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Report to the Chairman, Select Committee on Narcotics Abuse and Control, House of Representatives

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CONTROLLED SUBSTANCES

Medicaid Data May Be Useful for Monitoring Diversion

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GAO

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Human Resources Division

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The Honorable Charles B. Rangel
Chairman, Select Committee on Narcotics
Abuse and Control
House of Representatives

Dear Mr. Chairman:

This report is in response to your request to assess the possible use of Medicaid data to produce information identifying health care providers who may be diverting controlled prescription drugs for illegal purposes.

As requested by your office, we will make no further distribution of this report for 30 days. At that time, we will send copies to the Director, Office of Management and Budget; the Secretary of Health and Human Services; the Attorney General; and interested congressional committees.

Sincerely yours,

Lawrence H. Thompson

Lawrence H. Thompson
Assistant Comptroller General

Executive Summary

Purpose

Controlled substances are chemicals such as heroin and cocaine that are subject to abuse because of their psychological or physical effects on the user—in the vernacular, they can make a person "high." Some prescription drugs like morphine and diazepam (commonly known as Valium) fall into the controlled substance category because they have effects similar to those of illicit drugs and, thus, are also subject to abuse. One concern in the nation's battle against drug abuse is the diversion to illegal use of prescription drugs obtained under the pretext of a legitimate medical need. Diversion can be attractive to drug abusers because prescription drugs are cheap and chemically pure compared to "hard" or illicit drugs. Diversion can occur at any level in the production and distribution system, from the manufacturer to the retail pharmacy.

The Chairman of the House Select Committee on Narcotics Abuse and Control asked GAO to develop information on the types of activities states use to combat drug diversion and on the potential for using Medicaid data to identify providers inappropriately prescribing or dispensing controlled substances. With the exception of small states, Medicaid agencies are required to have a Medicaid Management Information System (MMIS), which contains program utilization data on recipients, physicians, and pharmacies. GAO reviewed the ability of these systems to produce information highlighting those providers who may be diverting controlled substances and discussed the usefulness of such information with licensing, regulatory, law enforcement, and other officials responsible for controlling drug diversion.

Background

Medicaid is a federally supported and state-administered assistance program that provides medical care for certain low-income individuals and families. Although coverage of prescription drugs is not a federal requirement, only two state Medicaid programs, Alaska's and Wyoming's, do not cover them. A number of states put limits on the types of controlled substances Medicaid recipients can receive under the program.

In fiscal year 1986, 22.5 million recipients participated in the Medicaid program and expenditures were almost $41 billion. Although nationwide data are not maintained on the use of controlled substances under the program, over $2.7 billion was spent on prescription drugs, which include controlled substances.

States have undertaken the primary responsibility for preventing controlled substance diversion at the retail level and for detecting and prosecuting cases when preventive efforts have failed. Organizational structures vary among states, but there are usually a number of agencies responsible for a piece of the licensing, regulatory, and enforcement functions relating to controlled substance violations. The states' MMISs often comprise the largest data bases on the prescribing and dispensing of controlled substances in a state, and aberrant patterns of utilization, when detected, can point to problems not limited to the Medicaid program.

Results in Brief

MMIS utilization reviews are designed to identify potential fraud and abuse throughout the spectrum of Medicaid covered services. Although these reviews do not routinely focus on controlled substances, data contained in the MMISs can be manipulated to produce reports that may be useful in the identification of providers who may be diverting controlled substances. Regulatory and licensing agencies in all the states GAO visited expressed an interest in receiving MMIS data for use in their investigations, but could not tell GAO how extensive their use would be. The possible usefulness of routinely providing MMIS controlled substance data to these agencies, however, can only be determined by conducting tests designed to make such an evaluation.

Because Medicaid and drug diversion control activities are housed in different agencies at both the federal and state levels, GAO believes such tests are unlikely unless a federal agency takes the lead.

GAO's Analysis

Most federal efforts to detect and prevent diversion of controlled substances are focused at the manufacturing and wholesale levels. To combat diversion at the retail (dispensing) level, states use various techniques including provider education, peer review, and on-site visits to pharmacies. In addition, there are a number of techniques used by Medicaid, which lessen the opportunity to divert drugs paid for by the program. (See pp. 14-16.)

