Drug Abuse in America – Prescription Drug Diversion

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Prescription Drug Diversion

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The Council of State Governments

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Executive Summary

Prescription medications are vital for many individuals suffering from anxiety, pain and various other medical conditions. There are millions of people nationwide, however, who buy, sell, steal and abuse these same drugs for recreational purposes. More than 6 million people aged 12 or older were current illicit users of prescription drugs in 2002.

The abuse and diversion of prescription drugs onto the street are serious problems. In 2001, prescription drug abuse and misuse were estimated to impose approximately $100 billion annually in health care costs.[1, 2] An important issue for policy-makers nationwide is how to control the diversion of prescription drugs while maintaining their availability for legitimate use.

State officials and the federal government have regulated prescription medications for more than 30 years, but they still end up on the street. The diversion of these drugs from medical purposes to the illegal market occurs in several ways, including:

- doctor shopping;
- illegal Internet pharmacies;
- drug theft;
- prescription forgery; and
- illicit prescribing by physicians.

In order to ensure the availability of prescription medications for serious medical conditions, such as cancer, while preventing their availability to substance abusers, states can actively attempt to prevent the diversion of prescription drugs to the illegal market. States can accomplish this through a combination of several strategies, such as:

- prescription drug monitoring programs;
- education of health care professionals; and
- theft and fraud prevention, including preventing pharmacy theft, prosecuting illegal Internet pharmacies and enforcing Medicaid controls.

This *TrendsAlert* provides an overview of prescription drug abuse in the United States and the various ways in which these drugs are diverted to the illegal market. The last section of this report outlines the options available for states to ensure the availability of prescription drugs for medical purposes while preventing their abuse and diversion.

1. Prescription Drug Abuse in the United States

There is no question that the abuse of prescription drugs is a problem in the United States. In 2002, 6.2 million people aged 12 or older were current illicit users of prescription drugs, including pain medications such as Percocet, Lortab and OxyContin; tranquilizers such as Valium and Xanax; stimulants, like Ritalin; and sedatives, which include sleeping pills.[3]

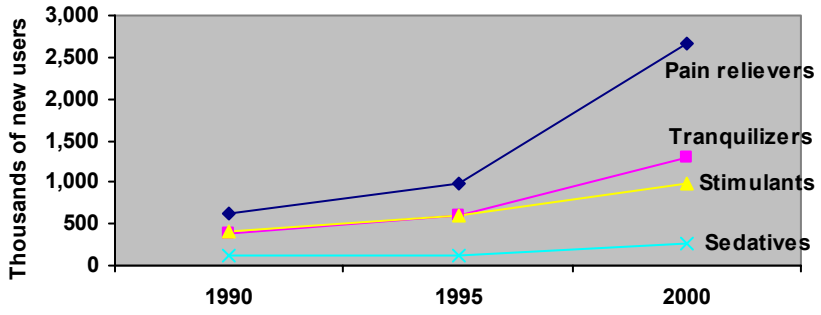
To understand how and why prescription drugs are diverted into the illegal market it is necessary to explore:

- trends in prescription drug abuse; and
- problems associated with abuse.

Trends in Prescription Drug Abuse

The abuse of prescription medications has been increasing steadily over the last 10 years, and every year more and more Americans try them for the first time. Figure 1.1 depicts the number of new nonmedical users of prescription drugs between 1990 and 2000. The number of individuals abusing pain medications for the first time grew from 628,000 in 1990 to nearly 3 million in 2000. The use of stimulants and tranquilizers for the first time has also been on the rise.[4] In addition, data on national admissions to substance abuse treatment services indicate that the number of admissions for prescription pain relievers increased 168 percent between 1992 and 2001.[5]

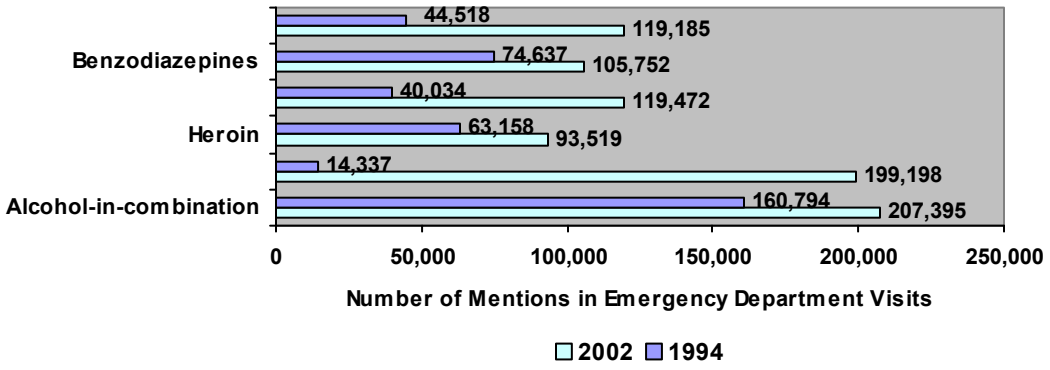
Figure 1.1 **New Nonmedical Users of Prescription Drugs, 1990-2000**



Source: Results from the 2002 National Household Survey on Drug Use and Health: National Findings, 2003.

Trends in drug-related emergency department visits also show that prescription drug abuse is on the rise. From 1994 to 2002, mentions of benzodiazepines (such as Valium and Xanax) increased 42 percent. Mentions of pain medications in emergency department visits increased from 44,518 in 1994 to more than 119,000 in 2002 – a 168 percent change.[6] In fact, Figure 1.2 shows that these prescription drugs are mentioned in emergency department visits related to drug abuse as frequently as heroin and marijuana.[7]

Figure 1.2 **Mentions of Selected Drugs in Emergency Department Visits Related to Drug Abuse, 1994 and 2002**



Source: The Dawn Report, November 2003.

Problems Associated with Abuse

Compared to other commonly abused drugs, like heroin and crack cocaine, prescription drugs are unique in that they can be obtained through legal channels. These drugs have become attractive to would-be substance abusers because they are manufactured legitimately and prescribed by physicians, giving them the illusion of safety. In reality, the addiction and withdrawal associated with the abuse of many prescription drugs can be more harmful than that associated with illegal drugs.[8]

If physical dependence is present and a person suddenly stops taking a prescription drug, such as Xanax, there is a high risk of seizures or even death.[9] Physical dependence, however, is not necessarily an indication of addiction. It simply means that the body has developed a tolerance and the user cannot stop taking the drug without gradually decreasing the dose in order to prevent withdrawal.[10]

Definitions Related to Prescription Drug Use and Abuse

- **Addiction** – A chronic disease characterized by compulsive drug seeking and drug use and changes in the brain's chemistry.
- **Dependence –** A physiological state occurring through regular use of certain medications, resulting in withdrawal when drug use stops.
- **Tolerance –** The result of repeated use of a drug in which higher doses are needed to experience the same effect as felt initially.
- **Withdrawal –** The symptoms experienced after suddenly stopping or reducing the chronic use of certain drugs.

