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PRESCRIPTION DRUGS

State Monitoring Programs Provide Useful Tool to Reduce Diversion



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Abbreviations

DEA	Drug Enforcement Administration
HIPAA	Health Insurance Portability and Accountability Act of 1996
ODC	Office of Diversion Control
PDMP	prescription drug monitoring program

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May 17, 2002

The Honorable James C. Greenwood
Chairman
The Honorable Peter Deutsch
Ranking Minority Member
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

The increasing diversion of prescription drugs for illegal use is a disturbing trend in the nation's battle against drug abuse. Prescription drug diversion is the channeling of licit pharmaceuticals for illegal purposes or abuse. It can involve activities such as "doctor shopping" by individuals who visit numerous physicians to obtain multiple prescriptions, illegal sales of prescription drugs by physicians or pharmacists, and prescription forgery. The most frequently diverted prescription drugs are those that are prone to abuse, addiction, and dependence,[1] such as hydrocodone (the active ingredient in Lortab and many other drugs), diazepam (Valium), methylphenidate (Ritalin), and oxycodone (the active ingredient in OxyContin and many other drugs). According to the Drug Enforcement Administration (DEA), increases in the extent of prescription drug abuse and in emergency room admissions related to prescription drug abuse, as well as an increase in the theft and illegal resale of prescription drugs, indicate that drug diversion is a growing problem nationwide. In 2000, the most recent year for which data are available, about 9 million Americans aged 12 and older reported using prescription drugs, including pain relievers, tranquilizers, stimulants, or sedatives, for nonmedical purposes.[2] The abuse of illegally diverted prescription drugs is associated with serious consequences, including addiction, overdose, and death.

[1]According to the National Institute on Drug Abuse, addiction is a chronic, relapsing disease, characterized by compulsive drug seeking and use and by neurochemical and molecular changes in the brain, whereas physical dependence is an adaptive physiological state that can occur with regular drug use and results in withdrawal symptoms when drug use is discontinued.

[2]1999-2000 National Household Survey on Drug Abuse, Substance Abuse and Mental Health Services Administration, Department of Health and Human Services.

Fifteen states currently operate prescription drug monitoring programs (PDMPs) as a means to control the illegal diversion of prescription drugs. PDMPs collect, review, and analyze prescription data from pharmacies. They provide data and analysis to state law enforcement and regulatory agencies to assist in identifying and investigating activities potentially related to the illegal prescribing, dispensing, and procuring of prescription drugs. Because of your interest in the issues of prescription drug diversion and control, you asked us to address the following questions: (1) How do the 15 PDMPs compare across states in terms of objectives, design, and operation? (2) What benefits have state PDMPs produced? (3) What challenges do states face in implementing and using PDMPs? (4) What efforts are being made at the national level to address the illegal diversion of prescription drugs?

To address the questions concerning the state PDMPs, we reviewed information from DEA and the National Alliance for Model State Drug Laws[3] on the features of the existing programs.[4] To gain a more in-depth understanding of these programs and the challenges they face, we studied the PDMPs in Kentucky, Nevada, and Utah. We selected these three because they were the most recently established programs. We interviewed PDMP administrators and stakeholders in these three states. Although the stakeholders varied in each state, they included officials of state medical and pharmacy associations, state attorneys general offices, state drug enforcement agencies, state police, and a state medical examiner's office. We also spoke with officials from practitioner licensure boards and state law enforcement agencies, as well as DEA representatives. We also discussed PDMPs with officials from Purdue Pharma L.P., the manufacturer of OxyContin and other prescription drugs. To determine what activities are being pursued at the national level to reduce illegal diversion of prescription drugs, we interviewed experts from DEA, the National Alliance for Model State Drug Laws, the National Association of State Controlled Substance Authorities, and the Bureau of Justice Assistance in the Department of Justice, and reviewed pertinent documents. We performed our work from October 2001 through April 2002 in accordance with generally accepted government auditing standards.

[3]In this report, we refer to this organization as the Alliance. The Alliance, a nonprofit association, is the successor to the President's Commission on Model State Drug Laws.

[4]All references to state laws relating to PDMPs were provided to us by the National Alliance for Model State Drug Laws and were not independently verified.

Results in Brief

All 15 state PDMPs collect information about the prescribing, dispensing, and use of prescription drugs and distribute it to medical practitioners, pharmacies, and state law enforcement and regulatory agencies, but the programs differ in terms of objectives, design, and operations. In addition to helping law enforcement identify and prevent prescription drug diversion, a program's objectives may include education of the public, physicians, and pharmacists regarding the nature and extent of the problem and medical treatment options for abusers of diverted drugs. With regard to design, the programs vary primarily in terms of the specific drugs they cover and the type of state agency in which they are housed. Some PDMPs cover only those prescription drugs that are most prone to abuse and addiction, whereas others provide more extensive coverage. In addition, most programs are administered by a state law enforcement agency, a state department of health, or a state board of pharmacy. Finally, some programs use the prescription data proactively, to identify trends or patterns of use, as well as to respond to requests from law enforcement officials, whereas others use it only to respond to requests.

States with PDMPs have realized benefits in their efforts to reduce drug diversion. These include improving the timeliness of law enforcement and regulatory investigations. For example, Kentucky's state drug control investigators took an average of 156 days to complete the investigation of an alleged doctor shopper prior to the implementation of the state's PDMP. The average investigation time dropped to 16 days after the program was established. In addition, law enforcement officials in Kentucky and other states view the programs as a deterrent to doctor shopping, because potential diverters are aware that any physician from whom they seek a prescription may first examine their prescription drug utilization history based on PDMP data.

