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# Prescription Drug Abuse

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# Summary

An estimated 6.5 million individuals currently abuse prescription drugs in the United States. Unlike policy on street drugs, federal policy on prescription drug abuse is complicated by the need to maintain access to prescription controlled substances (PCS) for legitimate medical use. The federal government has several roles in reducing prescription drug abuse.

**Coordination.** The Office of National Drug Control Policy (ONDCP) coordinates and tracks prescription drug abuse reduction efforts and funding of multiple federal agencies.

**Regulation.** The primary federal statutes governing prescription drug regulation are the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Comprehensive Drug Abuse Prevention and Control Act of 1970, commonly called the Controlled Substances Act (CSA).

**Law Enforcement.** Federal law enforcement, primarily the Drug Enforcement Administration (DEA), aims to prevent, detect, and investigate the diversion of prescription drugs while regulating the supply for legitimate medical, commercial, and scientific purposes.

**Health.** Federal agencies and programs involved in health may address prescription drug abuse through service delivery (e.g., the Veterans Health Administration), financing (e.g., Medicare), and research (e.g., the National Institute on Drug Abuse).

The federal government, state and local governments, and various private entities (e.g., pharmacies) are currently undertaking a range of approaches to reducing prescription drug abuse.

**Scheduling of PCS.** The scheduling status of a PCS (1) affects patient access to PCS (e.g., by limiting refills); (2) affects the degree of regulatory requirements (e.g., supply chain recordkeeping); and (3) determines the degree of criminal punishment for illegal traffickers.

**Safe Storage and Disposal.** DEA regulates storage of PCS by registered entities (e.g., pharmacies); provides registered entities with options for proper disposal of PCS; and sponsors National Prescription Drug Take-Back Days to assist citizens in safe disposal of PCS.

**Focusing Law Enforcement.** Federal law enforcement efforts may focus on geographic areas with higher rates of prescription drug abuse or on High Intensity Drug Trafficking Areas (HIDTA) that experience a higher volume of illicit trafficking of PCS.

**Using Data to Identify Risk.** Most states operate prescription drug monitoring programs—databases of prescriptions filled for PCS. Other public and private entities also have data that may be analyzed to identify high-risk behavior among prescribers, dispensers, or patients.

**Awareness and Education.** Efforts to increase awareness and education about prescription drug abuse may focus on health care providers, patients, or the general public.

**Treatment.** Some prescription drug abuse may be avoided in treating underlying conditions (e.g., pain) or may be treated with pharmacologic or non-pharmacologic interventions. New products may improve treatment for both underlying conditions and prescription drug abuse.

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# Background

Prescription drug abuse has been described as an epidemic,[1] with an estimated 6.5 million current prescription drug abusers—including 4.3 million abusing prescription pain relievers (opioids).[2] On average, 44 people die from an overdose of a prescription painkiller each day in the United States.[3] While prescription painkillers are not the only prescription drugs of abuse (see text box), they are the most commonly abused and receive the most attention from federal policymakers.

**Prescription Drug Abuse and Prescription Controlled Substances (PCS)**

Prescription drug abuse is a commonly accepted term for a wide range of behaviors related to the use of prescription medications with addictive potential—prescription controlled substances (PCS).

Prescription drug abuse is not limited to addiction; it includes, for example, taking a medication for the purpose of getting high or taking a medication that was prescribed for someone else.[4]

PCS generally fall into three categories, although various sources use different categories or terms:[5]

- *Pain relievers* (e.g., OxyContin®) may also be called *painkillers*, *analgesics*, or *opioids*.
- *Depressants* (e.g., Xanax®) are used to treat conditions such as anxiety or insomnia; they may also be called *central nervous system (CNS) depressants*, *tranquilizers*, *sedatives*, or *benzodiazepines*;
- *Stimulants* (e.g., Ritalin®) are used to treat conditions such as attention-deficit/hyperactivity disorder (ADHD); they may also be called *amphetamine-like drugs*.

Federal policy on PCS aims to balance the need to *limit abuse* of prescription controlled substances (PCS) with the need to *maintain access* to PCS for legitimate medical use. The federal government's approach to addressing prescription drug abuse has increasingly relied on coordination across agencies, including both law enforcement and health agencies.

This report begins with a summary of recent efforts to address prescription drug abuse—focused on prescription painkiller abuse. The remainder of the report is organized in two parts: (1) federal roles in reducing prescription drug abuse and (2) current approaches aimed at reducing prescription drug abuse. Federal roles include coordination across agencies; regulation of drugs; law enforcement activities; and health services, financing, and research. Approaches to reducing prescription drug abuse include scheduling of PCS; safe storage and disposal; focusing law enforcement; using data to identify risk; awareness and education; and treatment.

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[1] See, for example, Trust for America's Health, *Prescription Drug Abuse: Strategies to Stop the Epidemic*, Washington, DC, October 2013.

[2] U.S. Department of Health and Human Services (HHS), Substance Abuse and Mental Health Services Administration (SAMHSA), *Behavioral Health Trends in the United States: Results from the 2014 National Survey on Drug Use and Health*, NSDUH Series H-50, HHS Publication No. (SMA) 15-4927, Rockville, MD, 2015. (Hereinafter, *NSDUH 2014*.) NSDUH does not use the term "prescription drug abuse" but refers to "nonmedical use of prescription-type drugs." NSDUH asks survey respondents to report only nonmedical drug use, defined as "use without a prescription of the individual's own or simply for the experience or feeling the drugs caused."

[3] HHS, Centers for Disease Control and Prevention (CDC), What the Public Needs to Know about the Epidemic, http://www.cdc.gov/drugoverdose/epidemic/public.html.

[4] Such behaviors are variously described as *illicit use*, *non-medical use*, or *misuse*, among other terms. See for example the terms used in (1) American College of Preventive Medicine, *Use, Abuse, Misuse & Disposal of Prescription Pain Medication: Clinical Reference*, Washington, DC, 2011; and (2) Federation of State Medical Boards, *Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain*, July 2013, pp. 15-18.

[5] See for example the terms used in (1) HHS, National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA), *Prescription Drug Abuse*, Research Report Series, NIH Publication Number 11-4881, revised October 2011; and (2) HHS, CDC, *Policy Impact: Prescription Painkiller Overdoses*, November 2011.

# Recent Efforts by Congress and the Administration

Congress has demonstrated an interest in addressing the problem of prescription drug abuse (and particularly prescription opioid abuse) by holding hearings[6] and introducing legislation taking various approaches to the problem. For example, the Comprehensive Addiction and Recovery Act of 2015 (H.R. 953, S. 524) would primarily authorize the Department of Health and Human Services (HHS), the Department of Justice (DOJ), and the White House Office of National Drug Control Policy (ONDCP) to administer grants and require HHS to convene task forces.[7] In contrast, the Ensuring Patient Access and Effective Drug Enforcement Act of 2015 (H.R. 471, S. 483) would primarily amend current law regarding registration to distribute or dispense PCS and require an inter-departmental report to Congress.

The Administration has also made efforts to address the problem, including an HHS opioid initiative[8] and a Presidential Memorandum requiring federal agencies to provide training in opioid prescribing to employees who prescribe controlled substances and to identify and address barriers to accessing medication-assisted treatment for opioid addiction.[9]

Both Congress and the Administration have directed funds toward reducing opioid abuse and overdoses. The Consolidated Appropriations Act, 2016 (P.L. 114-113) includes some funding for opioid-specific programs, most of which is identified in the explanatory statement accompanying the act.[10] For example, the agreement provides $25 million for the Substance Abuse and Mental Health Services Administration (SAMHSA) to expand prescription opioid and heroin abuse treatment services in high-risk communities. The President's Budget for FY2017 proposes both mandatory and discretionary funding for HHS to address prescription opioid and heroin abuse, with an emphasis on expanding the use of medication-assisted treatment.[11]

# Federal Roles in Reducing Prescription Drug Abuse

The federal government works to reduce prescription drug abuse in a variety of roles, including coordination across agencies; regulation of drugs; law enforcement activities; and health services,

[6] See, for example, U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Health, *Examining Legislative Proposals to Combat our Nation's Drug Abuse Crisis*, 114th Cong., 1st sess., October 8, 2015; and U.S. Congress, Senate Committee on the Judiciary, *Attacking America's Epidemic of Heroin and Prescription Drug Abuse*, 114th Cong., 2nd sess., January 27, 2016.