The legitimate need for these drugs and the demand for them by substance abusers and addicts are opposing issues that have to be addressed together in order to make them available while preventing their abuse.

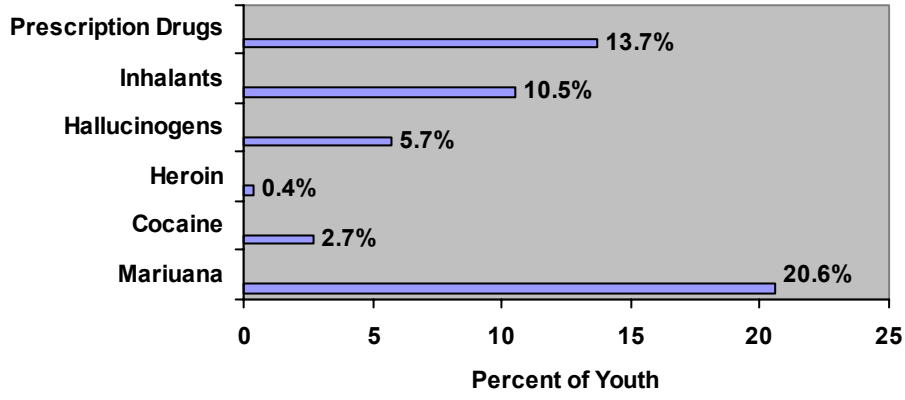
This is particularly the case with prescription pain relievers. Because of drugs like OxyContin, individuals with severe, long-term pain no longer have to suffer. The people who receive these medications due to legitimate need are not typically the same people who become abusers. Research indicates that someone with no history of addiction seldom becomes addicted to his or her prescribed medications.[11]

Many states have had to face the reality that the illegal use of prescriptions drugs takes lives. In 2001, 67 deaths in Virginia were attributed to oxycodone, the main ingredient in OxyContin and Percocet.[12] In Florida, there were 328 deaths attributed to heroin overdoses in 2001 compared to 957 deaths due to overdoses of the prescription pain medications oxycodone and hydrocodone, such as the brand name drugs Vicodin and Lortab.[13] The trend continued in 2002, when more Floridians died from prescription drug overdoses than use of illegal drugs.[14]

Prescription drugs are often easier to obtain than illegal drugs, such as heroin. The Internet contributes to this problem through the hundreds of Web sites that sell prescription drugs without a prescription. (The next section explores the diversion of prescription drugs through the Internet.)

Due to the ease of obtaining prescription drugs and the common misconception that they are "safe" to abuse, the trend of prescription drug abuse by our nation's youth is steadily increasing.

Figure 1.3 **Percent of Youth Aged 12 to 17 Who Have Used Illicit Drugs in Lifetime, 2002**



Source: Results from the 2002 National Household Survey on Drug Use and Health: National Findings, 2003.

American youth abuse prescription drugs more frequently than heroin, cocaine and every other illicit drug except marijuana.[15] Figure 1.3 shows the percentage of youth aged 12 to 17 who have used illicit drugs, including the nonmedical use of prescription medications, at least once in their life.

In addition, the annual "Monitoring the Future Survey" of 50,000 high school students nationwide recently reported that substance abuse by teenagers has dropped overall with the exception of two prescription pain medications – OxyContin and Vicodin.[16]

The challenge of allowing people with serious health concerns access to medications while preventing these drugs from being diverted into the hands of abusers and addicts is considerable, but not impossible, to overcome.[17] In order to understand how to upset the flow of prescription drugs onto the streets it is important to understand which drugs are being targeted and how they are diverted from medical sources.

2. The Diversion of Prescription Drugs

Prescription drug diversion is simply the deflection of prescription drugs from medical sources into the illegal market.[18] The exact amount of prescription medications diverted is unclear, but a 2001 survey of 34 law enforcement agencies reported 5,802 cases of diversion in 2000 alone.[19] Prescription drugs can be a lucrative business, selling on the street for as much as 10 times what they are worth retail. An 80 mg OxyContin pill, for example, costs about $6 at a pharmacy and sells for $65 to $80 on the street.[20]

Before detailing the options available to states to control diversion, we must first consider:

- the attributes of some commonly abused drugs;
- the regulation of prescription drugs; and
- how diversion occurs.

Overview of Selected Prescription Drugs

Over the years, prescription medications have become the most effective form of treatment for managing many health conditions, especially chronic pain.[21] Table 2.1 details the prescription medications most commonly abused, what they are prescribed for and how they affect the body.

Table 2.1 **Commonly Abused Prescription Medications**

Type	Opioids	Central Nervous System Depressants	Stimulants
Examples	OxyContin, Darvon, Vicodin, Dilaudid, Demerol, Lomotil	Mebaral, Nembutal, Valium, Librium, Xanax, Halcion, ProSom	Dexedrine, Ritalin, Meridia
Purpose	Post-surgical pain relief, management of acute or chronic pain, relief of coughs or diarrhea	Anxiety, tension, panic attacks, acute stress reactions, sleep disorders, anesthesia	Narcolepsy, attention-deficit hyperactivity disorder, depression, obesity, asthma
Actions	Attach to receptors in the brain and spinal cord, blocking transmission of pain messages to the brain	Slow brain activity, producing a calming effect	Enhance brain activity, causing an increase in alertness, attention and energy
Short-term effects	Blocked pain messages, drowsiness, constipation, depressed respiration	"Sleepy" and uncoordinated feeling during the first few days as the body becomes accustomed (tolerant) to the effects, but these feelings diminish	Elevated blood pressure, increased heart rate, increased respiration, suppressed appetite, sleep deprivation

Table 2.1 **Commonly Abused Prescription Medications (continued)**

Type	Opioids	Central Nervous System Depressants	Stimulants
Long-term effects	Potential for tolerance, physical dependence, withdrawal and/or addiction	Potential for tolerance, physical dependence, withdrawal and/or addiction	Potential for addiction
Possible problems	Severe respiratory depression or death following a large single dose	Seizures following a rebound in brain activity after reducing or discontinuing use	Dangerously high body temperatures or irregular heartbeat after taking high doses, cardiovascular failure or lethal seizures

Source: National Institute of Drug Abuse Research Report Series, Prescription Drugs: Abuse and Addiction, NIH Publication No. 01-4881, 2001.

Several prescription drugs have received a lot of media attention in recent years – particularly the pain medication OxyContin; benzodiazepines, such as Xanax; and the stimulant Ritalin.

The Food and Drug Administration (FDA) approved OxyContin in 1995. Viewed by many as a revolutionary time-release pain medication, it provides the user with a longer duration of pain relief not possible with any other drug. Between 1996 and 2000, the number of OxyContin prescriptions exploded, rising to 6 million.[22] By 2002, 9.6 million prescriptions had been written.[23] Since 1996, reports of abuse have begun to rise as well.

