenses, administers a controlled substance in the course of professional practice).

¹¹ See 21 C.F.R. § 1301.71 (2006).

¹² See American Medical Association, Council on Scientific Affairs, *Recycling of Nursing Home Drugs*, Dec. 1997, available at [<http://www.ama-assn.org/ama/pub/category/print/13655.html>].

¹³ 21 C.F.R. §§ 1300, 1301, 1304, 1307 (2006).

disposal.”¹⁴ Using this system, the drugs are not deemed to be dispensed until provided by the ADS, so any unused drugs remain in pharmacy stock.

Federal Food, Drug, and Cosmetics Act

Recycling programs must also comply with statutes that regulate the safety and efficacy of prescription drugs. Federally, this regulation occurs under the FFDCA. One of the purposes of the FFDCA is to ensure drug safety by prohibiting the introduction of adulterated or misbranded foods, drugs, or cosmetics into interstate commerce.¹⁵ Therefore, programs to recycle unused prescription drugs may encounter barriers if such recycling could lead to drug adulteration or misbranding.

The federal Food and Drug Administration’s (FDA) policy guidance reflects these concerns. In guidance that dates back to 1980, the agency states, “[a] pharmacist should not return drug products to his stock once they have been out of his possession. It could be a dangerous practice for pharmacists to accept and return to stock the unused portions of prescriptions that are returned by patrons, because he would no longer have any assurance of the strength, quality, purity, or identity of the articles.”¹⁶ However, the FDA has no specific regulations regarding drug recycling programs and leaves these programs to the discretion of the state so long as state legislation does not offend applicable regulations relating to the safety and efficacy of prescription medications.¹⁷

Health Insurance Portability and Accountability Act

A smaller administrative obstacle to the effective implementation of drug recycling programs is the billing requirements under HIPAA.¹⁸ This law requires electronic transactions for operations conducted by pharmacies — the entities that are responsible for accepting unused medications in many recycling programs. Every transaction that occurs within a pharmacy must be part of the HIPAA Transactions Code Set. However, there is currently no code for returning an unused drug to stock for credit. Without this

¹⁴ See Preventing the Accumulation of Surplus Controlled Substances at Long Term Care Facilities, 70 F.R. 25462, 25462 (May 13, 2005).

¹⁵ See 21 U.S.C. § 331(a).

¹⁶ Food and Drug Administration, Compliance Policy Guides, § 460.30, Return of Unused Prescription Drugs to Pharmacy Stock (1980).

¹⁷ Florida House of Representatives Staff Analysis: Cancer Drug Donation Program, Dec. 19, 2005, available at [<http://www.myfloridahouse.gov/Sections/Documents/loadoc.aspx?FileName=h0371.HCG.doc&DocumentType=Analysis&BillNumber=0371&Session=2006>] (explaining that pharmacists may be legally liable for injuries arising from contamination or adulteration of drugs they accepted and returned to stock.)

¹⁸ Providers that would participate in drug recycling programs are likely subject to HIPAA, because HIPAA applies to health care providers who bill or receive payment for health care in the normal course of business and do so via electronic medium. Health Insurance Portability and Accountability Act, §160.103(B)(3)(1).

code, such transactions cannot be properly documented and accounted for, posing an obstacle for pharmacists and doctors who would participate in drug recycling programs.¹⁹

Current State Practice

In recent years, several states have attempted to combat waste associated with discarding unused medications by creating drug recycling programs.²⁰ These programs aren't "as simple as returning 'leftovers.'"²¹ Rather, most state legislation typically specifies who may return the unused medication, who may accept the medication, what types of medications may be returned, and to whom the medications may be redistributed.²² This section provides examples of current practices regarding such recycling programs.

Authorized Participants. Most laws specify who may return, who may accept, and/or who may receive unused medications.²³ Some states allow patients to donate, while others restrict the practice to pharmacies, doctors and wholesale distribution centers. Iowa, which falls in the former category, allows any person to donate unused medications.²⁴ In contrast, California law allows donations only from drug manufacturers, licensed health care facilities, and pharmacies.