[7] The bill would also prohibit the Department of Education from including on the Free Application for Federal Student Aid form any question about the conviction for the possession or sale of illegal drugs, and would require the Comptroller General to report on how the Medicaid Institutions for Mental Disease exclusion affects access to treatment. See CRS In Focus IF10222, *Medicaid's Institutions for Mental Disease (IMD) Exclusion*.

[8] HHS, *Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths*, March 16, 2015.

[9] White House, Presidential Memorandum—Addressing Prescription Drug Abuse and Heroin Use, October 21, 2015. For more information about medication-assisted treatment, see CRS In Focus IF10219, *Opioid Treatment Programs and Related Federal Regulations*.

[10] "Explanatory Statement Submitted by Mr. Rogers of Kentucky, Chairman of the House Committee on Appropriations Regarding House Amendment No. 1 To The Senate Amendment On H.R. 2029," *Congressional Record*, daily edition, December 17, 2015.

[11] HHS, *Budget in Brief*, February 9, 2016, http://www.hhs.gov/about/budget.

financing, and research.[12] This section provides an overview of these roles, along with references to other CRS reports that address some of these roles in more detail.[13]

## Coordination

Multiple federal agencies participate in the mission to reduce prescription drug abuse—the White House Office of National Drug Control Policy (ONDCP) coordinates and tracks these agencies' efforts and related federal funding. In its 2014 *National Drug Control Strategy* (the Strategy), ONDCP identifies three policy priorities where the Administration believes there can be substantial progress over the short term; these priorities include reducing prescription drug abuse. In its prescription drug abuse prevention plan, *Epidemic: Responding to America's Prescription Drug Abuse Crisis* (published in 2011), ONDCP outlined how the federal government intends to address prescription drug abuse. The plan expanded upon the Strategy's action items that specifically addressed demand reduction. Some action items included additional training and education for physicians and pharmacists, improved drug disposal programs, enhanced prescription drug monitoring programs (PDMPs), and improved cooperation and information sharing among PDMPs.[14]

Coordinated efforts involve (1) educating parents, youth, patients, and health care providers; (2) tracking and monitoring of prescribing activity; (3) developing prescription drug disposal regulations and programs; and (4) taking enforcement action against pain clinics and prescribers who improperly prescribe and dispense narcotics. A number of federal agencies are directly involved in these efforts, including the Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA); in addition, the federal government financially supports some state prescription drug abuse prevention efforts. State efforts include the operation of prescription drug monitoring programs and participation in drug task forces.[15]

## Regulation

The primary federal statutes governing the regulation of prescription drugs are the Federal Food, Drug, and Cosmetic Act (FFDCA)[16] and the Comprehensive Drug Abuse Prevention and Control Act of 1970, commonly referred to as the Controlled Substances Act (CSA).[17]

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[12] The federal government may be involved in efforts to reduce prescription drug abuse in other ways, as many federal agencies engage in activities related to reducing drug abuse in general (not limited to prescription drug abuse).

[13] The White House Office of National Drug Control Policy (ONDCP) tracks federal agencies' drug-related activities and spending, including but not limited to activities and spending on prescription drug abuse. See Office of National Drug Control Policy, http://www.whitehouse.gov/ondcp.

[14] Office of National Drug Control Policy, *Epidemic: Responding to America's Prescription Drug Abuse Crisis*, pp. 1-7.

[15] For more information on coordination of federal efforts to reduce prescription drug abuse, see Office of National Drug Control Policy, *Epidemic: Responding to America's Prescription Drug Abuse Crisis*, 2011. For activities within the Department of Health and Human Services (HHS), see HHS, Behavioral Health Coordinating Committee, Prescription Drug Abuse Subcommittee, *Addressing Prescription Drug Abuse in the United States: Current Activities and Future Opportunities*, Washington, DC, 2013.

[16] 21 U.S.C. §§301 et seq.

[17] 21 U.S.C. §§801 et seq.

## Federal Food, Drug, and Cosmetic Act (FFDCA)

The FFDCA gives the Food and Drug Administration (FDA) responsibility for ensuring the safety and effectiveness of prescription and nonprescription drugs sold in the United States, among other things. An agency within the Department of Health and Human Services (HHS), FDA regulates the full life-cycle of a drug product, starting with initial clinical trials (and sometimes before that), through the approval process, and then for as long as the product remains on the U.S. market. FDA activities that apply to all drugs—such as drug approval, labeling, and postapproval surveillance—can be tailored to the challenges of regulating PCS, where the risk of addiction may pose a safety concern. Other FDA activities—namely the work of the Controlled Substances Staff—are focused specifically on curbing prescription drug abuse. (See text box.)

### FDA's Controlled Substances Staff

FDA has a unit specializing in controlled substances within the Center for Drug Evaluation and Research. Among other responsibilities, the Controlled Substances Staff

- recommends drug scheduling actions for HHS to submit to DEA under the Controlled Substances Act, based on analyses of the scientific and medical aspects of a drug's risk of abuse and dependence;
- provides annual estimates of the amounts of specific controlled substances that will be needed for medical and scientific use, which DEA uses in setting annual manufacturing quotas for controlled substances;
- represents FDA in relevant activities with other federal offices, including DEA, ONDCP, SAMHSA, and the National Institute on Drug Abuse (NIDA);
- makes recommendations regarding abuse liability and possible risk management requirements during the pre-approval review process (using data from SAMHSA, NIDA, DEA, and FDA surveillance programs); and
- continues to advise other FDA offices on scheduling, labeling, and risk management programs after drugs are approved for marketing.[18]

FDA reviews each new drug application[19] submitted by a drug manufacturer[20] with three major concerns: (1) safety and effectiveness in the drug's proposed use; (2) appropriateness of the proposed labeling; and (3) adequacy of manufacturing methods to ensure the drug's identity, strength, quality, and purity.[21] Reviewers can consider abuse potential (and possibly deterrence characteristics) within any of these elements. FDA approval of a drug for marketing may include specific conditions, such as restrictions on distribution, labeling disclosures, or postapproval studies that the manufacturer must conduct after marketing begins.

[18] HHS, FDA, Center for Drug Evaluation and Research (CDER), Manual of Policies & Procedures (MAPP). See in particular MAPP 4200.1: Consulting the Controlled Substance Staff on INDs and Protocols That Use Schedule I Controlled Substances and Drugs; MAPP 4200.3: Consulting the Controlled Substance Staff on Abuse Liability, Drug Dependence, Risk Management, and Drug Scheduling; and MAPP 4200.4: Office of Generic Drugs (OGD) Consultation with the Controlled Substance Staff (CSS) on Subject Abbreviated New Drug Application (ANDA) Submissions. See also HHS, FDA, "Controlled Substance Staff Functional Roles."

[19] By submitting a new drug application (NDA), a manufacturer requests permission to market a new drug, one whose active ingredient, or dosage form, or intended use has not yet been reviewed and approved by FDA. The NDA includes the results of clinical trials, information about the manufacturing process and facilities, labeling information, and a proposed risk evaluation and mitigation strategy (REMS), if appropriate. After an innovator drug (brand-name new drug) has run through its patent and other market exclusivity periods, manufacturers may submit abbreviated NDAs (ANDAs) to request permission to market generic versions of the innovator drug.