Officials from DEA, the Alliance, and state PDMPs told us that states considering establishing a PDMP, or expanding an existing one, face several challenges. These include educating the public and policymakers about the extent of prescription drug diversion and abuse in their state and the benefits of a PDMP, responding to the concerns of physicians, patients, and pharmacists regarding the confidentiality of prescription information, and funding the cost of program development and operations. Given a state's particular funding availability and budget priorities, program costs can be a major hurdle. The start-up costs for the three most recent PDMPs were $415,000 for Kentucky, $134,000 for Nevada, and $50,000 for Utah. Estimated annual operating costs for these PDMPs varied from a high of about $500,000 in Kentucky, to $150,000 in Utah and $112,000 in Nevada. Costs in these three states vary because of differences

in the PDMP systems implemented, the number of pharmacies reporting drug dispensing data, and the number of practitioners and law enforcement agencies seeking information from the systems. (See app. I.)

National efforts to assist states in addressing illegal diversion have focused on providing guidance and technical assistance. The Alliance has provided a useful source of information for the development of recent state programs. In addition to identifying the key features of a model PDMP, the Alliance has provided a draft model law for states interested in establishing their own PDMP. The Alliance has also provided technical assistance to states in implementing the recommendations in the model program. Funding has recently been made available for grants to states that are planning to start a PDMP or expand an existing program. Two million dollars in grants from the Department of Justice's Bureau of Justice Assistance are to be administered jointly with the DEA.

DEA, the Alliance, and the PDMPs in Kentucky, Nevada, and Utah reviewed a draft of this report and in general agreed with its contents. Their technical comments have been incorporated where appropriate.

Background

The diversion and abuse of prescription drugs are associated with incalculable costs to society in terms of addiction, overdose, death, and related criminal activities. DEA has stated that the diversion and abuse of legitimately produced controlled pharmaceuticals constitute a multibillion-dollar illicit market nationwide.[5] One recent example of this growing diversion problem is the controlled substance oxycodone, the active ingredient in over 20 prescription drugs, including OxyContin, Percocet, and Percodan. OxyContin has become the nation's number one prescribed narcotic medication for treating chronic severe and moderate pain. A single 40-milligram OxyContin tablet legally selling for about $4 is worth about $40 on the illicit market. As of February 2002, OxyContin has been involved in 464 deaths from prescription drug abuse, as reported by DEA on the basis of medical examiners' autopsy findings for 2000 and 2001 from 32 states.

[5]Drug Enforcement Administration and the National Alliance for Model State Drug Laws, *A Closer Look at State Prescription Monitoring Programs* (http://www.deadiversion.usdoj.gov/pubs/program/rx-monitor/summary.htm accessed September 17, 2001).

Combating the illegal diversion of prescription drugs while ensuring that the pharmaceuticals remain available for those with legitimate medical need involves the efforts of both federal and state government agencies. The Controlled Substances Act of 1970[6] provides the legal framework for the federal government's oversight of the manufacture and wholesale distribution of controlled substances. The states address these issues through their regulation of the practice of medicine and pharmacy.[7]

Controlled Substances Act

The Controlled Substances Act of 1970 established a classification structure for drugs and chemicals used in the manufacture of drugs that are designated as controlled substances. Controlled substances are classified into five schedules on the basis of their medicinal value and potential for abuse, addiction, and dependence. Schedule I drugs—including heroin, marijuana, and hallucinogens such as LSD and PCP—have a high potential for abuse and no currently accepted medical use. Schedule II drugs—including methylphenidate (Ritalin) and opiates such as hydrocodone, morphine, and oxycodone—have a high potential for abuse and may lead to severe physical dependence, but have a currently accepted medical use. Drugs on Schedules III through V have medical uses and successively lower potentials for abuse and dependence. Schedule III drugs include anabolic steroids, codeine, hydrocodone in combination with aspirin or acetaminophen, and some barbiturates. Schedule IV contains such drugs as the anti-anxiety medications diazepam (Valium) and alprazolam (Xanax). Schedule V includes preparations such as cough syrups with codeine. All drugs but those in Schedule I are legally available to the public with a prescription.[8]

Under the act, DEA has the authority to regulate transactions involving the sale and distribution of controlled substances at the manufacturer and wholesale distributor levels. DEA's Office of Diversion Control (ODC) provides legitimate handlers of controlled substances—including manufacturers, distributors, hospitals, pharmacies, practitioners, and researchers—with registration numbers, which are used in all transactions

[6]Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Pub. L. No. 91-513, §§100-103, 84 Stat. 1236, 1242-1284).

[7]According to the Kentucky PDMP administrator, the state has also chosen to regulate drug manufacturers and wholesalers.

[8]Some Schedule V drugs that contain limited quantities of certain narcotic and stimulant drugs are available over the counter without a prescription.

involving controlled substances. Registrants must comply with a series of regulatory requirements relating to drug security and accountability through the maintenance of inventories and records. Although all registrants, including pharmacies, are required to maintain records of controlled substance transactions, only manufacturers and distributors are required to report their transactions involving Schedule II drugs and Schedule III narcotics, including sales to the retail level, to ODC. The data provided to ODC are available for use in investigations of illegal diversions at the manufacturer and wholesaler levels. Although data are reported to ODC regarding purchases by pharmacies, the act does not require the reporting of dispensing information by pharmacies at the patient level to ODC.

State Regulation of the Practice of Medicine and Pharmacy

State laws govern the prescribing and dispensing of prescription drugs by licensed health care professionals. All states require that physicians practicing in the state be licensed, and state medical practice laws generally outline standards for the practice of medicine and delegate the responsibility of regulating physicians to state medical boards. State medical boards license physicians and grant them prescribing privileges.[9] In addition, state medical boards investigate complaints and impose sanctions for violations of the state medical practice laws.