In 2002, 1.9 million people aged 12 or older reported using OxyContin for a nonmedical reason at least once during their lifetime.[24] This is up from only 221,000 in 1999. Due to its controlled-release function, OxyContin contains higher doses of the opioid oxycodone than other related drugs, such as Percocet. Abusers have realized that if they crush or chew the pills the controlled-release function is compromised, giving the user one excessive dose of the drug resulting in a high comparable to one from heroin. OxyContin abuse has brought much attention to the problem of prescription drug abuse in the United States. Many substance abuse treatment facilities nationwide report that 30 percent to 90 percent of new admissions are OxyContin-related.[25]

Two other prescription medications making headlines are the anxiety drug, Xanax, and Ritalin, which is prescribed for attention-deficit hyperactivity disorder (ADHD). Along with other prescription drugs, the abuse of Xanax is rising, especially in combination with other drugs such as alcohol and stimulants.[26]

The stimulant Ritalin is also often used with other drugs and/or alcohol. Reports of Ritalin abuse are becoming more common, especially among college students. One study found that one-fifth of college students interviewed had taken Ritalin at least one time.[27] Campuses all over the country report that these drugs are as common as marijuana and are heavily relied upon for late-night studying.[28]

Regulation of Prescription Drugs

The federal government has controlled prescription medications for more than 30 years. The Controlled Substances Act (CSA), which is Title II of the Comprehensive Drug Abuse Prevention Act of 1970, requires any pharmacy, hospital, physician, manufacturer or distributor that works with any of the substances listed under the CSA to register with the Drug Enforcement Administration (DEA).[29]

This registration helps the government monitor the movement of controlled substances from the manufacturer and distributor to the pharmacy. Unfortunately, controls at the retail level are not as stringent.[36]

DEA officials use the Automated Reports and Consolidated Orders System (ARCOS) to track specific drugs from manufacturer to retail distributor.[37] This system enables the agency to track these substances as they are manufactured and ultimately prescribed to the user.[38] The DEA analyzes ARCOS data and provides it to state agencies at no cost.[39] States can use the information to determine retail distributors, such as physicians or pharmacists, who receive unusual quantities of certain drugs.[40]

Table 2.2 describes the five schedules that characterize all controlled substances based on the CSA. The act authorizes the DEA to prevent the diversion of drugs under Schedules II through V while ensuring they are available for medical need.[41] The agency does this through activities such as maintaining the national registration program (described above), conducting investigations and establishing production quotas.[42]

Example 2.1 **DEA's National Action Plan to Address OxyContin Abuse and Diversion**

The DEA National Action Plan was developed in 2001 to deter abuse and diversion of OxyContin.[30] Never before has the agency targeted a specific brand name for scrutiny.[31] The plan has four distinct components:

- Enforcement and intelligence – The DEA has focused attention and existing resources on abuse and diversion. This effort involves the cooperation of federal, state and local law enforcement agencies.[32]
- Regulatory and administrative – The DEA is using all regulatory and administrative authority to prevent diversion and continually seeks support of other regulatory agencies.[33]
- Industry cooperation – The DEA is developing cooperative relationships with the pharmaceutical industry, particularly the manufacturer of OxyContin, Purdue Pharma LP.[34]
- Awareness, education and outreach initiatives – The DEA is working to increase awareness of the dangers of abuse while recognizing its necessity for the treatment of pain.[35]

Drugs can be moved from one schedule to another if new information regarding medical necessity or abuse potential surfaces. Recently, the DEA has expressed interest in moving hydrocodone, which includes the pain medications Lortab and Vicodin, to Schedule II, the category of medically accepted drugs with the highest potential for abuse.[43] DEA officials claim that the reasoning behind the proposed move is the rise in hydrocodone abuse and trafficking over the last several years.[44]

Table 2.2 **Controlled Substances by CSA Schedule**

CSA Schedule	Description	Examples
I	• High potential for abuse • Not currently accepted for medical use • Not considered safe	Ecstasy, heroin, LSD, marijuana
II	• High potential for abuse • Accepted for medical use • Abuse may lead to severe dependence	Cocaine, Methadone, OxyContin, Percocet
III	• Potential for abuse less than schedules I and II • Accepted for medical use • Abuse may lead to moderate or low physical or high psychological dependence	Lorcet, Vicodin, Lortab, anabolic steroids
IV	• Low potential for abuse relative to schedule III • Accepted for medical use • Abuse may lead to limited dependence relative to schedule III	Xanax, Valium, Klonopin, Ativan
V	• Low potential for abuse relative to schedule IV • Accepted for medical use • Abuse may lead to limited dependence relative to schedule IV	Robitussin A-C, Motofen, Kapectolin PG

States also have some control over the scheduling of prescription drugs. State laws can require that a prescription be filled within a certain amount of time after it is written.[45] In addition, states can classify drugs at a higher level than the CSA or place a drug on the state "controlled substance list" if it is not on the federal schedule.[46] Six states, for example, use classification systems containing a different number of schedules, and three states' systems completely differ from the federal CSA.[47]

Some states re-classify drugs at a higher or lower level than the federal CSA. Rohypnol, also known as the "date rape" drug, is found on the CSA under Schedule IV. Six states classify this drug at the highest schedule I, but four states do not schedule it at all.[48] States also regulate prescription drugs through the implementation of prescription monitoring programs, which are discussed later in this report.

Along with states and the DEA, the FDA also has oversight over prescription drugs. The administration approves drugs for medical use and regulates marketing.[49] It weighs the risks and benefits of drugs before approval and ensures that advertising is truthful and appropriately communicated.[50] The FDA is currently working with pharmaceutical companies that manufacture controlled-release pain medications to apply risk management plans to ensure the availability of these drugs for legitimate need while minimizing the incidence of abuse.[51]

Despite the fact that prescription drugs have legitimate medical purposes, they are diverted into the illegal market to be sold for recreational use, costing states billions of dollars in areas such as law enforcement, health care, social services and court costs.

Methods of Diversion

While youth typically acquire drugs by stealing from their relatives or buying from classmates who sell their legitimate prescriptions,[52] the diversion of prescription drugs among adults typically occurs through:

- doctor shopping;
- illegal Internet pharmacies;
- drug theft;
- prescription forgery; and
- illicit prescriptions by physicians.