[20] The Federal Food, Drug, and Cosmetic Act (FFDCA) refers to the sponsor of an application or the holder of an approved application. Because that entity is often the product's manufacturer or its employee, this report uses the term manufacturer throughout. Note that the manufacturer may also be the responsible person, for purposes of enforcement.

[21] FDA, "New Drug Application (NDA): Introduction."

FDA may require a risk evaluation and mitigation strategy (REMS) under specified conditions—including if it determines such a strategy is necessary to ensure that the benefits of a drug (e.g., pain relief) outweigh its risks (e.g., potential for abuse).[22] A REMS may include drug safety information for patients and health care providers, as well as elements to assure safe use (ETASU). An ETASU is a restriction on distribution or use that is intended to (1) allow access to those who could benefit from the drug while minimizing their risk of adverse events, and (2) block access to those for whom the potential harm would outweigh potential benefit. By including these restrictions, FDA can approve a drug that it otherwise would have to keep off the market because of the risk it would pose.[23]

As part of the approval process, FDA reviews the manufacturer's labeling, which must begin with a highlights section that includes, if appropriate, black-box warnings (so called because they are bordered in black to signify their importance).[24] Regulations specify other required elements of labeling, including risk of drug abuse and dependence.[25] The Food and Drug Administration Amendments Act of 2007 (FDAAA)[26] added authority for the agency to require a labeling change upon learning of new relevant safety information.[27] In September 2013, FDA announced that it would use that new authority to require changes to the labeling of extended-release and long-acting opioids used to treat pain.[28]

FDA postmarket drug safety and effectiveness activities address aspects of drug production, distribution, and use. In addition to REMS and labeling requirements, FDA addresses product integrity and supply chain security, adverse event reporting, surveillance (including the Sentinel program), information dissemination, off-label use, direct-to-consumer advertising, and postmarket studies. The Secretary may require a study or a clinical trial involving a drug that is already on the market based on newly available information.[29] In September 2013, FDA

[22] FFDCA §505-1 [21 U.S.C. §355-1]. For further discussion of REMS, including ETASU, see CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, by Susan Thaul.

[23] FDA may require a REMS when a manufacturer submits a new drug application, after initial approval or licensing, when a manufacturer presents a new indication or other change, or when the agency becomes aware of new information and determines a REMS is necessary. A REMS may apply to an individual drug or all drugs in a defined class (e.g., long-acting and extended-release opioid products). See HHS, FDA, "Approved Risk Evaluation and Mitigation Strategies (REMS)"; HHS, FDA, "Opioid Drugs and Risk Evaluation and Mitigation Strategies (REMS)"; and HHS, FDA, "Questions and Answers: FDA Requires a Risk Evaluation and Mitigation Strategy (REMS) for Long-Acting and Extended-Release Opioids."

[24] "Boxed warning. Certain contraindications or serious warnings, particularly those that may lead to death or serious injury, may be required by the FDA to be presented in a box" (21 C.F.R. §201.57(c)(1)).

[25] 21 C.F.R. §201.56(d). Additional requirements include indications and usage, dosage and administration, dosage forms and strengths, contraindications, warnings and precautions, adverse reactions, drug interactions, use in specific populations, overdosage, clinical pharmacology, nonclinical toxicology, clinical studies, references, how supplied/storage and handling, and patient counseling information. For older drugs, labeling content requirements are listed in 21 C.F.R. §201.56(e).

[26] P.L. 110-85.

[27] FFDCA §505(o) [21 U.S.C. §355].

[28] HHS, FDA, "FDA announces safety labeling changes and post-market study requirements for extended-release and long-acting opioid analgesics," FDA News Release, September 10, 2013. Changes to the Indications and Usage section: from "for the management of *moderate to severe pain* when a continuous, around-the-clock opioid analgesic is needed for an extended period of time" to "for the management of *pain severe* enough to require *daily*, around-the-clock, long-term opioid treatment *and for which alternative treatment options are inadequate*" (emphasis added). An example of FDA-approved labeling for opioid products is OxyContin® (oxycodone hydrochloride controlled-release) Tablets, for oral use, CII, Initial U.S. Approval: 1950, label approved April 16, 2013.

[29] FDAAA added this authority, codified as FFDCA §505(o).

announced several studies it was directing the manufacturers of extended-release or long-acting opioid analgesic drugs to conduct.[30]

FDA has a task force focused on combatting abuse of opioid pain relievers at various points throughout the drug life cycle described above.[31] (See text box.)

**FDA Task Force Target Areas**

- **Drug Development**: workshops and public meetings to improve understanding of basic science and to develop abuse-deterrent formulations
- **Opioid Labeling**: meetings of an advisory committee and (separately) scientific experts and the public
- **Prescriber Education**: outreach and collaboration, REMS, labeling
- **Patient Education**: REMS, Medication Guides, safe disposal, and partnerships with not-for-profit campaigns and councils
- **Exploring Innovative Packaging/Storage to Prevent Abuse**: medication dispensing systems
- **Encouraging the Development of Products that Treat Abuse and Overdose**: public meeting regarding new formulations of naloxone (a medication that can reverse the effects of an opioid overdose) for use in non-medical settings
- **Role of Other Agencies**: engaging federal, state, and local agencies, as well as health care professionals, patients, and addiction/pain specialists

In February 2016, FDA announced an opioids action plan, under which the agency will expand the use of expert advisory committees regarding approval of opioid products that do not have abuse-deterrent properties and pediatric opioid labeling; change labeling for immediate-release opioids; increasing manufacturers' postmarket data requirements; update an existing REMS; issue draft guidance on approval standards for general abuse-deterrent formulations; review options to increase access to naloxone (a drug that can reverse opioid overdose), support opioid prescribing guidelines, and "facilitate development of evidence and improved treatments;" and reassess the current risk-benefit framework for approval of opioids to incorporate public health effects of misuse.[32]

For more information about FDA's role in drug safety and effectiveness—not limited to PCS—see CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, by Susan Thaul.

## Controlled Substances Act (CSA)

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.[33] *Most prescription drugs are not controlled substances and*

[30] HHS, FDA, "ER/LA Opioid Analgesic Class Labeling Changes and Postmarket Requirements," letter template to ER/LA opioid application holders, signed by Bob Rappaport, M.D., Director, Division of Anesthesia, Analgesia, and Addiction Products), linked to September 10, 2013 press release ("FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics," FDA News Release, September 10, 2013).

[31] HHS, FDA, "FDA's Efforts to Address the Misuse and Abuse of Opioids," February 6, 2013.

[32] HHS, FDA, *Fact Sheet—FDA Opioids Action Plan*, February 4, 2016, http://www.fda.gov/newsevents/newsroom/factsheets/ucm484714.htm.

[33] The Comprehensive Drug Abuse Prevention and Control Act of 1970, commonly referred to as the Controlled Substances Act (CSA), is codified at 21 U.S.C. §§801 et seq.

*therefore are not regulated under the CSA*.[34] However, some prescription drugs—in particular those most susceptible to abuse such as powerful pain relievers[35]—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.