Every state requires resident pharmacists and pharmacies to be licensed. The regulation of the practice of pharmacy is based on state pharmacy practice acts and regulations enforced by the state boards of pharmacy. The state boards of pharmacy are also responsible for ensuring that pharmacists and pharmacies comply with applicable state and federal laws and for investigating and disciplining those that fail to comply. All state pharmacy laws require that records of prescription drugs dispensed to customers be maintained and that state pharmacy boards have access to the prescription records.

[9]The types of practitioners who prescribe drugs and may be monitored by a PDMP vary among states. Physicians are the majority of covered practitioners, but in most states many nonphysicians also have prescribing authority, including physician assistants, dentists, optometrists, podiatrists, veterinarians, and certain types of nurses, such as nurse practitioners and advanced practice nurses.

State PDMPs

PDMPs are designed to facilitate the collection, analysis, and reporting of information on the prescribing, dispensing, and use of prescription drugs within a state. An overriding goal of PDMPs is to uphold both the state laws ensuring access to appropriate pharmaceutical care by citizens and the state laws deterring diversion.

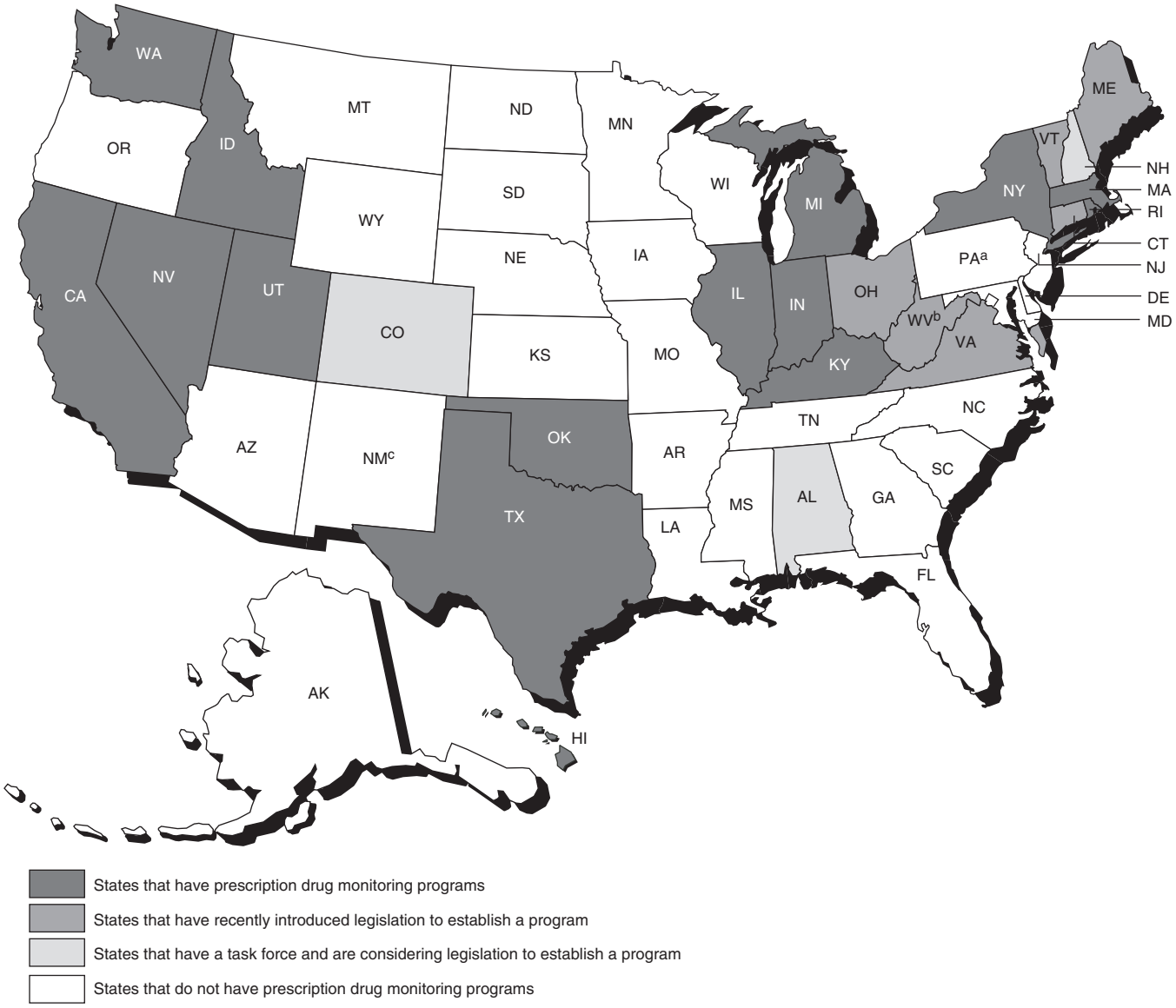
The first PDMP was established in California in 1940. The number of states with PDMPs has grown only slightly over the past decade, from 10 in 1992[10] to 15 in 2002. (See fig. 1.) Nevertheless, PDMPs cover about 47 percent of the nation's population, about 47 percent of the nation's DEA-registered practitioners, and about 45 percent of the nation's pharmacies.[11]

The nationwide number of PDMPs has been changing. West Virginia terminated its PDMP in 1998, and New Mexico in 2000. West Virginia has taken steps to create a new PDMP, however. Legislation to establish a new program, again to be operated by the state's board of pharmacy, was enacted and approved by the governor in March 2002. In addition, a number of other states have enacted or are considering legislation to establish a program. (See fig. 1.)

[10]U.S. General Accounting Office, *Prescription Drug Monitoring: States Can Readily Identify Illegal Sales and Use of Controlled Substances*, GAO/HRD-92-115 (Washington, D.C.: July 21, 1992).