A critical element needed to make all these techniques work is information on the extent of controlled substance activity in the state and where diversion is taking place. A number of data systems are available that, when used individually and collectively, provide this information. MMIS is one of these systems. (See pp. 16-19.)

State Medicaid agencies use MMIS paid claim data to detect both recipient and provider abuse. When provider utilization reviews are done, examining controlled substances is but one part of larger reviews geared to uncovering many possible types of Medicaid misutilization. In other words, in scanning the gamut of potentially abused items, some controlled substance data elements are included in these utilization reviews. GAO believes that this is appropriate for Medicaid agencies because their primary responsibilities are to assure that recipients obtain needed services and program costs are controlled. Control of drug diversion would be, at most, a by-product of their Medicaid administrative functions. (See pp. 19-22.)

GAO manipulated the controlled substance data available in Texas' and New York's MMISs for pharmacies to focus the data on controlled substance dispensing patterns. The same type of analyses could be performed for physicians. GAO discussed these analyses with state officials responsible for licensing and regulating physicians and pharmacists in matters relating to professional conduct. Overall, officials said the data would be useful for identifying problem providers. Officials with New York's State Department of Health said they are currently using MMIS data for trending and targeting purposes. A Wisconsin official said the data had been used but is not now because the state perceives less prescription drug abuse. The other state officials GAO discussed MMIS data with believed it would be useful and stated that they would be interested in receiving it on a regular basis. (See pp. 23-24.)

GAO also discussed the information on controlled substance prescribing and dispensing available from MMIS with state law enforcement officials. Opinions on whether they would use the data if it were routinely provided were mixed. Texas and Louisiana narcotics officials believed the information would be useful in identifying physicians prescribing high volumes of controlled substances. An official from the New York State Police Department said that he could not provide a definite answer on the routine use of the data until the department had a chance to examine it. An official from the Wisconsin Bureau of Narcotics and Vice said his agency's activities were primarily directed at illegal controlled substances. Medicaid law permits the disclosure of MMIS data to law enforcement agencies for use in criminal investigations and to state licensing officials for use in disciplinary action. However, the ultimate usefulness of routinely providing regulatory, licensing, and law enforcement agencies with analyses of Medicaid controlled substance data depends on the results that are achieved through use of such analyses. (See pp. 25-26.)

Recommendation

GAO recommends that the Secretary of Health and Human Services, in consultation with the Department of Justice in its role of assisting state and local law enforcement agencies, take the initiative and test the usefulness and cost of analyzing MMIS controlled substance data and providing it to regulatory, licensing, and law enforcement agencies for identifying sources of drug diversion.

Agency Comments

As requested by the Committee's office, GAO did not obtain official agency comments on the report. However, its contents were discussed with officials of the federal and state agencies discussed in the report, and their comments were incorporated where appropriate.

Contents

Abbreviations

AMA	American Medical Association
ARCOS	Automation of Reports and Consolidated Orders System
DAWN	Drug Abuse Warning Network
DEA	Drug Enforcement Administration
GAO	General Accounting Office
HCFA	Health Care Financing Administration
HHS	Department of Health and Human Services
MFCU	Medicaid Fraud Control Unit
MMIS	Medicaid Management Information System
PADS	Prescription Abuse Data Synthesis
SURS	Surveillance and Utilization Review System

Introduction

Each year, over 1.5 billion prescriptions are dispensed by pharmacies in the United States. The majority of these prescriptions are for drugs that are not abused; however, a number of drugs that can be legally dispensed are subject to abuse and are regulated under the Controlled Substances Act (21 U.S.C. 801) to protect against their abuse. These controlled substances have legitimate medical uses but, because of their physical or psychological effects, have a potential to be abused and, consequently, are subject to diversion for improper use. The extent of prescription drug abuse is evident from the fact that over half of the drug-abuse-related treatments in emergency rooms result from legal drugs. Added to this are the economic incentives for drug diversion, evident from the fact that a single hydromorphone (dilaudid) tablet available from a retail pharmacy for less than $1 has been resold "on the street" for $50 or more.

