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PRESCRIPTION DRUGS

State Monitoring Programs May Help to Reduce Illegal Diversion

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Why GAO Did This Study

The increasing diversion of prescription drugs for illegal purposes or abuse is a disturbing trend in the nation's battle against drug abuse. Diversion can include such activities as prescription forgery and "doctor shopping" by individuals who visit numerous physicians to obtain multiple prescriptions. The most frequently diverted prescription drugs are controlled substances that are prone to abuse, addiction, and dependence, such as hydrocodone (the active ingredient in Lortab and many other drugs) and oxycodone (the active ingredient in OxyContin and many other drugs).

Some states use prescription drug monitoring programs to control illegal diversion of prescription drugs that are controlled substances.

GAO was asked to examine (1) how state monitoring programs compare in terms of their objectives and operation and (2) the impact of state monitoring programs on illegal diversion of prescription drugs.

This testimony is based on GAO's report, *Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion*, GAO-02-634 (May 17, 2002). In that report, the programs in Kentucky, Utah, and Nevada were selected for more in-depth study because they were the most recently established programs at the time.

www.gao.gov/cgi-bin/getrpt?GAO-04-524T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse at (202) 512-7119.

PRESCRIPTION DRUGS

State Monitoring Programs May Help to Reduce Illegal Diversion

What GAO Found

GAO found that the 15 state monitoring programs in place in 2002 differed in their objectives and operation. The programs were intended to facilitate the collection, analysis, and reporting of information about the prescribing, dispensing, and use of controlled substances. They provided data and analysis to state law enforcement and regulatory agencies to assist in identifying and investigating activities potentially related to illegal drug diversion. The programs could be used by physicians to check a patient's prescription drug history to determine if the individual was doctor shopping to seek multiple controlled substances. Some programs also offered educational programs for the public, physicians, and pharmacists regarding the nature and extent of the problem and medical treatment options for abusers of diverted drugs. The programs varied primarily in terms of the specific drugs they covered and the type of state agency in which they were housed. Some programs covered only those prescription drugs that are most prone to abuse and addiction, whereas others provided more extensive coverage. In addition, most programs were administered by a state law enforcement agency, a state department of health, or a state board of pharmacy.

GAO also found that state monitoring programs may have realized benefits in their efforts to reduce drug diversion. These included improving the timeliness of law enforcement and regulatory investigations. Each of the three states studied reduced its investigation time by at least 80 percent. In addition, law enforcement officials told GAO that they 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 histories based on monitoring program data. For example, as drug diverters became aware of Kentucky's ability to trace their drug histories, they tended to move their diversion activities to nearby nonmonitored states.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today and thank you for the opportunity to discuss our work on state prescription drug monitoring programs and their use in addressing the diversion of prescription drugs for illegal use.

The increasing diversion of prescription drugs for illegal purposes or abuse is a disturbing trend in the nation's battle against drug abuse.¹ Diversion activities can include "doctor shopping" by individuals who visit numerous physicians to obtain multiple prescriptions, illegal sales of prescription drugs by physicians or pharmacists, prescription forgery, and purchasing drugs from Internet pharmacies without valid prescriptions. The most frequently diverted prescription drugs are controlled substances² that are prone to abuse, addiction, and dependence,³ 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 visits 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.

Some states operate prescription drug monitoring programs as a means to control the illegal diversion of prescription drugs. My remarks today will focus on (1) how state monitoring programs compare in terms of their objectives and operation and (2) the overall impact of state monitoring programs on illegal diversion of prescription drugs. My comments are based on our May 2002 report on state monitoring programs and their

¹Office of Drug Control Policy, "U.S. Drug Prevention, Treatment, Enforcement Agencies Take on 'Doctor Shoppers', 'Pill Mills,'" Mar. 1, 2004, www.whitehousedrugpolicy.gov (downloaded Mar. 2, 2004).

²Under the Controlled Substances Act, which was enacted in 1970, drugs are classified as controlled substances and placed into one of five schedules based on their medicinal value, potential for abuse, and safety or dependence liability.

³According 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.

usefulness as a tool for reducing diversion.⁴ For that report we reviewed information from DEA and the National Alliance for Model State Drug Laws on the features of existing programs. To gain a more in-depth understanding of these programs and the challenges they face, we also studied the programs in Kentucky, Nevada, and Utah. We selected these three states because at the time they had the most recently established programs.