[11]These percentages include two states that subsequently terminated their PDMPs—New Mexico and West Virginia.

Figure 1: Status of Prescription Drug Monitoring Programs, by State, April 2002



[a]Pennsylvania does not have a PDMP, but requires pharmacies to submit data to the state attorney general's office.

[b]West Virginia terminated its PDMP in 1998 and has enacted legislation in 2002 to create a new program.

[c]New Mexico terminated its PDMP in 2000.

Source: National Alliance for State Model Drug Laws, 2002, and discussions with officials in New Mexico, Pennsylvania, and West Virginia.

National Alliance for Model State Drug Laws

Since 1993, the Alliance has served as a resource center for states interested in identifying legislative and program improvements in drug abuse reduction and prevention. Each year since fiscal year 1995, the Alliance has received a $1 million grant from the Department of Justice, administered by the President's Office of National Drug Control Policy. These funds are used to identify legislative, policy, and program initiatives to address the supply of, abuse of, and addiction to alcohol and other drugs. The model laws cover a broad range of issues, including money laundering, forfeiture, housing, education, treatment, prevention, and intervention. The funds also support statewide model drug law summits that serve as intensive needs assessments and planning vehicles for the states. The Alliance has also sponsored a Prescription Monitoring Work Group composed of representatives from pharmaceutical manufacturers, state licensing boards for physicians and pharmacists, state attorneys general, and administrators of state PDMPs.

PDMPs Vary in Objectives, Design, and Operation

The 15 PDMPs have a common goal of reducing prescription drug diversion and abuse, but vary in their objectives, design, and operation. In addition to helping law enforcement identify and prevent prescription drug diversion, state programs may include education objectives to provide information to physicians, pharmacies, and the public. Program design also varies across states, in terms of which drugs are covered, how prescription information is collected, and which agency is given responsibility for the program. Additionally, methods for analyzing the data to detect potential diversion activity differ among PDMPs. Finally, the cost of the program varies according to differences in these design and operational factors.

Program Objectives Include Education as Well as Law Enforcement

Although the primary objective of PDMPs is to assist law enforcement in detecting and preventing drug diversion, states have also used the programs for educational purposes. Programs assist law enforcement authorities both by providing information in response to requests for assistance on specific investigations and by referring matters to law enforcement officials when PDMP evaluations reveal atypical prescribing or dispensing patterns that suggest possible illegal diversion. PDMPs have also been used to educate physicians, pharmacies, and the public about the existence and extent of diversion, diversion scams, and the drugs most likely to be diverted by individuals. Programs have provided educational materials to physicians on ways to prevent drug diversion and to educate their patients about the diversion problem. They have evaluated prescribing patterns to identify medical providers that may be

overprescribing and inform them that their patterns are unusual. They have also identified patients who may be abusing or diverting prescription drugs and provided this information to practitioners. For example, PDMPs in Nevada and Utah send physicians drug utilization letters containing patient information that signal potential diversion activity, including the number and types of drugs prescribed to the patient during a given time period and the pharmacies that dispensed the drugs. PDMPs have also provided physicians with information on addiction treatment options for patients identified as drug abusers or diverters. For example, Nevada's PDMP encourages physicians to refer identified doctor shoppers to pain management or drug treatment programs that can help them manage their chronic pain more effectively or treat their addiction.

Program Designs Differ Across States

Program design varies across state programs, in terms of which drugs are covered, how prescription information is monitored and collected, and which agency is given the responsibility for the program. (See table 1.)

Table 1: Characteristics of State Prescription Drug Monitoring Programs

State	Year implemented	Controlled substance schedule(s) monitored	Type of monitoring system	Administrative agency
California[a]	1940	II	Electronic and triplicate form[b]	Pharmacy and law enforcement
Hawaii	1943	II	Electronic	Law enforcement
Idaho	1967	II, III and IV	Electronic	Pharmacy board
Illinois	1961	II	Electronic	Public health
Indiana	1995	II	Electronic	Law enforcement
Kentucky	1999	II, III, IV and V	Electronic	Public health
Massachusetts	1992	II	Electronic	Public health
Michigan[c]	1989	II	Single form	Commerce
Nevada	1997	II, III, and IV	Electronic	Pharmacy board and law enforcement
New York[d]	1977	II	Electronic	Public health
Oklahoma	1991	II	Electronic	Law enforcement
Rhode Island	1979	II, III	Electronic	Public health
Texas[e]	1982	II	Electronic	Law enforcement
Utah	1997	II, III, IV, and V	Electronic	Commerce's Licensing Division
Washington[f]	1987	Determined by disciplinary authority	Triplicate form[b]	Public health

[a]California is currently testing an electronic monitoring program for Schedule II controlled substances. Until the pilot program is completed on July 1, 2003, pharmacies will also have to continue submitting copies of the triplicate forms to the state monitoring agency.

[b]A triplicate prescription form is a paper prescription form issued by the state to prescribers, who must use it when writing prescriptions for covered controlled substances. The prescriber keeps one copy after writing the prescription, and the pharmacist keeps a copy when the prescription is filled and sends the third copy to the state PDMP.

[c]In 2001, Michigan enacted legislation to convert its PDMP to an electronic monitoring program. Until the new electronic system is implemented, the program will continue to require pharmacies to submit copies of state-issued official prescription forms for schedule II controlled substances.

[d]As of January 1, 2002, New York switched to an electronic monitoring system from a paper-based system using a triplicate form. The new electronic system is supplemented by a state-issued, single-copy prescription form that includes a number of security features to prevent counterfeits.