The Chairman, House Select Committee on Narcotics Abuse and Control, asked us to look into several issues related to diversion of prescription drugs under the Medicaid program. After preliminary work, we agreed with the Committee's office to obtain information on the types of activities states use to identify diversion of controlled substances and whether Medicaid information on prescription drug dispensing could be useful to authorities responsible for (1) investigating drug diversion and (2) disciplining health care professionals who participate in drug diversion schemes.

The Controlled Substance Component of Prescription Drugs

The Controlled Substances Act divides drugs that can be physically or psychologically harmful into five categories or schedules based on their potential for abuse, accepted medical use, and accepted safety under medical supervision. Schedule I controlled substances have no accepted medical use in the United States, are not available to the public through legal channels, and have a high abuse potential. Schedules II through V controlled substances have accepted medical uses and abuse potentials correlated to their assigned category number. Schedule II are the most dangerous and schedule V are the least. Table 1.1 provides examples of some of the more commonly recognized drugs included in each schedule.

Table 1.1: Examples of Schedules I-V Controlled Substances

	Examples
Schedule I	Marijuana, heroin, and lysergic acid-diethylamide (LSD).
Schedule II	Morphine, methadone, and cocaine.
Schedule III	Glutethimide (Doriden), aspirin with codeine, and other compound drugs containing specified amounts of a controlled substance, such as a combination of pentobarbital and an unscheduled drug.
Schedule IV	Phenobarbital, diazepam (Valium), and dextropropoxyphene (Darvon).
Schedule V	Compound mixtures or preparations containing limited amounts of narcotic drugs. Drugs taken for antitussive and antidiarrheal purposes fall under this schedule.

The level of the schedule under which a drug is placed also determines the nature and level of control exercised to prevent its abuse and diversion. Schedules I and II drugs are more strictly controlled than schedules III through V drugs. Controlled substances discussed in this report include only those legally manufactured and distributed; that is, those included in schedules II through V.

Legal controlled substances are appealing for abuse because, compared to illicit drugs, they are relatively low priced and are chemically reliable; that is, unlikely to contain harmful components or by-products. Diversion of legal controlled substances involves obtaining or selling them for supposedly legitimate medical purposes but abusing them or reselling them for abusive purposes. Diversion of these drugs can occur at all levels: manufacturing, distributing, marketing, prescribing, and dispensing. The Drug Enforcement Administration (DEA) has estimated that most abused prescription drugs are obtained at the retail level. DEA, within the Department of Justice, administers the Controlled Substances Act and requires all companies and individuals who handle controlled substances to register with it. About 95 percent of those registered are health care providers, such as physicians and pharmacies operating on the retail level.

Controlling prescription drugs is the responsibility of both the federal and state governments. Federal controls are focused at the manufacturing and wholesale levels, while the states have the primary responsibility for controlling the retail level. This includes licensing, regulatory, and law enforcement responsibilities.

Medicaid and Controlled Substances

Medicaid is a federal/state program, authorized by title XIX of the Social Security Act, under which the federal government assists the states in paying for health services needed by low-income individuals. States design and operate their Medicaid programs within broad federal requirements, and the federal government pays from 50 to about 80 percent of state costs for health services. Under Medicaid, states must cover persons who receive cash assistance from the Aid to Families with Dependent Children or Supplemental Security Income programs and may cover other people whose incomes are insufficient to pay for needed health services. In fiscal year 1986, the Medicaid program assisted 22.5 million recipients, spending $41 billion.

States must cover a number of health services, including hospital and physician services, and may cover any other health or rehabilitation services recognized under state law. Every state except Alaska and Wyoming has elected to cover prescription drugs under Medicaid. The states have established various restrictions on the coverage of prescription drugs ranging from limits on the number of prescriptions that can be filled in a certain time period to the exclusion of particular drugs from coverage. Many states have specifically restricted the availability of controlled substances under their Medicaid prescription drug programs through such means as not covering particular controlled substances and requiring prior authorization by the state as a condition for payment for controlled substances.

The Medicaid statute requires states to have an automated Medicaid Management Information System (MMIS).[1] MMISs are required to have a Surveillance and Utilization Review Subsystem (SURS) capable of analyzing paid claims data to identify aberrant providers and recipients. Normally, prescription drug claims data include information for the type of drug dispensed, the quantity dispensed, the dispensing pharmacy, the prescribing physician, and the recipient of the drug. SURS typically uses statistical techniques to identify for further review those providers and recipients whose patterns of service provision or use vary significantly from the norm. SURS should be capable of doing such analyses specifically for controlled substances. Review of aberrant providers and recipients can lead to educational or disciplinary action, or even criminal investigation.