In brief, we found that 15 states operated monitoring programs in 2002 as a means to control the illegal diversion of prescription drugs that are controlled substances.⁵ Although these programs were all intended to facilitate the collection, analysis, and reporting of information about the prescribing, dispensing, and use of controlled substances, they differed in their objectives and operation. They all provided data and analysis to state law enforcement and regulatory agencies in order to assist in identifying and investigating activities potentially related to the illegal prescribing, dispensing, and procuring of controlled substances. Further, some programs could be used by physicians to check a patient's prescription drug history to determine if the individual may have been doctor shopping to seek multiple controlled substances. Some programs also offered educational programs for the public, physicians, and pharmacists regarding the nature and extent of the problem and medical treatment options for abusers of diverted drugs. The operation of the monitoring programs varied primarily in terms of the specific drugs they covered and the type of state agency in which they were housed. Some programs covered only those prescription drugs that are most prone to abuse and addiction, whereas others provided more extensive coverage. In addition, most programs were administered by a state law enforcement agency, a state department of health, or a state board of pharmacy.

We found that state monitoring programs realized benefits in their efforts to reduce drug diversion. These included improving the timeliness of law enforcement and regulatory investigations. Each of the three states we

⁴For more details on these programs, see U.S. General Accounting Office, *Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion*, GAO-02-634 (Washington, D.C.: May 17, 2002).

⁵The 15 states were California, Hawaii, Idaho, Illinois, Indiana, Kentucky, Massachusetts, Michigan, Nevada, New York, Oklahoma, Rhode Island, Texas, Utah, and Washington. In 1998, West Virginia terminated its monitoring program, but began operating a program again in 2003, bringing the total of state programs to 16. In addition, Virginia began operating a pilot program in the southwestern part of the state in fall 2003.

studied reduced its investigation time by at least 80 percent. In addition, law enforcement officials told us that they 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 histories based on monitoring program data. For example, as drug diverters became aware of Kentucky's ability to trace their drug histories, they tended to move their diversion activities to nearby nonmonitored states.

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. One recent example of this growing diversion problem concerns the controlled substance oxycodone, the active ingredient in over 20 prescription drugs, including OxyContin, Percocet, and Percodan. OxyContin is the number one prescribed narcotic medication for treating moderate-to-severe pain in the United States.⁶ Currently, a single 20-milligram OxyContin tablet legally selling for about \$2 can be sold for as much as \$25 on the illicit market in some parts of Kentucky.

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 1970⁷ provides the legal framework for the federal government's oversight of transactions involving the sale and distribution of controlled substances at the manufacturer and wholesale distributor levels. The states address these issues through their regulation of the practice of medicine and pharmacy.

⁶U.S. General Accounting Office, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*, GAO-04-110 (Washington, D.C.: Dec. 23, 2003).

⁷Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Pub. L. No. 91-513, §§100 *et seq.*, 84 Stat. 1236, 1242 *et seq.*).

Controlled Substances Act

The Controlled Substances Act established a classification structure for drugs and chemicals used in the manufacture of drugs that are designated as controlled substances.⁸ Controlled substances are classified by DEA into five schedules on the basis of their medicinal value, potential for abuse, and safety or dependence liability. 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 among drugs with an accepted medical use and may lead to severe psychological and physical dependence. Drugs on schedules III through V have accepted 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 antianxiety medications diazepam (Valium) and alprazolam (Xanax). Schedule V includes preparations such as cough syrups with codeine. All scheduled drugs except those in schedule I are legally available to the public with a prescription.⁹

Under the act, DEA provides legitimate handlers of controlled substances—including manufacturers, distributors, hospitals, pharmacies, practitioners, and researchers—with registration numbers, which are used in all transactions 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 DEA. The data provided to DEA are available for use in monitoring the distribution of controlled substances throughout the United States, in identifying retail-level registrants that received unusual quantities of controlled substances, and in investigations of illegal diversions at the manufacturer and wholesaler levels. Although data are reported to DEA regarding purchases by pharmacies, the act does not require the reporting of dispensing information by pharmacies at the patient level to DEA.

⁸Section 201, classified to 21 U.S.C. § 811.

⁹Some schedule V drugs that contain limited quantities of certain narcotic and stimulant drugs are available over the counter without a prescription.

State Regulation of the Practice of Medicine and Pharmacy

State laws govern the prescribing and dispensing of prescription drugs by licensed health care professionals. State medical practice laws generally delegate the responsibility of regulating physicians to state medical boards, which license physicians and grant them prescribing privileges.¹⁰ In addition, state medical boards investigate complaints and impose sanctions for violations of the state medical practice laws. States regulate the practice of pharmacy 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. According to the National Association of Boards of Pharmacy, all state pharmacy laws require that records of prescription drugs dispensed to patients be maintained and that state pharmacy boards have access to the prescription records.

State Monitoring Programs Varied in Objectives and Operation

State prescription drug monitoring programs varied in their objectives and operation. While all programs were intended to help law enforcement identify and prevent prescription drug diversion, some programs also included education objectives to provide information to physicians, pharmacies, and the public. Program operation also varied across states, in terms of which drugs were covered and how prescription information was collected. Which agency, such as a pharmacy board or public health department, was given responsibility for the program also varied across states. Additionally, methods for analyzing the data to detect potential diversion activity differed among state programs.