[e]Beginning in September 1999, Texas permitted pharmacies to submit prescription data electronically rather than submitting paper copies of prescription forms. In March 2002, Texas switched from triplicate to single-copy forms with a number of security features to prevent counterfeits. The requirement to submit prescription forms to the state agency will continue until the electronic system is fully implemented.

[f]The Washington program applies only to licensed practitioners whose prescribing practices require monitoring because of past drug abuse or inappropriate prescribing. The drugs the program covers vary, depending on the prescriber, from one controlled substance to all prescriptions.

Source: National Alliance for Model State Drug Laws. Information is current through February 4, 2002.

State programs vary in the controlled substance schedules they cover, in part because of differences in available resources and other state-specific factors such as levels of drug abuse. As shown in table 1, nine PDMPs cover only Schedule II controlled substances, which have the highest potential for abuse and addiction. Two states, Kentucky and Utah, cover all schedules, and Nevada covers Schedules III and IV, as well as II. Washington's program is used as a disciplinary tool and covers a variety of controlled substance schedules on a case-by-case basis for each practitioner. Most experts agree that covering all schedules prevents drug diverters from avoiding detection by bypassing Schedule II drugs and switching to drugs in other schedules. Program officials in Kentucky and Utah also told us that covering all schedules allows them flexibility to respond if drugs on other schedules become targets for diversion. Covering more than Schedule II drugs greatly increases the number of prescriptions that must be reported to the state PDMP. This can require additional resources to review and interpret the additional data and conduct necessary follow-ups. These officials, as well as officials from DEA and the Alliance, agree that comprehensive coverage of all schedules offers the most effective monitoring program. However, the Alliance's work group recommended that each state determine the schedules its program will cover.

Most PDMPs use electronic monitoring systems, in which pharmacies transmit prescription data for covered drugs electronically to the designated state agency or a private contractor at least once a month. Experts agree that electronic systems make it easier for law enforcement to identify drug diverters, reduce investigation time and paperwork, and provide easier access to information. Recently, New York and Illinois converted from paper-based to electronic programs, and Texas and Michigan have recently passed legislation to convert their programs to electronic systems.

Five states—California, Idaho, Michigan,[12] New York, and Texas—supplement their electronic systems with state-issued paper prescription forms to help prevent forgeries and counterfeits. These forms can be either single or triplicate and are made available by the state to prescribers. New York and Texas have recently switched or are in the process of switching from triplicate to single forms. The single forms include a number of safety features that prevent them from being

[12]Michigan is moving to an electronic system.

photocopied or scanned, such as watermarks. Kentucky requires prescribers to use non-state-issued secure safety forms when dispensing controlled substances.

States have assigned the administrative responsibility for PDMPs to various state agencies and regulatory bodies. Most programs are administered by a law enforcement agency, a state department of health, or a state board of pharmacy.

A Few PDMPs Operate Proactively, but Most Operate Reactively

States use different approaches to analyzing the prescription information they receive. A few states routinely analyze prescription data collected by the PDMPs to identify individuals, physicians, or pharmacies that have unusual use, prescribing, or dispensing patterns that may suggest potential drug diversion, abuse, or doctor shopping. States refer to this as a proactive approach to identifying drug diversion. Trend analyses are shared with appropriate entities, such as law enforcement, practitioners, and regulatory and licensing boards. In contrast, most state PDMPs generally use the prescription data to respond to requests for information. These requests may come from physicians or from law enforcement or state officials based on leads about potential instances of diversion. According to state program officials, most PDMPs operate in the latter fashion because of the increased amount of resources required to operate a proactive system.

Design and Operational Factors Affect Program Costs

The differences in program costs among all PDMP states reflect a number of design and operational factors. In addition to the choice of controlled substance schedules monitored, these factors include computer programming choices, number and type of staff and contractors, turnaround times and report transmittal methods, number and type of requests, and number of reporting entities, such as pharmacies.

If the PDMP is electronically based, there are ongoing computer maintenance and programming costs. If a private contractor collects the raw data from dispensers and converts them to a standardized format, the PDMP pays annual contracting costs for database maintenance. Kentucky and Nevada privately contract with the same company to collect data for their program database. Utah, in contrast, collects and maintains drug-dispensing data in-house, using its own software and hardware.

The number and type of staff a state chooses to operate its PDMP also vary and affect program costs. Kentucky's PDMP employs four full-time

and four part-time staff to help ensure the accuracy of its reports, including a pharmacist-investigator who reviews each report before it is sent. Nevada's PDMP operates with one employee because a private contractor collects the data. In contrast, Utah's PDMP, with three full-time employees and no private contractor, has one program administrator who collects all dispensing data and converts them to a standardized format for monitoring, and maintains the database. The two other staff answer requests.

If the PDMP seeks to provide same-day responses to report requests, the costs involved in returning the response to the requester may increase. For example, Kentucky has spent up to $12,000 in 1 month for faxing reports. PDMP officials from Kentucky, Nevada, and Utah estimated 3- to 4-hour turnaround times for PDMP data requests, and all mainly use faxing, rather than more costly mailing, to return the report to the requester. Same-day PDMP responses may be preferable for physicians who want the prescription drug history for a patient being seen that day, and for law enforcement users who need immediate data for investigations of suspected illegal activity.

As users become more familiar with the benefits of PDMP report data, requests and the attendant costs to provide them may increase. In Kentucky, Nevada, and Utah, usage has increased substantially, mostly because of the increased number of requests by physicians to check patients' prescription drug histories. In Kentucky, these physician requests increased from 28,307 in 2000, the first full year of operation, to 56,367 in 2001, an increase of nearly 100 percent. Law enforcement requests increased from 4,567 in 2000 to 5,797 in 2001, an increase of 27 percent. Similarly, Nevada's requests from all authorized users have also increased—from 480 in 1997, its first full year, to 6,896 in 2001, an increase of about 1,400 percent.