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.[36] The order of the schedules reflects substances that are progressively less dangerous and addictive. Schedule II includes the drugs morphine, codeine, OxyContin®, and Ritalin®. Schedule III includes ketamine, buprenorphine, and anabolic steroids, while Schedule IV includes Xanax® and Valium®. Schedule V includes, among other things, cough medicines that contain a limited amount of codeine (Robitussin AC®).[37]

The CSA and its implementing regulations contain several provisions that specifically regulate the acts of prescribing and dispensing controlled substances. For example, it is unlawful for any person to prescribe or dispense controlled substances without having a current, valid DEA registration.[38] 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 of the CSA may be dispensed without a prescription.[39] 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."[40] 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."[41]

The CSA aims to reduce the potential diversion of PCS out of legitimate distribution channels by imposing specific obligations on the following participants in the prescription drug delivery and supply chain:[42]

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[34] DEA has estimated that between 10-11% of all drug prescriptions written in the United States are for PCS. Dispensing of Controlled Substances to Residents at Long Term Care Facilities, 75 *Federal Register* 37,465 (June 29, 2010).

[35] *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).

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

[37] U.S. Department of Justice (DOJ), Drug Enforcement Administration (DEA), Office of Diversion Control, *Practitioner's Manual: An Informational Outline of the Controlled Substances Act*, 2006, pp. 5-6.

[38] 21 U.S.C. §§822, 841(a)(1).

[39] 21 U.S.C. §829. As indicated earlier, substances in Schedule I have no currently accepted medical use in treatment in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse. Thus, such substances may not be the subject of a valid prescription under federal law.

[40] 21 C.F.R. §1306.04(a); United States v. Moore, 423 U.S. 122 (1975).

[41] 21 U.S.C. §824(a)(4); 21 C.F.R. §1301.36.

[42] *Responding to the Prescription Drug Abuse Epidemic: Hearing Before the Caucus on International Narcotics Control, U.S. Senate*, 112th Cong. (2012) (statement of Joseph T. Rannazzisi, DEA).

- Wholesale distributors of controlled substances who supply pharmacies with their drug inventories must proactively monitor and report to DEA any "suspicious orders of controlled substances."[43]
- Physicians must abide by the federal regulatory requirement to write a controlled substance prescription only "for a legitimate medical purpose" and "in the usual course of [their] professional practice."[44]
- Pharmacists are responsible for verifying the validity of prescriptions[45] before dispensing[46] controlled substance medication to patients (referred to as "ultimate users" under the CSA).

For more information about the CSA—not limited to PCS—see CRS Report RL34635, *The Controlled Substances Act: Regulatory Requirements*, by Brian T. Yeh, and CRS Report R40548, *Legal Issues Relating to the Disposal of Dispensed Controlled Substances*, by Brian T. Yeh.

### *Ryan Haight Online Pharmacy Consumer Protection Act*

Although many online pharmacies are legitimate businesses that offer safe and convenient services similar to those provided by traditional neighborhood pharmacies and large chain drugstores, other online pharmacies—often referred to as "rogue sites"—engage in practices that are illegal, such as selling unapproved or counterfeit drugs or dispensing drugs without a prescription.[47] These rogue sites are often difficult for law enforcement to shut down because they "have an extremely high turnover and may attempt to avoid detection by changing their Web names and addresses."[48] They also often employ fake logos of government agencies or professional associations that make them appear to be legitimate or otherwise sanctioned by law.[49]

In response to the problem of these rogue Internet websites that illegally sell and dispense PCS in violation of the CSA, the 110th Congress passed the Ryan Haight Online Pharmacy Consumer Protection Act of 2008[50] (hereinafter called "Ryan Haight Act"), which amended the CSA to expressly regulate online pharmacies. The Ryan Haight Act added a new provision to the CSA that prohibits the delivery, distribution, or dispensing of controlled substances over the Internet without a "valid prescription."[51] Only with respect to this new subsection of the CSA, a "valid prescription" is statutorily defined to mean a prescription that is issued for a legitimate medical purpose in the usual course of professional practice, by a practitioner who has conducted at least one medical evaluation of the patient in the physical presence of the practitioner.[52] Although the

[43] 21 C.F.R. §1301.74.

[44] 21 C.F.R. §1306.04(a); United States v. Moore, 423 U.S. 122 (1975).

[45] 21 C.F.R. §1306.04(a).

[46] The CSA defines "dispense" to mean "to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery." 21 U.S.C. §802 (10).

[47] Government Accountability Office, *Internet Pharmacies: Federal Agencies and States Face Challenges Combating Rogue Sites, Particularly Those Abroad* (GAO-13-560, July 2013), at 1.

[48] Nat'l Ctr. on Addiction & Substance Abuse at Columbia Univ., *"You've Got Drugs!" V: Prescription Drug Pushers on the Internet*, July 2008, at 9.

[49] Ibid. at 10.

[50] P.L. 110-425.

[51] 21 U.S.C. §829(e).

[52] Ibid. The Ryan Haight Act provides exemptions from the in-person evaluation requirement under certain

Ryan Haight Act does not apply to the Internet sale of non-controlled pharmaceutical drugs,[53] the vast majority of prescriptions sold by an online pharmacy involve controlled substances.[54]

Under the Ryan Haight Act, pharmacies must be authorized by the DEA to deliver, distribute, or dispense controlled substances by means of the Internet.[55] A registered online pharmacy must report to the DEA Administrator the total quantity of each controlled substance that the pharmacy has dispensed each month.[56] In addition, online pharmacies must clearly display on their website homepage a statement that they comply with federal and state law concerning the delivery or sale of controlled substances, as well as post certain disclosure information such as the name and address of the pharmacy (as it appears on the pharmacy's DEA registration certificate), the pharmacy's telephone number and email address, a list of states in which the pharmacy is licensed to dispense controlled substance, and the identification and contact information of the pharmacist-in-charge.

Finally, the Ryan Haight Act amended the CSA to authorize a state attorney general to bring a civil action in federal court against an online pharmacy for violations of the Ryan Haight Act, in order to stop the illegal conduct, enforce compliance with the law, or obtain damages, restitution, or other compensation that a court finds appropriate.[57]

### *Secure and Responsible Drug Disposal Act of 2010*

A possible approach to addressing the prescription drug abuse problem is to reduce the accessibility and availability of unused medications that accumulate in household medicine cabinets.[58] Patients may want to get rid of their expired or unused drugs by giving them back to pharmacies or to their prescribing physicians. Yet, when Congress originally drafted the CSA, "it did not account for circumstances in which controlled substances were lawfully dispensed to and possessed by an ultimate user but not fully used."[59] Thus, as originally enacted the CSA prohibited patients from transferring their unwanted, unused, or expired PCS to any another entity for disposal purposes, unless local law enforcement had obtained a waiver from DEA to take custody of the unused controlled substances from patients and destroy them.[60]

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circumstances in which an evaluation has been conducted via telemedicine.

[53] 154 CONG. REC. S10,185 (daily ed. September 30, 2008) (statement of Sen. Feinstein) ("The [Ryan Haight Act] does not address the delivery, distribution, or dispensing of any noncontrolled substance by the Internet or any other means. This bill does not infringe upon the powers of the Department of Health and Human Services and its Secretary with respect to noncontrolled substances. Nor does it infringe upon the traditional power of the States to regulate the practices of medicine and pharmacy with respect to the prescription of noncontrolled substances.").

[54] *Online Pharmacies and the Problem of Internet Drug Abuse: Hearing Before the Subcomm. on Crime, Terrorism, and Homeland Security of the H. Comm. on the Judiciary,* 110th Cong. 4 (2008) (statement of Joseph T. Rannazzisi, DEA).

[55] 21 U.S.C. §823(f).

[56] 21 U.S.C. §827(d)(2). However, pharmacies are exempt from such reporting requirement if they do not exceed in a given month either of two thresholds: (1) 100 or more prescriptions dispensed, or (2) 5,000 or more dosage units of all controlled substances combined. Ibid.

[57] 21 U.S.C. §882(c).

[58] 155 CONG. REC. E386 (daily ed. February 25, 2009) (statement of Rep. Jay Inslee) ("Family medicine cabinets all across America have turned into the drug dealers of today").