State monitoring programs are intended to facilitate the collection, analysis, and reporting of information on the prescribing, dispensing, and use of prescription drugs within a state. The first state monitoring program was established in California in 1940, and the number of programs has grown slowly. We reported that the number of states with programs has grown from 10 in 1992 to 15 in 2002; the number of programs stands at 16 in 2004.

¹⁰The types of practitioners who prescribe drugs and may be monitored by a state program vary among states. Physicians are the majority of covered practitioners, but in most states many nonphysicians who also have prescribing authority may be covered, including physician assistants, dentists, optometrists, podiatrists, veterinarians, and certain types of nurses, such as nurse practitioners and advanced practice nurses.

We found that state programs varied in their objectives. All states used monitoring programs primarily to assist law enforcement in detecting and preventing drug diversion, and but some also used the programs for educational purposes. Programs assisted 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 evaluations of program data revealed atypical prescribing or dispensing patterns that suggested possible illegal diversion. The programs evaluated prescribing patterns to identify medical providers who may have been overprescribing and inform them that their patterns were unusual. They also identified patients who may have been abusing or diverting prescription drugs and provided this information to practitioners. For example, the programs in Nevada and Utah sent letters to physicians containing patient information that could 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. Monitoring programs have also been used to educate physicians, pharmacies, and the public about the existence and extent of diversion, diversion scams, the drugs most likely to be diverted by individuals, and ways to prevent drug diversion.

Monitoring programs also differed in operational factors, some of which have cost implications. These factors included the choice of controlled substance schedules monitored, approaches to analyzing and using data, computer programming choices, number and type of staff and contractors, turnaround times and report transmittal methods, and number and type of requests for information.

State programs varied in the controlled substances they covered, in part because of differences in available resources and other state-specific factors such as level of drug abuse. Two of the states we studied—Kentucky and Utah—covered schedules II through V. These states’ program officials told us that covering those schedules allowed them flexibility to respond if drugs on other schedules became targets for diversion. Most experts agree that covering all controlled substance schedules prevents drug diverters from avoiding detection by bypassing schedule II drugs and switching to drugs in other schedules.

States used different approaches to analyze the prescription information they received. A few states used a proactive approach, routinely analyzing prescription data collected by the programs to identify individuals, physicians, or pharmacies that had unusual use, prescribing, or dispensing patterns that could suggest potential drug diversion, abuse, or doctor

shopping. Trend analyses were shared with appropriate entities, such as law enforcement, practitioners, and regulatory and licensing boards. In contrast, most state programs generally used the prescription data in a reactive manner to respond to requests for information. These requests may have come from physicians or from law enforcement or state officials based on leads about potential instances of diversion. According to state program officials, most programs operated in a reactive fashion because of the increased amount of resources required to operate a proactive system.

Some state programs had electronic reporting systems, while others were paper-based. If data are reported electronically, there are ongoing computer maintenance and programming choices and their attendant costs. Similarly, some state programs engaged private contractors to collect and maintain the data, while others did so in-house. If a private contractor collects the raw data from dispensers and converts them to a standardized format, the program pays annual contracting costs for database maintenance. Kentucky and Nevada privately contracted with the same company to collect data for their program databases. Utah, in contrast, collected and maintained drug dispensing data in-house, using its own software and hardware.

The number and type of staff a state chose to operate its monitoring program also varied. In 2002, Kentucky's program employed four full-time and four part-time staff to help ensure the accuracy of its reports, including a pharmacist-investigator who reviewed each report before it was sent. Nevada's program operated with one employee because a private contractor collected the data. In contrast, in 2002 Utah's program, with three full-time employees and no private contractor, had one program administrator who collected all dispensing data, converted them to a standardized format for monitoring, and maintained the database. The two other staff answered requests.

If the program seeks to provide more timely responses to report requests, such as same-day responses, the costs involved in returning the response to the requester may increase. For example, in 2001 Kentucky spent up to \$12,000 in 1 month for faxing reports. Monitoring program officials from Kentucky, Nevada, and Utah told us in 2002 that they estimated 3- to 4-hour turnaround times for program data requests, and all mainly used faxing, rather than more costly mailing, to send reports to requesters. Same-day 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 monitoring program report data, requests for information and other demands on the programs may increase. In Kentucky, Nevada, and Utah, use had increased substantially, mostly because of an increase in the 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 also increased—from 480 in 1997, its first full year, to 6,896 in 2001, an increase of about 1,300 percent.