Doctor Shopping

"Doctor shopping," one of the most popular methods of obtaining prescription drugs for illegal use,[53] typically involves an individual going to several different doctors complaining of a wide array of symptoms in order to get prescriptions. This type of diversion can also involve individuals who use people with legitimate medical needs, like cancer patients, to go to various physicians in several cities to get prescription medications.[54]

Doctor shoppers may target physicians who easily dispense prescriptions without thorough examinations or screening. In Arizona, for example, a DEA investigation found an individual who used a legitimate medical condition to get prescriptions from doctors in two states.[55] The individual collected 8,000 to 9,000 pills during one year and sent them to Maryland to be sold on the street.[56]

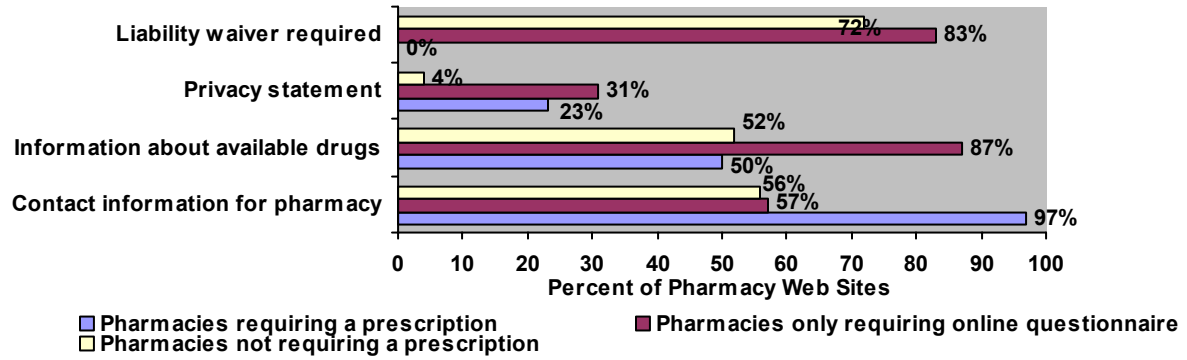
Illegal Internet Pharmacies

Since 1999, Internet pharmacies have provided a convenient alternative for individuals wishing to fill their prescriptions.[57] The Internet, however, has also become a tool for the illegal diversion of prescription drugs. Rogue sites, many under the guise of a legitimate pharmacy, provide controlled substances to people without prescriptions. This is particularly troubling with respect to the 30 million youth nationwide with Internet access.[58]

A report by the U.S. General Accounting Office (GAO) estimated the number of Internet pharmacies operating between May 1999 and September 2000. Figure 2.1 displays information collected on the 190 Internet pharmacies reviewed. Of the 111 pharmacies requiring a prescription, 97 percent provided contact information on the site, compared to only 57 percent of sites offering medications without a prescription or after completing an online questionnaire.[59] Other information missing from the Web sites

included the states in which they were licensed to dispense medications and the name of the physician responsible for issuing prescriptions.[60] In 2003, the FDA estimated the number of Internet pharmacies selling drugs illegally to be about 400 with approximately 50 percent located outside the United States.[61]

Figure 2.1 **Web Site Content of 190 Internet Pharmacies, 2000**



Source: U.S. General Accounting Office, Internet Pharmacies: Adding Disclosure Would Aid State and Federal Oversight, October 2000

There are several concerns regarding these rogue Internet pharmacies, such as the ability to evade state licensing requirements and standards; dispensing controlled substances without a prescription; and providing fake, sub-standard, or inappropriate medication.[62] A major problem in locating and dismantling these sites is that they appear and disappear quickly. One illegal Internet pharmacy may operate across several states and outside the United States, complicating enforcement because state regulations cannot reach across state lines to shut down the entire operation.[63]

Regardless of the method used by an Internet pharmacy to dispense medications, state and federal laws governing traditional drugstores apply to Internet sales as well. In order to comply with state law, every pharmacist and pharmacy must be licensed in the state where they are dispensing medication.[64] Some states also insist that out-of-state pharmacies be licensed in their state in order to dispense medications to state residents.[65]

Drug Theft

Prescription drug theft can occur at any point from the manufacturer to the patient. Thefts are on the rise largely due to the drastic increase in prescription drug abuse and high street prices.[66] There have been accounts of doctors' offices robbed of prescription samples and patients' homes being broken into for their medications.

In 2001, robbers looking to steal OxyContin held the staff and patients of a Massachusetts nursing home hostage.[67] In Ohio, an addict reportedly committed at least seven aggravated robberies in early 2000 to obtain the drug.[68] According to the DEA, OxyContin alone resulted in 2,494 theft and loss incidents between January 2000 and June 2003.[69]

Recently, the instances of theft getting the most attention are pharmacy robberies. In Utah, several pharmacies pulled OxyContin off their shelves after five pharmacies were robbed at gunpoint for the drug.[70] In March, burglars stole more than $15,000 in various prescription medications from a pharmacy in Texas.[71] A pharmacy in Ohio reported a break in that resulted in the loss of prescription drugs such as the pain reliever, Darvocet and the muscle relaxant, Soma.[72]

Prescription Forgery

Forgery occurs in one of two ways. The first involves making or stealing blank prescription pads in order to write fake prescriptions.[73] Forgery also occurs when legitimate prescriptions are altered, typically to

increase the quantity.[74] Pharmacists may get involved in prescription drug diversion by selling the controlled substances and then using their database of physicians and patients to write enough forged prescriptions to cover what they sold illegally.[75] Health care professionals, however, do not commit the vast majority of prescription forgery.

Reports of forgeries range from one individual attempting to obtain Xanax to intricate drug rings involving the manufacturing of blank prescription pads. In 2002, a Florida woman was caught attempting to use a retired doctor's name to call in a prescription. In 2000, Maine law enforcement officials discovered a network of individuals forging prescriptions, filling them at several different pharmacies and using their Medicaid cards to cover the cost.[76]

Illicit Prescriptions by Physicians

The vast majority of health care professionals never use their access to controlled substances to provide drugs for illegal use. To prescribe a controlled substance lawfully, the prescription must be issued for a legitimate purpose, the physician must be acting in the usual course of his or her practice, and the patient's medical record must be complete and point to the prescribed drug as a reasonable treatment choice.[77]

The criminal cases involving physicians who do become involved in diverting prescription drugs for huge profits, however, often make headlines. A Florida doctor, for example, was sentenced to 63 years in prison for his role in four deaths due to opiate overdoses.[78] In Kentucky, a doctor was convicted recently of conspiring to distribute prescription drugs illegally and writing prescriptions without legitimate medical reason.[79]

A frequently reported method physicians use to prescribe illegally is through "pill mills." This involves setting up a pseudo clinic for "stress" or "pain" where substance abusers can receive prescriptions under the guise of legitimate medical need.[80] In one federal case in Kentucky, a physician set up a clinic that reportedly was a major supplier of prescription pain medications between 1996 and 2002.[81] After pleading guilty, the doctor testified to prosecutors that he saw more than 80 patients daily and made nearly $1 million per year.[82]

The profits enjoyed by these unscrupulous physicians are often at the expense of taxpayers. In Florida alone, for example, 61 overdose deaths were connected to 16 physicians each billing Medicaid for $1 million or more over three years.[83] One of the doctors faces manslaughter charges related to deaths of six of her patients.[84] In another case, a doctor running a clinic reputed to be a pill mill was convicted of prescribing hundreds of thousands of pills.[85] Medicaid was billed for hundreds of the patients seen, although many of the diagnoses and treatment plans were not accompanied by any medical record indicating necessity.[86]

3. Options for States to Control Prescription Drug Diversion

Ensuring the availability of prescription medications for serious medical conditions, such as cancer, while preventing their diversion to the illegal market is an important consideration for any diversion control system. In some areas of the country, declines in diversion have been attributed to the combination of control methods, such as education, legislation and prescription regulation.[87] States can work to prevent the diversion of prescription medications by:

- considering prescription drug monitoring programs;
- promoting drug education for health care professionals; and
- controlling theft and fraud by preventing pharmacy theft, prosecuting illegal Internet pharmacies and enforcing Medicaid controls.