[59] Disposal of Controlled Substances, 77 *Federal Register* 75,784, 75,786 (proposed December 21, 2012).

[60] Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration, 74 *Federal Register* 3480, 3483 (January 21, 2009); *Drug Waste and Disposal: When Prescriptions Become Poison: Hearing Before the Senate Special Comm. on Aging,* 111th Cong., 2nd sess. (2010) (statement of Director Kerlikowske,

To make it easier and more convenient for patients to dispose of unwanted controlled substances, the 111th Congress enacted the Secure and Responsible Drug Disposal Act of 2010 (hereinafter called "Disposal Act"),[61] which amended the CSA to allow a patient to deliver controlled substances to an entity that is authorized by federal law to dispose of them, providing that such disposal occurs in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances. These implementing regulations, published in the *Federal Register* on September 9, 2014, substantially expand the options available to patients for safe and secure disposal of their unwanted controlled substance medication.[62]

The regulations governing secure disposal of controlled substances allow three primary options for patient disposal of controlled substances. The first option is for federal, state, tribal, or local law enforcement agencies to conduct periodic drug "take-back" events to collect controlled substances from unwanted users; private entities or community groups may also partner with law enforcement to hold community take-back events.[63] Second, DEA-registered manufacturers, distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, or retail pharmacies that wish to become collectors of unwanted controlled substances for disposal purposes must seek authorization from DEA to do so.[64] Authorized collectors may then conduct "mail-back" programs that utilize the mail system for convenient transfer of the unwanted controlled substances, although the physical packages in which the drugs are shipped must comply with certain requirements (for example, tamper-resistance and tracking numbers) that DEA has specified.[65] The third option permits law enforcement agencies or authorized collectors to manage, maintain, and empty secure collection receptacles at their DEA registered location.[66] A long-term care facility may also dispose of controlled substances on behalf of its residents (or former residents) by using on-site collection receptacles that are installed, managed, and maintained by authorized retail pharmacies or hospitals/clinics with an on-site pharmacy.[67] Finally, the regulations provide requirements that collectors must follow regarding methods of destroying controlled substances and destruction procedures, in order to render the collected controlled substances "non-retrievable."[68]

## Law Enforcement

Prescription drug abuse presents unique challenges to law enforcement because unlike illicit substances such as heroin, prescription drugs are often *initially* obtained through lawful channels and *subsequently* diverted from their lawful purpose. Federal law enforcement, primarily DEA, aims to prevent, detect, and investigate the diversion of prescription drugs while regulating the supply for legitimate medical, commercial, and scientific purposes.[69] State governments, law

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at 6).

[61] P.L. 111-273.

[62] Disposal of Controlled Substances, 79 *Federal Register* 53,520 (September 9, 2014).

[63] Ibid. at 53,568, adding new 21 C.F.R. §1317.65(a).

[64] Ibid. at 53,567, adding new 21 C.F.R. §1317.40(a).

[65] Ibid., adding new 21 C.F.R. §1317.70(a). Mail-back programs may also be administered by federal, state, tribal, or local law enforcement.

[66] Ibid. at 53,568, adding new 21 C.F.R. §1317.75(a).

[67] Ibid. at 53,569, adding new 21 C.F.R. §1317.75(d)(2)(iii) and 21 C.F.R. §1317.80.

[68] Ibid., adding new 21 C.F.R. §1317.90 and 21 C.F.R. §1317.95. The regulations define "non-retrievable" to mean a controlled substance that has been permanently and irreversibly altered such that it is "unavailable and unusable for all practical purposes." Ibid. at 53,560, adding new 21 C.F.R. §1300.05.

[69] DEA enforces the provisions of the Controlled Substances Act (21 U.S.C. §§801 et seq); the framework through

enforcement agencies, and health departments also engage in diversion control efforts through the development and operation of prescription drug monitoring programs (PDMPs) among other activities.[70]

DEA directly engages in diversion control. The mission of DEA's Office of Diversion Control is "to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs."[71] In addition to diversion control activities, such as sponsoring National Prescription Drug Take-Back Days,[72] the Office of Diversion Control also oversees registrations for those who seek to manufacture, import, export, sell, or dispense narcotics.[73] DEA actions generally focus on doctors prescribing PCS or traffickers of PCS (rather than individuals using PCS); DEA lists 31 administrative actions against registrants (primarily doctors) in CY2013 and maintains a multi-year list of criminal cases against doctors.[74]

## Health

Federal agencies and programs that provide health care services may prescribe PCS for underlying conditions (e.g., pain, insomnia, or ADHD) and may treat patients for prescription drug abuse or related problems (e.g., overdose or withdrawal). Relevant federal agencies include the Department of Veterans Affairs (VA), the Department of Defense (DOD), the Indian Health Service (IHS) within the Department of Health and Human Services (HHS), the Bureau of Prisons (BOP) within Department of Justice (DOJ), and some smaller programs. Some agencies that deliver health care services also finance health care services and conduct research.

Federal agencies and programs may also support health care services by providing grants, reimbursing providers, or paying a portion of insurance premiums. In so doing, they may pay for the treatment of underlying conditions, prescription drug abuse, or related problems. Relevant federal programs include Medicare, the federal portion of Medicaid, grant programs within the

which the federal government regulates the use of controlled substances for legitimate medical, commercial, and scientific purposes.

[70] Other actions taken by state law enforcement include participation in the High Intensity Drug Trafficking Area (HIDTA) Program and other enforcement activity to address doctor shopping and pill mills.

[71] U.S. Department of Justice (DOJ), Drug Enforcement Administration (DEA), Office of Diversion Control, *Program Description*.

[72] See "Safe Disposal: DEA Drug Take Back" section of this CRS report.

[73] In addition, this office oversees quota applications for drugs used in producing methamphetamine (i.e., ephedrine, pseudoephedrine, and phenylpropanolamine). The Combat Methamphetamine Epidemic Act of 2005 (CMEA; P.L. 109-177) established that the Attorney General must determine the total quantity and establish production quotas for ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured each calendar year. CMEA also prohibits the importation of ephedrine, pseudoephedrine, or phenylpropanolamine, except in amounts the Attorney General allows as necessary to provide for medical, scientific, or other legitimate purposes. The Assessment of Annual Needs (AAN) establishes the quantities of ephedrine, pseudoephedrine, and phenylpropanolamine that may be manufactured domestically and/or imported into the United States to provide adequate supplies of each chemical for (1) the estimated medical, scientific, research, and industrial needs of the United States, (2) lawful export requirements, and (3) the establishment and maintenance of reserve stocks. The responsibility of developing and calculating the AAN was delegated to the DEA Administrator, and the Administrator, in turn, delegated this function to the Deputy Administrator. CMEA also requires behind-the-counter sales of ephedrine, pseudoephedrine, and phenylpropanolamine, among other restrictions.

[74] DOJ, DEA, Office of Diversion Control, *Cases Against Doctors*, http://www.deadiversion.usdoj.gov/crim_admin_actions/.

Substance Abuse and Mental Health Services Administration (SAMHSA) and other agencies, and the Federal Employees Health Benefits Program (FEHBP).

Federal agencies and programs may also conduct or support research activities relevant to prescription drug abuse, ranging from bench science conducted in laboratories to program evaluations conducted in the field. The National Institutes of Health (NIH) conducts and funds relevant research—primarily but not exclusively through the National Institute on Drug Abuse (NIDA).[75] The Centers for Disease Control and Prevention (CDC) conducts public health surveillance (including, for example, deaths attributable to PCS overdoses) through the National Center for Health Statistics and provides information about PCS overdose through the National Center for Injury Prevention and Control.[76] SAMHSA fields surveys about drug use that provide national statistics[77] and also maintains a National Registry of Evidence-based Programs and Practices.[78] FDA has required manufacturers of extended-release and long-acting opioid drugs to conduct specific postmarket studies within designated time periods.[79]

# Current Approaches Aimed at Reducing Prescription Drug Abuse

The federal government, state and local governments, and various private entities (e.g., pharmacies) are currently undertaking a range of approaches to reducing prescription drug abuse. Such approaches may focus on health care professionals, law enforcement, or current or potential abusers.