Additionally, as drug marketing practices change and monitoring programs mature, the operational needs may shift as well. For example, states face new challenges with the advent of Internet pharmacies, because they enable pharmacies and physicians to anonymously reach across state borders to prescribe, sell, and dispense prescription drugs without complying with state requirements.¹¹ In addition, if users want program 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, programs would have to initiate periodic data analysis to determine trends or patterns. Such program enhancements would entail additional costs, however, including costs for computer programming, and data analysis.

States that are considering establishing or expanding a monitoring program face a variety of other 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 program, 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

¹¹For more details on Internet pharmacies, see U.S. General Accounting Office, *Internet Pharmacies: Adding Disclosure Requirements Would Aid State and Federal Oversight*, GAO-01-69 (Washington, D.C.: Oct. 19, 2000).

funding to initiate and develop the program and to maintain and modify it over time.¹²

State Monitoring Programs Have Helped Shorten Investigation Times and May Reduce Illegal Drug Diversion

We found that states with monitoring programs 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. We also found that the presence of a monitoring program in a state may help reduce illegal drug diversion there, but that diversion activities may increase in contiguous states without programs.

The ability of the programs to focus law enforcement and regulatory investigators who are working on suspected drug diversion cases on 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 programs 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, the programs can provide information that allows investigators to pinpoint the physicians' offices and pharmacies where drug records must be reviewed to verify suspected diversion and thus can eliminate the need to search records at physicians' offices and pharmacies that have no connection to a case.

In each of the three states we studied, state monitoring programs led to reductions in investigation times. For example, prior to implementation of Kentucky's monitoring program, 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, or a 90 percent reduction in investigation time. Similarly, Nevada reduced its investigation time from about 120 days to

¹²Federal grants are available to states to establish new monitoring programs and to enhance existing programs under the Harold Rogers Prescription Drug Monitoring Program. DEA's Office of Diversion Control, in collaboration with the Department of Justice's Bureau of Justice Assistance, provides grants to states to establish new programs and to enhance existing monitoring programs through the Harold Rogers Prescription Drug Monitoring Program. The fiscal year 2003 grantees are Alabama, Florida, Maine, New Mexico, and Wyoming for new programs, and California, Idaho, Nevada, and New York for enhanced programs. The grantees in fiscal year 2002 were Ohio, Pennsylvania, Virginia, and West Virginia for new programs, and California, Kentucky, Massachusetts, Nevada, and Utah for enhanced programs.

about 20 days, a reduction of 83 percent, and a Utah official told us that it experienced an 80 percent reduction in investigation time.

Officials from Kentucky, Nevada, and Utah told us in 2002 that their programs may have helped reduce the unwarranted prescribing and subsequent diversion of abused drugs in their states. In both Kentucky and Nevada, an increased number of program reports were being used by physicians to check the prescription drug use histories of current and prospective patients when deciding whether 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 could request a drug history report on the same day as the patient's appointment, and usually received the report within 4 hours of the request. In 2002, Kentucky's program typically received about 400 physician requests daily, and provided data current to the most recent 2 to 4 weeks.

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

¹³OxyContin, 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).

¹⁴New Mexico's monitoring program was terminated in June 2000.

Another indication of the effectiveness of a monitoring program is that its existence in one state appears to increase drug diversion activities in contiguous states without programs. When states begin to monitor drugs, drug diversion activities tend to spill across boundaries to states without programs. One example is provided by Kentucky, which shares a boundary with seven states, only two of which had programs in 2002—Indiana and Illinois. As drug diverters became aware of the Kentucky program’s ability to trace their drug histories, they tended to move their diversion activities to nearby nonmonitored states. OxyContin diversion problems worsened in Tennessee, West Virginia, and Virginia—all contiguous states without programs—because of the presence of Kentucky’s program, according to a 2001 joint federal, state, and local drug diversion report.¹⁵

Concluding Observations

Although monitoring programs can enhance the ability of states to detect and deter illegal diversion of prescription drugs, the number of states with such programs has grown only slightly over the past 12 years from 10 in 1992 to 16 in 2004. 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 monitoring programs low. Cooperative efforts at the state and national levels are seeking to overcome these challenges and increase the number of states with programs.

Mr. Chairman, this concludes my prepared statement. I would be pleased to respond to any questions you or other Members of the Subcommittee may have.

Contact and Acknowledgments

For more information regarding this testimony, please contact Marcia Crosse at (202) 512-7119. Individuals making key contributions to this testimony include Martin T. Gahart, Roseanne Price, and Opal Winebrenner.

¹⁵Appalachia High Intensity Drug Trafficking Area Investigative Support Center, with the assistance of the National Drug Intelligence Center, *The OxyContin Threat in Appalachia* (London, Ky.: Aug. 2001).

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