Figure 3.1 **Policy Options for Controlling Prescription Drug Diversion**

Policy Option	Pros	Cons
Prescription drug monitoring programs • Multiple prescriptions • Electronic transmission	• Shortens investigation time • Detects and deters diversion	• Privacy concerns • Possible impact on prescribing patterns
Drug education for health care professionals • Seminars • Model guidelines • Continuing medical education programs	• Promotes "best practices" for patient care • Can lower expenses, especially associated with Medicaid	• Vast number of issues competing for providers' attention
Theft and fraud controls • Pharmacy theft prevention • Internet pharmacy regulation • Medicaid fraud control	• Protects availability of drugs for legitimate medical need • Safeguards public health and privacy	• Ineffective if not timely • Requires financial and human capital

Prescription Drug Monitoring Programs

Prescription drug monitoring programs (PDMPs) collect information to assist state law enforcement and regulatory agencies in identifying and investigating illegal practices related to controlled substances.[88] They are intended to support state laws to ensure legitimate access to the drugs, while preventing illegal diversion.[89]

Overview of Current Programs

Currently, 20 states operate a PDMP. Table 3.1 provides information on the programs currently active in the United States. In recent years, state officials have been pushing for prescription drug monitoring programs in other states, including Florida, Ohio, Maryland, New Jersey and Pennsylvania.[90]

Example 3.1 **The National Alliance for Model State Drug Laws**

Model laws and policies offer states solutions for problems associated with substance abuse. The National Alliance for Model State Drug Laws has held 21 "state model law" conferences in which state officials can meet with substance abuse professionals, law enforcement and community leaders to improve state drug policies.

The alliance has a history of assisting states with efforts to address the abuse and diversion of prescription drugs. They have identified the key features of a prescription monitoring program and have drafted a model law that states can adopt. For more information, visit http://www.natlalliance.org.

Current programs involve either the use of multiple prescriptions or electronic transmission. Multiple prescription programs require physicians to use multiple-copy, state-issued prescription pads that contain serial numbers. One copy is sent to the state regulatory agency after the prescription is filled. In 1990, a bill was introduced mandating states to institute a federal triplicate program, but it was defeated.[91] During the last decade, these programs have increasingly been replaced by electronic variations. Electronic prescription drug monitoring programs require pharmacists to transmit prescription information via computer to the designated state agency.[92]

All programs collect the same information with regard to the prescribing and dispensing of controlled substances. The 20 active programs vary, however, in their objectives, how they are set up and what agency is charged with oversight.[93] The primary mission of PDMPs is to assist in detecting and preventing prescription drug diversion, although many programs also use the data for education and early intervention.[94]

Table 3.1 **State Prescription Monitoring Programs, August 2003**

State	Program type	Drugs covered*	Details
California	Triplicate, electronic	II	Originally enacted in 1939, physicians are required to obtain state-issued prescription forms
Hawaii	Electronic	II, III, IV	Originally enacted in 1943
Idaho	Electronic	II, III, IV, V	Originally enacted in 1967, patient profiles not available to physicians
Illinois	Electronic	II	Originally enacted in 1961
Indiana	Electronic	II	Patient profiles not available to physicians
Kentucky	Electronic	II, III, IV, V	Provides patient profiles to physicians at no cost
Maine	Electronic	II, III, IV	Enacted in 2003
Massachusetts	Electronic	II	Patient profiles not available to physicians
Michigan	Electronic	II, III, IV, V	Patient profiles not available to physicians
Nevada	Electronic	II, III, IV	Reports can be used by physicians
New York	Single copy, electronic	II, and Benzodiazepines	Originally enacted in 1972, physicians are required to obtain state-issued prescription forms
Oklahoma	Electronic	II	Patient profiles not available to physicians
Rhode Island	Electronic	II, III	Originally enacted in 1978, moved to an electronic system in 1997
Tennessee	Electronic	II, III, IV	Enacted in 2003
Texas	Single copy, electronic	II	Physicians are required to obtain state-issued prescription forms
Utah	Electronic	II, III, IV, V	Enacted in 1995
Virginia	Electronic	II	Enacted in 2002 as a two-year pilot program limited to southwest Virginia
Washington	Triplicate	Varies	Used for disciplinary purposes only
West Virginia	Electronic	II, III, IV	Terminated in 1998, re-enacted in 2002
Wyoming	Electronic	II, III, IV	Enacted in 2003

*Refers to controlled substances by schedule (I-V) as established by the Controlled Substances Act of 1970

Source: Pain and Policy Studies Group, University of Wisconsin Comprehensive Cancer Center, 2003; U.S. General Accounting Office, "Prescription drugs: state monitoring programs provide useful tool to reduce diversion," May 2002.

Implementation and Operating Costs

The costs associated with prescription drug monitoring programs vary from state to state. In 2002, The GAO evaluated these costs for Kentucky, Nevada and Utah. Table 3.2 details the implementation and operating costs for these states.

Table 3.2 **Costs Associated with Three Prescription Drug Monitoring Programs**

State (year implemented)	Start-up Costs	Annual Operating Costs
Kentucky (1999)	$415,000	$500,000
Nevada (1996)	$134,000	$112,000
Utah (1996)	$50,000	$93,000

Source: U.S. General Accounting Office, Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion, May 2002.

The three state programs detailed above operate using state funds, but states can offset start-up costs through federal funding. Kentucky, Massachusetts and Oklahoma used federal funds to initiate their PDMPs.[95] The average start-up cost for a PDMP is $300,000 per state.[96]

Grants are available to begin a program or enhance existing programs. In 2002, nine states were awarded a share of $2 million in federal grant money to address prescription monitoring programs.[97] The

Bureau of Justice Assistance Harold Rogers Prescription Drug Monitoring Program awards these grants to states. The bureau awarded grants for fiscal year 2003 to the following states: Alabama, California, Florida, Idaho, Maine, Nevada, New Mexico, New York and Wyoming, three of which will use funds to start a new program. For more information, visit www.ojp.usdoj.gov/BJA/grant/prescripdrugs.html.