## Scheduling of PCS

The particular scheduling status of a PCS has several significant consequences: (1) it directly affects patient access to the medication (in terms of the number of allowable refills and whether prescriptions must be written or may be conveyed over the telephone by the physician to the pharmacist); (2) it affects the degree of regulatory requirements that controlled substance handlers (manufacturers, distributors, pharmacies, and physicians) must follow (such as security restrictions and recordkeeping obligations); and (3) it determines the degree of criminal punishment for illegal traffickers of the controlled substance.

The CSA and its implementing regulations offer limitations on the prescribing and dispensing of a PCS that vary depending on the schedule in which the medication is placed. For example, no controlled substance listed in Schedule II may be dispensed to a patient by a pharmacist without a *written* prescription[80] from a practitioner, except in certain cases where the practitioner

[75] HHS, NIH, NIDA, *Drugs of Abuse: Prescription Drugs*, http://www.drugabuse.gov/drugs-abuse/prescription-drugs.

[76] HHS, CDC, *Injury Prevention & Control: Prescription Drug Overdose*, http://www.cdc.gov/drugoverdose/index.html.

[77] HHS, SAMHSA, *National Survey on Drug Use and Health (NSDUH)*, http://www.samhsa.gov/data/population-data-nsduh.

[78] See http://www.nrepp.samhsa.gov/.

[79] HHS, FDA, *New Safety Measures Announced for Extended-release and Long-acting Opioids*, http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm363722.htm.

[80] 21 U.S.C. §829(a); see also 21 C.F.R. §1306.05 (manner of issuance of prescriptions for Schedule II controlled substances). Written prescriptions include electronic prescriptions using applications that meet specified requirements.

administers the controlled substance directly to the patient.[81] However, controlled substances in Schedules III-V may be dispensed by a pharmacy pursuant to either a written or oral prescription, including a facsimile of a written prescription;[82] these substances may also be administered or dispensed directly by the practitioner in the course of his professional practice without a prescription.[83] Pharmacists are prohibited from refilling prescriptions for Schedule II substances.[84] Pharmacists may fill or refill prescriptions for controlled substances in Schedules III and IV up to five times within six months after the date on which the prescription was issued, unless the prescribing practitioner authorizes a renewal of the prescription.[85]

The schedule status of a PCS also determines the nature and extent of federal regulatory requirements for lawful handlers of controlled substances. For example, manufacturers and distributors are required to store Schedule I and II substances in electronically monitored safes, steel cabinets, or vaults that meet or exceed certain specifications,[86] while Schedule III, IV, or V substances may be stored in less secure enclosures. They must also receive a special order form from a purchaser prior to shipping Schedule I and II drugs.[87] The form is preprinted by DEA with the name and address of the purchaser, and the drugs must be shipped by the supplier filling the order to the purchaser's registered location.[88] DEA further monitors the distribution of controlled substances by requiring manufacturers and distributors of Schedule I and II drugs to file reports[89] on acquisition and distribution of controlled substances through the Automated Reports and Consolidated Orders System (ARCOS).[90] DEA also limits the quantity of Schedule I and II controlled substances which may be produced in a given calendar year.[91]

Finally, the authorized criminal penalties and fines are greater for drug trafficking offenses involving Schedule I and II substances than for those in the other schedules.

The CSA provides both legislative and administrative mechanisms for substances to be added to a schedule; removed from the scheduling framework altogether; and rescheduled or transferred from one schedule to another. Congress may change the scheduling status of a drug or substance through legislation. For example, in the 113th Congress, legislation has been introduced that would reschedule marijuana from its current placement in Schedule I to Schedule II,[92] while

[81] 21 U.S.C. §829(a); see also 21 C.F.R. §1306.11(b) (authorizing individual practitioners to administer or dispense controlled substances directly to patients without prescription).

[82] 21 U.S.C. §829(b). If the prescription is made orally, the pharmacist must promptly reduce to writing all of the information required to be in a prescription under 21 C.F.R. §1306.05, except for the signature of the practitioner. 21 C.F.R. §1306.21(a).

[83] 21 U.S.C. §829(b); 21 C.F.R. §1306.21(b).

[84] 21 U.S.C. §829(a) ("No prescription for a controlled substance in schedule II may be refilled.").

[85] 21 U.S.C. §829(b); 21 C.F.R. §1306.22(a).

[86] See 21 C.F.R. §§1301.72(a)(1)(i)-(iii) (specifications required for safes and steel cabinets storing Schedule I and II drugs or substances); see also 21 C.F.R. §§1301.72(a)(2) and 1301.72(a)(3)(i)-(vi) (specifications required for vaults storing Schedule I and II drugs or substances).

[87] DEA Form 222 is only issued to customers who are properly registered with the DEA.

[88] 21 C.F.R. §1305.13(c).

[89] 21 C.F.R. §§1304.31 and 1304.32.

[90] 21 C.F.R. §1304.33.

[91] See 21 U.S.C. §§826(a)-(e) (general provisions regarding the establishment of production quotas for Schedule I and II controlled substances).

[92] H.R. 4498.

another bill would direct the Attorney General to "issue a final order that removes marijuana in any form from all [CSA] schedules."[93]

DEA, HHS, or (by petition) any interested person may initiate federal rulemaking proceedings to add, delete, or change the schedule of a drug or substance administratively.[94] For example, DEA in 2009 requested from HHS an evaluation and recommendation concerning whether to reschedule hydrocodone combination products (HCPs) such as Vicodin® from Schedule III to Schedule II. In December 2013, HHS recommended to DEA that HCPs should be reclassified to the more restrictive Schedule II.[95] On August 22, 2014, DEA published a final rule in the *Federal Register* that administratively reschedules HCPs from Schedule III to Schedule II, which subjects anyone who manufactures, distributes, or dispenses HCPs to the more stringent regulatory requirements and administrative, civil, and criminal sanctions that are applicable to Schedule II controlled substances.[96]

## Safe Storage and Disposal

Safe storage and proper disposal of medication are viewed as ways to prevent the diversion of prescription drugs.[97] The federal government supports these prevention measures in several ways. DEA regulations require all applicants and registrants to comply with strict storage requirements for prescription medication. Also, as required under the Controlled Substances Act and DEA regulations, registrants have several options for proper disposal of medication. Congress may have an interest in monitoring the effectiveness of existing safe storage and disposal activities to determine whether additional legislative action (e.g., changes in authorizations or funding) is warranted.

### Safe Storage: Security Requirements

For the purposes of ensuring the secure storage and distribution of controlled substances and listed chemicals, all applicants and registrants must generally "provide effective controls and procedures to guard against theft and diversion of controlled substances."[98] DEA regulations further require all applicants and registrants to substantially comply with specific security standards for storage of controlled substances (and other specified chemicals).[99] Applicants and registrants must also be prepared to make adjustments to their security systems in the event that a controlled substance is transferred to another schedule or removed from control under the CSA.[100]

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[93] H.R. 499.

[94] 21 U.S.C. §811(a).

[95] DEA, *DEA Publishes Proposal to Reschedule Hydrocodone*, February 27, 2014, at http://www.dea.gov/divisions/hq/2014/hq022714.shtml.

[96] Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products From Schedule III to Schedule II, 79 *Federal Register* 49661 (August 22, 2014).