Additionally, as a PDMP matures, the needs it addresses may change, and operating costs may increase as a result. If users want PDMP reports to reflect more timely information, dispensing entities would have to report their data at the time of sale, rather than submitting data biweekly or monthly, to capture the most recent prescription dispensing. If users want to be alerted if a certain drug, practitioner, or pharmacy may be involved in a developing diversion problem, PDMPs would have to initiate periodic data analysis to determine trends or patterns. Such PDMP enhancements would entail additional costs, including costs for computer programming, and data analysis. Kentucky's PDMP is currently seeking $1.4 million in additional operating funds to meet costs related to increased PDMP usage

by all users, particularly physicians, and to be able to provide periodic reports about state drug usage trends and possible diversion.

State Programs Have Helped Shorten Investigation Time and Reduced Illegal Drug Diversion

States with PDMPs have experienced considerable reductions in the time and effort required by law enforcement and regulatory investigators to explore leads and the merits of possible drug diversion cases. The presence of a PDMP helps a state reduce its illegal drug diversion, but diversion activities may increase in contiguous states without PDMPs.

Investigation Time and Productivity Have Improved

The ability of PDMPs to focus law enforcement and regulatory investigators on suspected drug diversion cases to specific physicians, pharmacies, and patients who may be involved in the alleged activities is crucial to shortened investigation time and improvements in productivity. States that do not have PDMPs must rely on tips from patients, practitioners, or law enforcement authorities to identify possible prescription drug abuse and diversion. Following up on these leads requires a lengthy, labor-intensive investigation. In contrast, PDMPs provide information that allows investigators to pinpoint the physicians' offices and pharmacies where drug records must be reviewed to verify suspected diversion and thus eliminates the need to search records at physicians' offices and pharmacies that have no connection to a case.

Prior to implementation of Kentucky's PDMP, its state drug control investigators took an average of 156 days to complete the investigation of alleged doctor shoppers. Following the implementation, the average investigation time dropped to 16 days. Similarly, Nevada reduced its investigation time from about 120 days to about 20 days, and a Utah official told us that they experienced an 80 percent reduction in investigation time.

Programs Have Helped Reduce Availability of Abused Drugs

Officials from Kentucky, Nevada, and Utah told us that PDMPs have helped reduce the unwarranted prescribing and subsequent diversion of abused drugs in their states. In both Kentucky and Nevada, an increasing number of PDMP reports are being used by physicians to check the prescription drug utilization history of current and prospective patients to determine whether it is necessary to prescribe certain drugs that are subject to abuse. Law enforcement officials told us that they view these drug history checks as initial deterrents—a front-line defense—to prevent

individuals from visiting multiple physicians to obtain prescriptions, because patients are aware that physicians can review their prescription drug history. For an individual who may be seeking multiple controlled substance prescriptions, the check allows a physician to analyze the prescription drug history to determine whether drug treatment appears questionable, and if so, to verify it with the listed physicians. In Kentucky, a physician can request a PDMP report the same day as a patient's appointment, and usually receives the patient's drug history report within 4 hours of making the request. Kentucky's PDMP typically receives about 400 physician requests daily, and can provide data current to the most recent 2 to 4 weeks.

The presence of a PDMP may also have an impact on the use of drugs more likely to be diverted. For example, DEA rank-ordered all states for 2000 by the number of OxyContin prescriptions per 100,000 people.[13] Eight of the 10 states with the highest number of prescriptions—West Virginia, Alaska, Delaware, New Hampshire, Florida, Pennsylvania, Maine, and Connecticut—had no PDMPs, and only 2 did—Kentucky and Rhode Island. Six of the 10 states with the lowest number of prescriptions—Michigan, New Mexico,[14] Texas, New York, Illinois, and California—had PDMPs, and 4—Kansas, Minnesota, Iowa, and South Dakota—did not.

The existence of a PDMP within a state, however, appears to increase drug diversion activities in contiguous non-PDMP states. When states begin to monitor drugs, drug diversion activities tend to spill across boundaries to non-PDMP states. One example is provided by Kentucky, which shares a boundary with seven states, only two of which have PDMPs—Indiana and Illinois. As drug diverters became aware of the Kentucky PDMP's ability to trace their drug histories, they tended to move their diversion activities to nearby nonmonitored states. OxyContin diversion problems have worsened in Tennessee, West Virginia, and Virginia—all contiguous non-

[13]OxyContin, Hearings Before the Subcommittee on the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies, House Committee on Appropriations, 107th Cong. Part 10, pp. 21, 22 (2001) (Statement of Asa Hutchinson, Administrator of the Drug Enforcement Administration).

[14]New Mexico's PDMP was terminated in June 2000.

PDMP states—because of the presence of Kentucky's PDMP, according to a joint federal, state, and local drug diversion report.[15]

Challenges Exist in Establishing and Expanding State PDMPs

States that are considering establishing or expanding a PDMP face a variety of challenges. One challenge is the lack of awareness of the extent to which prescription drug abuse and diversion is a significant public health and law enforcement problem. States also face concerns about the confidentiality of the information gathered by the PDMP, voiced by patients who are legitimately using prescription drugs and by physicians and pharmacists who are legitimately prescribing and dispensing them. Another challenge states face is securing adequate funding to initiate and develop the program and to maintain and modify it over time.