State agencies report that PDMPs reduce or eliminate prescription forgery and are useful for detecting doctor shopping and illegal practices by physicians and pharmacists.[101] The GAO agrees. A GAO evaluation of PDMPs found that Kentucky's program reduced the average investigation time of a doctor shopper from 156 days to only 16 days.[102]

Opponents of electronic PDMPs claim that collecting this information electronically presents potential privacy and confidentiality issues.[103] The database is not accessible to the public, however, and can only be viewed by doctors, law enforcement and the state agency charged with oversight.[104]

Example 3.2 **Developing "Abuse Proof" Pain Medication**

The maker of OxyContin, Purdue Pharma, in conjunction with the FDA continues to research the development of an "abuse proof" pill.[98]

The new pill would combine a narcotic pain medication, such as OxyContin, with the antagonist, naltrexone.[99] Crushing the pill – as done by abusers aiming to defeat the time-release property of OxyContin – would release the naltrexone, terminating the drug's effects.[100] Other pharmaceutical companies are also currently researching the development of abuse-deterrent pain medications.

Another criticism of prescription regulation, be it the CSA or a monitoring program, is that it creates a "chilling effect" in which doctors hesitate or cease to prescribe the regulated drugs, which may affect patient care. Some reports have suggested that states with PDMPs have seen 35 to 50 percent reductions in the prescribing of regulated controlled substances.[105] The DEA reports, however, that from 1990 to 1998 the overall production of Schedules II and III narcotics has steadily increased.[106] In addition, data indicate that overall prescribing and consumption of these drugs have increased despite the fact that more states collect prescription data.[107]

In order to alleviate any concern about the use of these programs and their effect on sound medical practice, pain and policy studies researchers indicate that certain objectives should be met. These objectives include: providing the medical community with exact information as to the purpose of PDMPs; devising clear policies with regard to the management of pain and other debilitating conditions (20 states have adopted model policies advised by the Federation of State Medical Boards); and using data to evaluate prescribing trends and the programs' effectiveness.[108] Some states have gone further to protect patients and physicians. Kentucky, for example, defines authorized users in the statutes and misuse of data can result in a felony conviction.[109]

Several groups have spoken out on state prescription monitoring programs. The American Alliance of Cancer Pain Initiatives, for example, stated that these programs could be part of a balanced approach to dealing with abuse and diversion of pain medications if:

- a medical review group is involved in developing and evaluating the program;
- the program is administered by a state agency regulating health care;
- serialized prescription forms are not used;
- all controlled substances (Schedules I to V) are covered;
- patient confidentiality is protected;
- health care professionals are educated about the program to alleviate concerns; and
- an evaluation component is included to measure the program's impact on patients' needs for the controlled substances.[110]

National Prescription Monitoring Program

There has been a recent push at the federal level to pass the National All Schedules Prescription Electronic Reporting Act (NASPER). Supporters claim that the national program is favorable because:

- the databank would allow physicians nationwide to access patient information to see whether a patient is taking medications prescribed by another physician;
- Schedule II, III and IV prescriptions would be monitored, allowing for consistent data collection across states;
- the program would be consistent with privacy rules existing in the current Health Insurance Portability and Accountability Act (HIPPA); and
- information would only be released to a practitioner or pharmacist providing treatment, or to law enforcement when requested based on evidence for cause.[111]

Proponents of the national program argue that people can cross state lines to access drugs in a state without a PDMP. There is evidence that prescription drug abuse and diversion does increase along the border of states with prescription monitoring programs. This has been evident in the five states bordering Kentucky that do not have monitoring programs.[112]

Advocates of the state-by-state approach claim that a national system is too expensive. State programs, they say, can achieve uniformity by setting minimum standards with the help of organizations such as the National Alliance on Model State Drug Laws.[113]

Regardless of the method used to monitor prescriptions, successful control of prescription drug diversion may also involve educating prescribers about drug diversion and abuse.

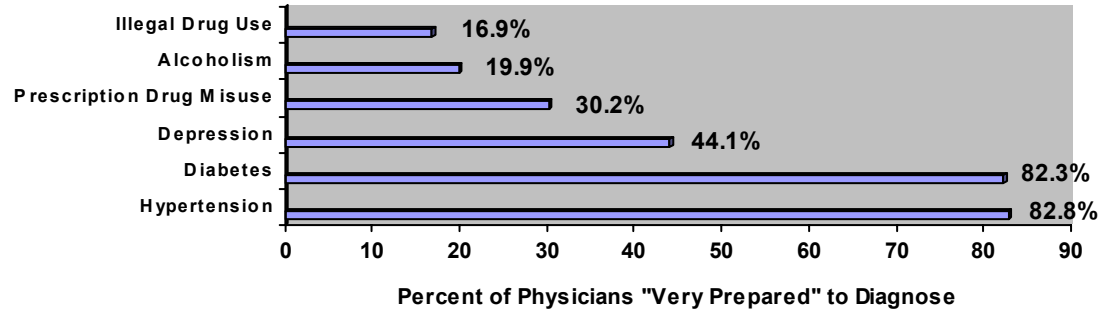
Drug Education for Health Care Providers

Certain medications have revolutionized the treatment of chronic pain in the United States; however, physicians must balance legitimate need with the possibility of abuse as they comply with state and federal regulations.[114] Health care practitioners are expected not only to prescribe medications appropriately, but also to prevent illegal diversion and identify drug abuse.[115] Education is a critical component of any program to control the diversion of prescription drugs.

Unfortunately, many physicians get little to no training in drug abuse.[116] In fact, a 1999 survey of primary care physicians found that there was a general lack of training in medical school about addiction and the signs of substance abuse.[117]

This leads to difficulty discussing substance abuse with patients and an inability to recognize the signs of addiction. The survey revealed that 46.6 percent of physicians had difficulty discussing prescription drug abuse with patients and only 32.1 percent carefully screened their patients for substance abuse.[118] Figure 3.1 shows that the majority of the physicians surveyed did not feel prepared to diagnose substance abuse.

Figure 3.1 **Conditions That Physicians Feel "Very Prepared" to Diagnose, 1999**



Source: The National Center on Addiction and Substance Abuse at Columbia University, Missed Opportunity: National Survey of Primary Care Physicians and Patients on Substance Abuse (New York: CASA, 2000)

Partnerships with Health and Professional Organizations

Organizations such as The American Academy of Family Physicians have taken steps to make doctors aware of practices such as doctor shopping. In addition, several state chapters have held seminars to educate physicians on appropriate pain management and how to screen for substance abuse.[119]

The American Society of Interventional Pain Physicians also assists in preventing diversion while maintaining the availability of prescription drugs for medical treatment. The society has devised guidelines for use of controlled substances in the management of pain, which include information on how to conduct a comprehensive evaluation to select patients for drug therapy, and how to use a "controlled substance agreement" as part of patient care.[120]

The Federation of State Medical Boards of the United States advocates model guidelines for physicians on evaluating the use of controlled substances for pain control. The guidelines include information on:

- evaluating a patient for drug treatment;
- writing the treatment plan;
- obtaining informed consent and agreement for treatment;
- reviewing the course of treatment periodically;
- consulting with other health care professionals;
- keeping accurate medical records; and
- complying with controlled substances laws and regulations.[121]

Example 3.3 Colorado Prescription Drug Abuse Task Force

Colorado recognizes the important role education plays in any effort to prevent the abuse and diversion of prescription drugs.