[97] Office of National Drug Control Policy, *Epidemic: Responding to America's Prescription Drug Abuse Crisis*, 2011.

[98] See 21 C.F.R. §1301.71 (general security requirements and standards for measuring compliance).

[99] 21 C.F.R. §1301.71(b) states: "Substantial compliance with the standards set forth in §§1301.72-1301.76 may be deemed sufficient by the Administrator after evaluation of the overall security system and needs of the applicant or registrant." Section 1301.71(b) also sets forth a list of fifteen discretionary factors for Administrator to consider when evaluating the overall security system of an applicant or registrant; see also 21 C.F.R. §1309.71(a)-(c) (general security requirements for List I chemicals).

[100] 21 C.F.R. §1301.71(c).

DEA regulations also detail specific security requirements for the different types of applicants and registrants. Non-practitioners (i.e., manufacturers, distributors, and narcotic treatment programs) are required to store Schedule I and II substances in electronically monitored safes, steel cabinets, or vaults that meet or exceed certain specifications.[101] Licensed practitioners must store controlled substances in a "securely locked, substantially constructed cabinet"[102] and must notify DEA of the theft or significant loss of any controlled substances within one business day of discovering such loss or theft.[103] Furthermore, all practitioners are prohibited from hiring employees who have been convicted of a drug-related felony or who have had a DEA registration denied or revoked.[104] DEA regulations recommend that non-practitioners carefully screen individuals before hiring them as employees, to ensure that job applicants do not have convictions for crimes or have engaged in unauthorized use of controlled substances.[105]

### Safe Disposal: DEA Drug Take Back

To assist citizens in proper disposal, DEA has sponsored several different types of take-back programs, including the following: permanent locations where unused prescription drugs are collected; special one-day events in which patients can drop off unwanted drugs at pharmacies or hazardous waste collection sites; and mail-in/ship-back programs.[106] As previously discussed, the Disposal of Controlled Substances final rule authorizes ultimate users[107] to transfer unwanted drugs to authorized collectors for safe and secure disposal.

Some local and state government agencies and grassroots organizations 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 methods of destruction that comply with federal and state laws and regulations, including those relating to public health and the environment.[108]

## Focusing Law Enforcement Efforts

Federal law enforcement efforts to combat prescription drug abuse may focus on specific geographic regions or on specific types of drugs, depending on how priorities are established.

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[101] See 21 C.F.R. §§1301.72(a)(1)(i)-(iii) (specifications required for safes and steel cabinets storing Schedule I and II drugs or substances); see also 21 C.F.R. §§1301.72(a)(2) and 1301.72(a)(3)(i)-(vi) (specifications required for vaults storing Schedule I and II drugs or substances).

[102] See 21 C.F.R. §1301.75 (physical security controls for practitioners).

[103] 21 C.F.R. §1301.76(b).

[104] 21 C.F.R. §1301.76(a).

[105] 21 C.F.R. §1301.90.

[106] *Drug Waste and Disposal: When Prescriptions Become Poison: Hearing Before the Senate Special Comm. on Aging*, 111th Cong., 2nd sess. (2010) (statement of Director Kerlikowske, at 6).

[107] The term "ultimate users" refers to the individuals for whom the prescription drugs were intended.

[108] 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 https://web.extension.illinois.edu/unusedmeds/disposal/Chapter2.pdf.

ONDCP analyzes geographic patterns of drug trafficking in High Intensity Drug Trafficking Areas (HIDTA).[109] For example, a 2011 drug market analysis of the Rocky Mountain HIDTA[110] shows that abuse of illegally diverted prescription drugs is "very high" in the region, and additionally this area has experienced increased overdose deaths.[111] Using drug trafficking metrics is more consistent with federal law enforcement's emphasis on traffickers and prescribers than, for example, using drug abuse metrics. While geographic patterns of prescription drug abuse are available for analysis,[112] the extent to which traffickers and prescribers are located in proximity to the individuals abusing prescription drugs is unclear.

Within the HIDTA Program, ONDCP funds the National Methamphetamine & Pharmaceuticals Initiative (NMPI), which targets specific types of drugs and chemicals. In addition to reducing the availability of methamphetamine and its precursor chemicals, NMPI aims "to reduce pharmaceutical drug crimes by utilizing best practices for investigations and intelligence collection and analysis."[113] NMPI strategic priorities that support prescription drug abuse prevention include

> [e]ffective pharmaceutical drug monitoring programs;
>
> [t]raining to federal, state, local, and tribal personnel on methamphetamine and pharmaceutical drug crimes, trends, drug-endangered children, and best practice solutions; and
>
> [e]nhance parcel interdiction and investigations.[114]

As part of this initiative, ONDCP also monitors pharmacy robberies, which may help identify trends in PCS diversion.[115]

## Using Data to Identify Risk

Various data sources may support analyses that can identify high-risk behavior indicating potential PCS diversion and abuse among prescribers, dispensers, patients, and others.

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[109] The HIDTA program, originally authorized by the Anti-Drug Abuse Act of 1988 (P.L. 100-690), provides assistance to federal, state, and local law enforcement operating in areas deemed as most-impacted by drug trafficking. The ONDCP director has the authority to designate areas within the United States that are centers of illegal drug production, manufacturing, importation, or distribution as HIDTAs—of which there are currently 28.

[110] The Rocky Mountain HIDTA region consists of 34 counties in Colorado, Montana, Utah, and Wyoming.

[111] U.S. Department of Justice, National Drug Intelligence Center, *Rocky Mountain High Intensity Drug Trafficking Area*, Drug Market Analysis 2011, September 2011, p. 11.

[112] In 2013, for example, 24.2% of the population in the West reported abusing prescription drugs in their lifetime as compared to 20.3% of the national population reporting this behavior. *NSDUH 2013*. See *Table 1.78B – Nonmedical Use of Prescription-Type Psychotherapeutics in Lifetime, Past Year, and Past Month among Persons Aged 12 or Older, by Geographic Characteristics: Percentages, 2012 and 2013*. NSUDH refers to nonmedical use of prescription-type psychotherapeutics rather than prescription drug abuse.

[113] Office of National Drug Control Policy, *HIDTA Initiatives*, http://www.whitehouse.gov/ondcp/hidta-initiatives.

[114] Ibid.

[115] U.S. Department of Justice, Community Oriented Policing Services, *ONDCP Working with Partners to Address Pharmacy Robberies and Rx Drug Abuse, Statement by Gil Kerlikowske*, Community Policing Dispatch, Volume 5, Issue 4, April 2012. For data on pharmacy robberies, see Jeff Browning, "Drug Theft Prevention," presentation at Pharmacy Diversion Awareness Conference, Albuquerque, NM, March 2-3, 2013.

## Prescription Drug Monitoring Programs (PDMPs)

Prescription drug monitoring programs (PDMPs) maintain statewide electronic databases of prescriptions dispensed for PCS. Analysis of information collected by PDMPs may help identify potential PCS diversion and abuse. Law enforcement uses of PDMP data include (but are not limited to) investigations of physicians who prescribe controlled substances for drug dealers or abusers, pharmacists who falsify records in order to sell controlled substances, and people who forge prescriptions.[116] Public health uses of PDMP data include (but are not limited to) preventing dangerous combinations of medications when physicians check a patient's PDMP record prior to prescribing a PCS or other medication. Congress appropriates funds to support state PDMPs through DOJ-administered grants—and previously through HHS-administered grants as well.

For more information about PDMPs, see CRS Report R42593, *Prescription Drug Monitoring Programs*, by Kristin Finklea, Lisa N. Sacco, and Erin Bagalman.