Authorized Medications. Some states do not place restrictions on the drugs included in their recycling program, while others specify the types they will accept. For example, Nebraska restricts its drug repository program to cancer drugs.²⁵ Wisconsin

¹⁹ See Fred Gebhart, *Medication Recycling: New Patients for Old Pills*, 149 DRUG TOPICS 37 (2005).

²⁰ As of 2005, the following states have medication recycling laws in place: Arkansas, Colorado, Connecticut, Florida, Georgia, Hawaii, Indiana, Iowa, Louisiana, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Jersey, New York, Ohio, Oklahoma, South Dakota, Texas, Utah, Vermont, Virginia, Wisconsin, and Wyoming. see National Conference of State Legislatures, *Recycling Unused Drugs, State Legislatures: Trends and Transitions*, Aug. 2005, [hereinafter *Trends and Transitions*] available at [https://www.ncsl.org/programs/pubs/slmag/2005/05SLJulAug_TandT.pdf]. Massachusetts and Rhode Island have laws to study the effects of drug recycling programs. Id.

²¹ See *Trends and Transitions*, *supra* note 20.

²² Many of the recycling programs are intended to benefit the state's low-income residents that are not otherwise eligible for other state programs. For example, Maine legislation specifies that to be eligible for the program, a person must have a family income below 350% of the federal poverty level, and may not be receiving MaineCare prescription drug benefits. An Act to Plan for a Pilot Program for Distributing Unopened Medicines and Medical Supplies, Private & Special Laws, ch. 20 (Me. 2005) .

²³ Most recycling programs are intended to benefit low-income residents who are not otherwise eligible for other state programs. See, e.g., *supra* note 23. Rhode Island's pilot program provides for donation to medically indigent state residents. R.I. Gen. Laws §§ 23-25.4-1 et seq (2006).

²⁴ See Iowa Code §§ 135M.1 et seq. (2005).

²⁵ See R.R.S. Neb. §§ 71-2422 et seq. (2006).

began its recycling program as a cancer drug repository, but later expanded it to include prescription drugs and supplies for all other chronic diseases such as diabetes.²⁶

Additional Precautions. States also impose restrictions to ensure that the medications are safe. Safety requirements are fairly uniform across most states. They typically require that medications be in their original, unopened sealed packaging or in single unit doses that are individually contained in unopened, tamper-evident packaging.²⁷ Most states also prohibit the return of medications that will expire within six months or appear to be adulterated or misbranded in any way.²⁸

Despite the precautions states have attempted to build into their recycling programs, some people remain unconvinced that these programs are completely safe.²⁹ Critics argue that insufficient safety controls may lead to adulterated, dangerous medicines, and drugs that land in the wrong hands. They also argue that the actual process of repackaging medications can pose safety hazards.³⁰ Nevertheless, states seem intent on continuing to tailor their legislation in order to conform to existing law, while simultaneously acting as laboratories to test new cost-effective measures.

²⁶ See Wis. Stat. § 255.056 (2006).

²⁷ See, e.g., Wyo. Stat. §§ 35-7-1601 et seq. (2006).

²⁸ See, e.g., *id.*

²⁹ See, e.g., Melissa Davis, *Omnicare's Recycling Headache*, THE STREET.COM, Sept. 8, 2005, [<http://www.thestreet.com/stocks/melissadavid/10241462.html>]. Patrick Burns of Taxpayers Against Fraud argues that dangers posed by the repackaging process are above and beyond other safety issues like contamination and misbranding. *Id.* Additionally, many interest groups such as the Long Term Care Pharmacists Alliance oppose drug recycling programs, because they believe the practice to be unsafe. See Long Term Care Pharmacy Alliance, *Return and Reuse of Nursing Home Drugs*, at [<http://www.ltcpa.org/policy/resources/papers/returnreuse.asp>] (last visited July 27, 2006).

³⁰ *Id.*