The Colorado Prescription Drug Abuse Task Force, organized in 1984, has developed education programs for health care professionals, compiled strategies for prevention of common diversion methods, provided statewide training for law enforcement, and implemented a pharmacy hotline to intervene in prescription drug fraud. For more information, visit www.corxtaskforce.org/index.html.

Several states have taken steps to educate physicians about prescription drugs. Medicaid physicians in Pennsylvania and Michigan get state-sponsored education about topics such as prescribing patterns, preferred drugs and utilization patterns.[122] Education is used as a tool to lower expenses and improve patient care.[123]

All states require physicians to obtain annual continuing medical education (CME) for license reregistration. Most states do not, however, mandate the content of the education. Health care providers have various competing priorities related to the practice of medicine, with prescribing controlled substances and preventing abuse and addiction often losing the competition. Only Oklahoma requires its physicians to receive CME on prescribing controlled substances.[124]

The 2004 National Drug Control Strategy addresses prescription drug abuse and the issue of educating health care professionals. It calls for CME programs that address best practices in pain management and the risks of abuse and addiction.[125] Mandating drug education as part of the state CME requirement would assist states in preparing health care professionals to prevent the diversion and abuse of prescription medications.

States may want to encourage and promote education and partnerships with law enforcement and health care professionals to ensure the safety of prescription medications for medical need and to prevent their abuse.

Theft and Fraud Controls

The diversion of prescription drugs through theft and fraud presents unique and costly problems for states. State agencies are largely in charge of enforcing pharmacy practices, including those of Internet pharmacies. In addition, the state-run Medicaid program costs states and taxpayers millions of dollars when used by physicians and recipients to finance the illegal use of prescription medications. The problem is that these illegal practices often go beyond one state's jurisdiction. In order to ensure that medications are available for medical conditions, the problem of theft and fraud must be addressed.

Pharmacy Theft Prevention

Pharmacy theft and robbery is a serious problem fueled by the growing abuse of prescription drugs and their high street dollar value.[126] Partnerships between law enforcement and health care professionals are important to deter pharmacy theft. The DEA's Pharmacy Theft Prevention Program, for example, involves the collaboration of pharmaceutical companies, state and federal regulatory agencies, and law enforcement.[130] The program aims to deter pharmacy thefts through outreach, education, and the organization of networks and alert systems.[131]

Example 3.4 Alaska's "Telepharmacy" System

Alaska Native Medical Center has developed a "telepharmacy" system allowing prescription drugs to be dispensed using vending machines.[127] The project, which began in December 2003, allows rural health care workers in nine communities to contact the medical center pharmacy to authorize the machine to dispense the needed drugs.[128]

This vending system allows medical center staff to track prescription medications using a bar code system and helps keep the medications secure. The machines are very large and have three locking mechanisms, making theft unlikely.[129] The program is funded through a U.S. Department of Health and Human Services grant. For more information, visit http://www.anmc.org/

RxPatrol is another example of a partnership to prevent pharmacy theft. The information clearinghouse, funded by Purdue Pharma, allows pharmacy staff to submit comprehensive theft report information via the Internet to be analyzed by RxPatrol staff and disseminated to law enforcement agencies.[132] Based on the information collected, RxPatrol conducts vulnerability assessments to develop profiles of pharmacies that may be susceptible to theft and strategies for preventing victimization.[133] This program brings together the pharmaceutical industry with law enforcement in order to protect pharmacists, prevent theft, and assist law enforcement investigations.[134] For more information, visit www.rxpatrol.org.

Internet Controls

State laws require that pharmacies keep records on all prescription drugs dispensed and allow the state pharmacy board access to all records.[135] Although legitimate pharmacy Web sites provide a convenient service to customers, illegal Internet pharmacies pose problems because they often reach across state lines, dispensing drugs anonymously in violation of state laws.[136]

Online prescribing can threaten public safety through problems such as:

- adverse drug interactions;
- misdiagnosis; and
- inability to recognize problematic conditions.[137]

The American Medical Association has recommended minimum guidelines for Internet prescribing by physicians. These standards include examination of the patient to determine if a medical problem is present; communication between physician and patient to discuss a treatment plan; physician access to the patient's medical history; and follow-up to monitor the patient's progress.[138]

States have the primary responsibility for regulating the pharmaceutical industry. Several state medical boards, including Texas, have adopted rules requiring a face-to-face examination in order to fill prescriptions via the Internet.[139] Other state medical boards have implemented similar rules, but without each state addressing this issue, Congress could step in with a federal requirement.[140] The problem is that a doctor in a non-regulated state can illegally prescribe drugs to a juvenile in a regulated state, tying the hands of the enforcement authority because the doctor is out-of-state.[141]

A 2000 GAO survey found that 25 of the 45 state medical boards responding had received complaints about physicians prescribing via the Internet, mostly regarding the lack of patient examination.[142] Currently, 30 states have laws preventing doctors from prescribing without first conducting a physical examination.[143] Several states, such as Connecticut, are going after Internet pharmacies by filing suit when out-of-state doctors illegally prescribe to their residents without having a license in their state.[144]

There is disagreement as to the level of federal regulation necessary to assist states in effectively controlling Internet prescribing and dispensing. Some state representatives favor federal bills that would establish minimum standards, such as HR 2652, the Internet Pharmacy Consumer Protection Act. This bill would amend the federal Food, Drug, and Cosmetic Act to require Internet pharmacies to include contact information for the business and a list of states in which the pharmacists and physicians are licensed to dispense prescriptions drugs. In addition the federal government has the ability to shut down illegal sites nationwide quickly, whereas each state having to challenge individual sites would be a slow process.[148]

Example 3.5 Targeting Internet Pharmacies in Kansas

In 1999, Kansas Attorney General Carla Stovall testified to Congress about the problems associated with Internet pharmacies and what can be done to combat the problem. When researching rogue Web sites, the Kansas Consumer Protection Division was able to obtain high-profile medications without a prescription.[145] Attorney General Stovall was the first to file suit against an illegal Internet pharmacy.[146] She recommends that states require Internet pharmacies to include contact information and the names and locations of prescribing physicians.[147]

While states have primary responsibility for regulating the pharmaceutical industry, the federal government is attempting to address the problem of Internet prescriptions. The FDA has been very active in pursuing illegal Web sites. Administration officials have met with state pharmacy boards, regulatory agencies and consumer groups in order to pursue these rogue sites.[150] The FDA has investigated many sites and has often found that one site is made up of multiple sites and links, which makes investigation challenging.[151]

Example 3.6 Certifying Internet Pharmacies

In 1999, The National Association of Boards of Pharmacy launched a program to help consumers identify legitimate Internet pharmacies.