## Other Data Sources

In addition to PDMPs, which were designed specifically to track PCS, various public and private entities have data potentially related to prescription drug abuse. For example, New York City's RxStat program combines multiple sources of health and crime data (including PDMP data) with sophisticated analytics to help target efforts to reduce prescription drug abuse.[117] At the federal level, FDA (along with public and private partners) is building a national system of health care databases that FDA can search for adverse events possibly associated with its regulated products—including PCS.[118]

Medicare, Medicaid, and private health insurers have data about the medical care for which they pay. Analyses similar to those used to detect potential fraud may be applied to identify behavior potentially contributing to prescription drug abuse. For example, Iowa's Medicaid program refers members who receive prescriptions from multiple pharmacies or multiple prescribers (among other possible criteria) to a "lock-in" program, which limits them to one primary care physician, one pharmacy, one hospital, and one specialist.[119] The Alliance to Prevent the Abuse of Medicines is reviewing legislative options for a similar program in Medicare, which would restrict certain beneficiaries to a single pharmacy and avoid disrupting access to needed medications.[120]

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[116] DOJ, DEA, Office of Diversion Control. Of note, DEA is not involved with the administration of any state PDMP. In February 2014, the U.S. District Court for the District of Oregon became the first court to rule that law enforcement agencies must obtain a search warrant to gain access to confidential prescription drug records from a state PDMP. Because prescription records are entitled to a heighted expectation of privacy, the federal court found that the DEA's use of its administrative subpoena power (under 21 U.S.C. §876) to obtain the records violates the Fourth Amendment's protection against "unreasonable searches and seizures." Oregon Prescription Drug Monitoring Program v. U.S. Drug Enforcement Administration, No. 3:12-cv-02023 (D. Or. February 11, 2014).

[117] Mayor's Task Force on Prescription Painkiller Abuse, *RxStat: Opioid Analgesic Use and Misuse in New York City*, New York, NY, September 2013; and "NYC RxStat: A Collaborative Approach to Surveillance of Prescription Drug Misuse and Associated Consequences," presentation at National Governor's Association Institute for Governors Criminal Justice Policy Advisors, Burlington, Vermont, June 8, 2015.

[118] HHS, FDA, "Sentinel Initiative," http://www.fda.gov/safety/fdassentinelinitiative/default.htm. See also "Mini-Sentinel," http://mini-sentinel.org/; and "Assessments of Exposures to Medical Products Details," http://mini-sentinel.org/assessments/medical_products/details.aspx?ID=204.

[119] HHS, Centers for Medicare & Medicaid Services (CMS), Center for Program Integrity, *Drug Diversion in the Medicaid Program: State Strategies for Reducing Prescription Drug Diversion in Medicaid*, January 2012.

[120] Alliance to Prevent the Abuse of Medicines, *Legislative Concepts*, April 2014, http://rxabusesolutions.org/legislative-concepts/. The Alliance to Prevent the Abuse of Medicines includes stakeholders in the PCS supply chain

Pharmacies have data about prescriptions written by providers and filled by patients. For example, a large chain pharmacy identified high-risk prescribers and (after multiple attempts to contact them) stopped filling prescriptions for controlled substances written by those who were unable or unwilling to provide legitimate reasons for their high-risk prescribing patterns.[121]

Similarly, large health care service delivery systems have data about their patients' diagnoses and treatments, as well as providers' practice patterns.

## Awareness and Education

ONDCP has described raising awareness through education as a "crucial first step in tackling the problem of prescription drug abuse."[122] Efforts to increase awareness and education about prescription drug abuse may focus on health care providers, patients, or the general public.

Although federal agencies do not generally regulate the practice of medicine, they may convene expert panels or encourage state-level activities to explore clinical decision support tools (e.g., electronic alerts or treatment guidelines).[123] In conjunction with a REMS specifically for extended-release and long-acting opioid analgesics,[124] FDA has published a "blueprint" for prescriber education[125] and has established a searchable on-line repository for educational activities that comply with the REMS.[126] The REMS also includes development of materials to educate patients when the prescription is written and when it is filled.[127] SAMHSA offers reports,[128] pamphlets,[129] and continuing medical education[130] about prescription drug abuse at no cost.

In addition to federal efforts, state or local governments and private entities may also engage in awareness and education activities. Several states have produced or sponsored Public Service Announcements to raise public awareness of prescription drug abuse.[131] The Federation of State

(e.g., American Medical Association, CVS Caremark, Cardinal Health) with the mission to "raise awareness of the issue of prescription drug abuse, partner with legislators to craft achievable solutions, and serve as a resource for policymakers and the media."

[121] Mitch Betses and Troyen Brennan, "Abusive Prescribing of Controlled Substances—A Pharmacy View," *New England Journal of Medicine*, no. 269 (September 12, 2013), pp. 989-991.

[122] White House Office of National Drug Control Policy (ONDCP), *Epidemic: Responding to America's Prescription Drug Abuse Crisis*, 2011, p. 2.

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Medical Boards has published a model policy to encourage state medical boards to adopt guidelines for use of prescription pain relievers in treating chronic pain.[132]

## Treatment

Prescription drug abuse may be prevented in some cases through choices in treatment of underlying conditions (e.g., pain), and it may be treated effectively through pharmacologic or non-pharmacologic interventions. New products may be developed for treating both underlying conditions and prescription drug abuse.

### Treatment of Underlying Conditions

Decisions about how to treat underlying conditions (e.g., pain, ADHD, or insomnia) might be made with attention to minimizing the risk of prescription drug abuse. For example, alternatives to prescription medications—such as surgery or physical therapy instead of pain relievers—may be available for some conditions.[133] VA and DOD have jointly issued clinical practice guidelines for treating chronic pain with prescription pain relievers, taking into account not only managing pain effectively but also limiting risk of abuse and monitoring for signs of abuse.[134] As an example of a state-level effort, Ohio's guidelines for prescribing controlled substances in emergency departments and acute care facilities suggest limiting prescriptions to a three-day supply, thus putting less of the medication in circulation.[135]

### Treatment of Prescription Drug Abuse

The National Institute on Drug Abuse (NIDA) recognizes both medications and behavioral treatments as effective approaches to treating drug abuse in general and prescription drug abuse in particular.[136] Which treatment is effective—particularly among pharmacologic treatments—varies by the drug of abuse. Addiction to opioids (including prescription pain relievers) may be treated using medication-assisted treatment such as methadone, buprenorphine, and naltrexone.[137] NIDA is funding research into medications to treat addiction to stimulants (e.g., Ritalin®); no medications are currently FDA-approved for this indication.[138] The federal government may support treatment of prescription drug abuse through direct service delivery, financing or grant funding, and regulation of opioid treatment programs.

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For more information about medication-assisted treatment of opioid addiction, see CRS In Focus IF10219, *Opioid Treatment Programs and Related Federal Regulations*, by Erin Bagalman.

### New Product Development

New pharmaceutical products may come in the form of new formulations of existing drugs (e.g., tamper-resistant or abuse-deterrent pain relievers), new drugs to treat underlying conditions (e.g., pain or insomnia) without addictive properties, or new drugs to treat addiction.

Abuse-deterrent drug formulations include additional substances intended to make the primary drug less subject to abuse. An example is the combination of buprenorphine and naloxone, where the naloxone is meant to prevent the buprenorphine from taking effect if the drug is injected rather than dissolved under the tongue.[139]

Tamper-resistant drug formulations are manufactured to prevent potential abusers from crushing them into a powder that can be snorted or dissolving them into a liquid that can be injected. An example is the reformulated version of extended release oxycodone, which is manufactured with a highly viscous (i.e., gooey) substance that prevents the pill from being crushed or dissolved.[140]

NIDA has identified the "development of effective, nonaddicting pain medications [as] a public health priority."[141] Non-pharmaceutical products or interventions may also be developed to treat underlying conditions such as pain, reducing the demand for PCS.

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