Extent of Diversion and Abuse Is Not Always Recognized

One challenge faced by states attempting to control diversion and abuse of controlled substances is a lack of awareness of the seriousness of this public health and law enforcement problem. Nationally, prescription drug abuse involves a multibillion-dollar illegal diversion market, results in deaths of abusers, and is as significant a problem as abuse of illegal drugs. In Kentucky, the state police alerted state officials, including the attorney general and the governor, about the extent of the state's prescription drug abuse problem. A task force was established with state legislators and representatives from law enforcement, public health, and education, which recommended that the state establish a PDMP. About 3 years later, the abuse and diversion of OxyContin in eastern Kentucky became a major concern, prompting the governor to create an OxyContin task force. The task force recommended enhancing the PDMP's capability to identify doctor shoppers by increasing the timeliness of data collection, analysis, and dissemination through development of an online, real-time data entry system for pharmacists. Another recommendation was to develop an educational program so PDMP users, such as physicians, pharmacists, and law enforcement officials, could better understand the system's enhanced capabilities.

[15]Appalachia High Intensity Drug Trafficking Area Investigative Support Center, with the assistance of the National Drug Intelligence Center, *The OxyContin Threat in Appalachia*, August 2001.

Physicians, Patients, and Pharmacists Express Concerns About Confidentiality

Both physicians who legitimately prescribe prescription drugs and patients who legitimately use them are concerned that the information collected, centrally maintained, and monitored by state PDMPs may be used inappropriately or compromised. All states, regardless of whether there is a state PDMP, have the authority under their laws to conduct investigations of the records of individuals alleged to be involved in prescription drug diversion and abuse, including the records of prescribing physicians and dispensing pharmacies. PDMPs, particularly those with electronic databases, raise additional confidentiality concerns, however, because their databases contain complete dispensing records that can more quickly identify individual patients, physicians, and pharmacies and provide an individual report on their prescription drug history. Physicians are concerned that their prescribing decisions and patterns may be questioned and that they could be investigated without sufficient cause. Some physicians contend that patients may suffer because physicians will be reluctant to prescribe appropriate controlled substances to manage a patient's pain or treat their condition. Patients are concerned that their personal information may be used inappropriately by those with authorized access or shared with unauthorized entities. Pharmacists have also expressed concerns. In New Mexico, the Board of Pharmacy repealed the administrative regulations necessary to operate the state's electronic PDMP following confidentiality concerns raised by some pharmacists who were apprehensive they might be targeted for investigation based on the volume of controlled substance drugs they dispensed.

Some states have attempted to address these concerns statutorily. For example, some state laws to regulate controlled substances and to operate a PDMP include health privacy protection provisions.[16] In addition, states with PDMPs generally have statutory and regulatory protections to limit access and use of confidential health care data, as well as statutory penalties for misuse. Under Kentucky's electronic PDMP, for example, the authorized users of its information are statutorily delineated, the knowing misuse of the data can result in a felony conviction, and the PDMP itself is statutorily accountable for ensuring that only authorized users receive its

[16]The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) generally preempts state health information privacy laws, unless they provide a higher level of protection than the act. (Pub. L. No.104-191, §262, 110 Stat. 1936, 2029.) However, these state privacy provisions may not be preempted if the Secretary of Health and Human Services determines that the state law has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substances (as defined in 21 U.S.C. §802), or that is deemed a controlled substance by state law. (45 C.F.R. §160.203 (a)(2))

data. Kentucky law also prohibits any person who receives PDMP data from sharing that information with anyone else, unless required by a court, and the Kentucky PDMP advises data recipients of this prohibition. Nevada's state law similarly protects the confidentiality of its PDMP information by requiring a court order for disclosure to nonauthorized entities. Also, Nevada's Board of Pharmacy has legal authority to discipline and fine an individual for violating the confidentiality law. For example, the board brought legal action against a pharmacist who provided an employer with prescription utilization information on a worker whom the employer subsequently fired. The pharmacist was fined $2,000 and was given probationary discipline.

Securing Program Funding Is a Critical Challenge

According to officials from the National Alliance for Model State Drug Laws, the National Association of Drug Diversion Investigators, and the DEA, securing program funding is a critical challenge faced by states that choose to develop, maintain, or expand a PDMP. They add that funding availability is crucial to states' ability to establish and continue PDMPs. Given a state's particular funding availability and priorities, PDMP costs can involve a major hurdle. According to state officials, the start-up costs for the three most recent PDMPs were $415,000 for Kentucky in 1999, $134,000 for Nevada in 1996,[17] and $50,000 for Utah in 1996. Estimated annual operating costs for these PDMPs varied from a high of about $500,000 in Kentucky to $112,000 in Nevada and $93,000 in Utah. These three PDMPs are supported by state funds and do not charge fees for providing data reports to their users. In contrast, the West Virginia PDMP was terminated in 1998 primarily because of a lack of state funding support, according to an official of the state board of pharmacy, which operated the program. The board had been required to fund the PDMP through the revenue generated by its licensing and related fees, without additional state funds, but was unable to sustain operation of both its licensing and regulatory program and its PDMP through these revenues alone.

[17]Nevada received a total of $265,000 for the first 2 years of the program's operations, including 2-year grants from two pharmaceutical companies and the state board of medical examiners.

National Efforts Have Focused on Providing Guidance and Technical Assistance

Efforts at the national level to assist states in addressing illegal diversion have focused on providing guidance and technical assistance. The National Alliance for Model State Drug Laws has identified the key features of a model PDMP and drafted a model law that states could adopt. Both the Alliance and DEA have provided information to states about the nature of drug diversion problems and guidance on how to deal with them. DEA has also assisted states in initiating new PDMPs and improving existing ones.

The Alliance Provides Models and Technical Assistance for States

The Alliance published the final report from its Prescription Monitoring Work Group in February 2002. The report identified the key features of a model PDMP. It recommended that PDMPs cover all schedules of controlled substances, use some form of an electronic monitoring system, safeguard the confidentiality of the prescription data collected, analyze the data to provide information for law enforcement and medical professionals, provide education to health professionals regarding the monitoring system and pain management, and include an evaluation component to assess its costs and benefits. Along with its work group report, the Alliance provided a draft model state law.