The Verified Internet Pharmacy Practice Sites program gives a Web site a "seal of approval" if it is licensed in each state in which it dispenses drugs, protects patients' privacy, and provides consultation between patients and pharmacists.[149] This voluntary program requires Internet pharmacies to submit an application to begin the review process.
For more information, visit http://www.nabp.net/vipps/.

The FDA and the DEA have formed a task force specifically addressing the illegal sale of controlled substances on the Internet. Operation Gray Lord will aggressively investigate and crack down on illegal sites, many of which are based in other countries.[152]

Maintaining state control over pharmacy regulation while effectively addressing the challenge of illegal Internet prescribing requires the cooperation of state regulatory agencies, law enforcement, industry officials and the federal government.

Medicaid Fraud

Law enforcement officials and substance abuse treatment providers alike report that the tax-financed Medicaid program is subsidizing drug abusers. A survey of substance abuse treatment providers in the Appalachian region, which includes Kentucky, West Virginia and Tennessee, reported that more and more clients use public insurance programs, like Medicaid, to get "legal" drugs to feed their addictions.[153] This has serious fiscal implications for the Medicaid program, which cost states more than $110 billion in fiscal year 2003.[154] In fact, fraud contributes to a $1 billion loss annually in Medicaid spending on prescription drugs.[155]

Example 3.7 Physician Background Checks in Kentucky

In March 2003, Kentucky's Gov. Paul Patton signed into law SB 195 requiring criminal background investigations for all new state medical license applicants. The new law also allows criminal investigations any other time "for good cause shown" at the request of the state medical board. This law assists the state in combating the problem of prescription drug abuse.

One patient may be able to pay only $3 for 100 80-mg pills of OxyContin through Medicaid and then resell the pills for up to $8,000 on the street.[156] In Maine, for example, a man was arrested and charged with selling $8,000 per week of OxyContin prescribed to his wife and paid for by Medicaid for pain related

to her cancer.[157] This can be an even bigger problem for drugs such as Lortab, which is less regulated and can be prescribed and refilled with fewer restrictions.[158]

Through an audit of its Medicaid program, Missouri identified at least 400 recipients potentially abusing prescription drugs.[159] The audit determined that during fiscal years 2000 and 2001 taxpayers spent more than $8.7 million for Medicaid recipients to receive prescriptions without adequate controls to ensure that those dollars were not spent to finance illegal use of the drugs.[160]

To address this problem, several states require prior approval for OxyContin and other medications before they are dispensed.[161] In addition, states can limit the quantity of certain controlled substances dispensed under the Medicaid program. New York, for example, limits Schedule II drugs to a 31-day supply when paid for by Medicaid.[162] In addition, states can prevent the fraudulent use of Medicaid cards by requiring picture identification to pick up a prescription.

State policy-makers have also attempted to combat Medicaid fraud by withholding or limiting benefits. Ten years ago, state legislators attempted to give state officials the power to end benefits for those caught abusing the system, but the legislation did not pass.[164] States could continue to push the federal government for the legislative authority to bar individuals from obtaining Medicaid benefits if they are caught abusing the program.[165] Currently, federal law only allows the U.S. Department of Health and Human Services (HHS) to limit benefits.

Example 3.8 The High-Intensity Drug Trafficking Area (HIDTA) Program

The HIDTA Program enhances and coordinates drug control efforts among federal, state and local law enforcement agencies. The Office of National Drug Control Policy determines HIDTA areas based on:

- the extent of drug production and trafficking;
- an effort by local law enforcement to aggressively respond to the drug problem; and
- the affect on other areas of the country thereby requiring federal resources to address the problem.[163]

For more information on this program, visit www.whitehousedrugpolicy.gov/hidta/index.html.

In order to prevent Medicaid fraud, several states use a “lock in” program that limits an individual to one doctor or pharmacy if they are caught abusing the system.[166] In order for the programs to work, however, they must be instituted swiftly when abuse is discovered. In some cases, it may take a year from the time the doctor shopping began for a person to be restricted to one doctor or pharmacy.[167]

States can also use technology to control Medicaid fraud. The Medicaid Abuse Drug Audit System (MADAS), for example, reviews Medicaid prescriptions of controlled substances to track unusual prescribing.[168] This computer software program, devised by HHS, is offered to the states at no cost. New York reported that MADAS has assisted in identifying approximately 800 doctor shoppers monthly.[169]

Another computer software option allows physicians to access their Medicaid patients’ prescription history, state prescribing guidelines and interactive screening tools.[170] One such system, eMPOWERx™, is used by 1,000 Medicaid physicians in Florida.[171] The system gives physicians a resource to prevent prescription diversion and reduces costs to the state’s Medicaid program.[172]

Medicaid fraud affects taxpayers in every state. Often, one scam involves multiple states and jurisdictions, requiring the cooperation of federal, state and local agencies.[173] Reducing fraud is possible with intergovernmental cooperation and an investment in prevention.

Conclusion

States hold the majority of the power to regulate the prescribing and dispensing of prescription drugs. Prescription drug abuse in the United States continues to soar, and the billions of dollars states spend to clean up the aftermath cannot be ignored. States can affect the supply of prescription drugs in the illegal market by working with federal agencies, licensing boards, health care providers, pharmaceutical manufacturers and law enforcement to devise policies and programs that address the problems outlined in this report.

When diversion control methods combine the appropriate use of regulation with education, prescription medications can continue to provide relief for the millions of people suffering from serious conditions.[174] The results of effective diversion controls are increased quality of life for people suffering from serious medical conditions and a decrease in prescription drugs bought and sold illegally.

Glossary

Addiction – A chronic disease characterized by compulsive drug seeking and drug use and changes in the brain's chemistry.

Aggravated robbery – The use of violence or threat and a weapon in the wrongful taking of property.

Attention deficit hyperactivity disorder – A diagnosis applied to children and adults who consistently display certain behaviors related to inattention, hyperactivity, and impulsivity for at least six months.

Chronic pain – Pain that persists over time and is often accompanied by significant psychological and emotional affects, limiting a person's ability to function fully.

Controlled-release medication – A medication that contains the structural means to treat the body controllably over a prolonged period by the slow release of the drug.

Diversion – The deflection of prescription drugs from medical sources to the illegal market.

Fraud – Intentional deception or misrepresentation in order to produce some benefit or reward.

Physical dependence – A physiological state occurring through regular use of certain medications resulting in withdrawal when drug use stops.

Prescription drug abuse – The intentional nonmedical use of a medication.

Robbery – The use of violence or threat in the wrongful taking of property.

Theft – The wrongful taking of property.

Tolerance – The result of repeated use of a drug in which higher doses are needed to experience the same effect as felt initially.

Withdrawal – The symptoms experienced after suddenly stopping or reducing the chronic use of certain drugs.

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