The Alliance also facilitates communication between states that are considering a PDMP and states that have programs in place, and provides technical assistance to states on implementing its recommendations. It reviews draft bills and provides information on current PDMP status, trends, and legal matters to state legislatures. For example, the Alliance work group recently stressed the need for states to assess the impact of the HIPAA privacy provisions on state PDMPs.

DEA Has Assisted States in Dealing with Drug Diversion and Abuse

Since the 1980s, DEA has been supportive of state PDMP efforts to detect and prevent illegal diversion of prescription drugs at the retail level. DEA's aid has been largely in the form of providing technical assistance to states that are seeking to reduce diversion and abuse, and only recently in the form of making start-up funding available to states.

Historically, DEA has routinely supplied educational materials to practitioners, dispensers, and the general public on drug diversion. It has also provided states with computerized information and intelligence on the distribution of certain controlled substances and coordinated major investigations. In addition, DEA has served as a program resource for states seeking assistance with developing PDMPs and drafting and promulgating regulations.

Over the past 11 years, three states have obtained federal funds to initiate PDMPs: Kentucky (1998), Massachusetts (1992), and Oklahoma (1991). More recently, additional funding has been made available for grants to states that are planning to start a PDMP or expand an existing program. Two million dollars in grants from the Department of Justice's Bureau of Justice Assistance is to be administered jointly with the DEA.[18] DEA and the Bureau of Justice Assistance designed the grant program to allow states with legislation or regulations for a PDMP program in place or pending to apply for funding. There are also grants available for states with existing PDMPs to improve program capabilities through enhanced technology. According to DEA, seven New Program Grants of $180,000 and two Enhanced Program Grants of $220,000 will be available. Several states have expressed an interest in applying for the grants because of their increased awareness of drug diversion.

Concluding Observations

Illegal diversion and abuse of prescription drugs and the associated criminal activity are growing problems in many states. Prescription drug monitoring programs offer states a more efficient means of detecting and deterring illegal diversion. These programs provide state health care licensing and regulatory agencies and law enforcement with quick access to comprehensive information on the prescribing, dispensing, and purchasing of controlled substances that are most likely to be targets for diversion.

Although state PDMPs have aided investigators and helped to reduce doctor shopping, the number of states with PDMPs has grown only slightly over the past decade, from 10 in 1992 to 15 in 2002. A lack of awareness of the magnitude of the problem, concerns about confidentiality on the part of patients, physicians, pharmacists, and legislators, and difficulty in accessing funding have kept the numbers of PDMPs low.

Cooperative efforts at the state and national levels are seeking to overcome these challenges and increase the number of states with programs. For states considering establishing PDMPs, the report by the Alliance's Prescription Monitoring Work Group provides a useful roadmap of the critical factors each state needs to consider in order to create an

[18]Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 2002, Pub. L. No. 107-77 (2001). The $2 million grant is itemized as the "Harold Rogers Prescription Drug Monitoring Program" (H.R. Conf. Rep. No. 107-278, at 90(2001)).

effective program. Moreover, the $2 million in grants available from the Bureau of Justice Assistance, and to be administered jointly with DEA, provides states with a potential source of funding to start a PDMP.

Agency Comments

We obtained comments on a draft of this report from DEA, the Alliance, and state PDMP officials in Kentucky, Nevada, and Utah. In general, they agreed with the report and thought it provided useful information on state drug monitoring programs. They also provided technical comments, which we incorporated where appropriate.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the Attorney General of the United States, the Administrator of the Drug Enforcement Agency, and others who are interested. We also will make copies available to others upon request. In addition, the report will be available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staffs have any questions about this report or would like additional information, please call me at (202) 512-7118. Another contact and key contributors to this report are listed in appendix II.



Janet Heinrich
Director, Health Care—Public Health Issues

Appendix I: Key Features of Selected State Prescription Drug Monitoring Programs

This table summarizes the key features of the state prescription drug monitoring programs (PDMPs) in Kentucky, Nevada, and Utah.

Table 2: Key Features of Selected State Prescription Drug Monitoring Programs

Key features	Kentucky	Nevada	Utah
Census 2000 population	4.04 million	1.99 million	2.23 million
Year operational	1999	1997	1997
Start-up funding	$415,000 in federal start-up grant funds	$134,000[a] in state funds	$50,000 in one time state funds
Controlled substance schedules monitored	II, III, IV, V	II, III, IV	II, III, IV, V
Electronic data collection and reporting	Yes	Yes	Yes
Private contractor receives dispensing information and creates database	Yes	Yes	No
Annual operating costs (estimate)	$500,000	$112,000	$150,000
Staff	4 full-time (1 licensed pharmacist investigator, 2 pharmacy technicians, 1 data entry operator) and 4 part-time	1 full-time with all administrative duties	3 full-time including manager and 2 support staff
Number of pharmacies reporting dispensing data (estimate)	1,300	387	375
Number of daily data requests received (estimate)	400	20	130 to 150
Report turnaround time to requestor (estimate)	4 hours	4 hours	3 hours
Penalty for unauthorized use or disclosure of PDMP data	Class D felony[b]	PDMP statute has no penalty	Third-degree felony[c]

[a]Nevada received $265,000 for the first 2 years of its program's operations, including 2-year grants from two pharmaceutical companies and the state board of medical examiners.

[b]Kentucky law defines a class D felony as one carrying a sentence of at least 1 year, but not more than 5 years in prison.

[c]Utah law defines a third-degree felony as one carrying a sentence of not more than 5 years in prison.

Source: GAO interviews with PDMP administrators.

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

John C. Hansen, (202) 512-7105

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