[1]Small states can receive waivers from this requirement if their population and Medicaid expenditures are below certain amounts.

At the federal level, Medicaid is administered by the Health Care Financing Administration (HCFA) within the Department of Health and Human Services (HHS). HCFA approves state Medicaid plans that meet federal requirements and monitors state operations to assure they meet these requirements, including those related to MMIS.

How Physicians and Pharmacists Can Divert Drugs

The numerous ways—both legal and illegal—by which abused prescription drugs can be obtained make the control of diversion difficult and different from the control of illicit drugs. In addition, no reliable information exists on the extent of the various ways prescription drugs are obtained for abuse. It is apparent, however, that drugs obtained through legal channels are involved in a major portion of the abuse that occurs.

In a 1983 study[2] the HHS Office of Inspector General described the various ways physicians and pharmacists participating in Medicaid divert controlled substances. The Inspector General described nine types of physicians and three types of pharmacists involved in drug diversion. Physicians described ranged from the "drug dependent" physician who diverts drugs for his/her use to the "script" doctor who deliberately prescribes drugs to patients for profit. Other listed types of physicians included the "duped/negligent" physician who unwittingly responds to recipient pressure, the "intimidated" physician who prescribes unnecessary drugs in response to implied threats or fear of harm, and the "accommodating" physician who responds to the plight of the disadvantaged by overgenerous prescribing.

The Inspector General's report characterized pharmacists involved in drug diversion in several ways: the "dishonest" pharmacist who uses a multitude of schemes for quick profit, the "unquestioning" pharmacist who fails to question or report suspicious prescriptions, and the "fearful" pharmacist who dispenses drugs out of threat or fear of bodily harm.

Nationwide data are not maintained on controlled substance use under Medicaid, but the program spent over $2.7 billion on prescription drugs in fiscal year 1986. Three of the four states we visited had controlled substance expenditures representing about 10 percent of Medicaid's prescription drug expenditures. Similar information was not readily available for the fourth state, Louisiana. Because of Medicaid's size, the files

[2]Office of the Inspector General, HHS, Prescription Drug Abuse and Diversion in the Medicaid Program, Oct., 1983.

created on prescription drugs represent one of the largest data bases of its kind on the prescribing and dispensing patterns of physicians and pharmacists.

Objectives, Scope, and Methodology

Our primary objectives were to (1) obtain information on the types of activities states undertake to identify sources of drug diversion, (2) ascertain the kinds of data on controlled substances included in MMISs, and (3) inquire into whether MMIS data could be useful to regulatory and law enforcement agencies outside of Medicaid in detecting controlled substance diversion by providers. These objectives were agreed to by the office of the House Select Committee on Narcotics Abuse and Control to meet the thrust of the Chairman's July 1986 letter to us regarding drug diversion under Medicaid.

We performed our work in Louisiana, New York, Texas, and Wisconsin. These states were selected on the basis of a variety of factors, among them the state Medicaid program's reimbursement practices for controlled substances, state size and location, and whether the state had a Medicaid Fraud Control Unit (MFCU).[3]

We met with officials of the states' Medicaid agencies and examined the data available on controlled substances from MMIS, particularly SURS and the Management and Report Subsystem. We determined how and by whom these data were utilized both within and outside the Medicaid program. In New York and Texas, to evaluate the utility of MMIS data, we analyzed controlled substance data and produced utilization data on providers with high levels of prescribing and dispensing.

Our analyses of providers were not intended to determine whether they overprescribed or overdispensed controlled substances. Instead, the analyses were intended to serve as indicators of potential problems and were used for discussion purposes with regulatory and investigatory agencies. We discussed the usefulness of analyses like ours with regulatory and law enforcement officials inside and outside the Medicaid agencies in the four states we visited.

We also examined selected aspects of the Medicaid program in the four states we visited and the states' overall approach to identifying and

[3]The Medicaid statute authorizes federal sharing in the costs of MFCUs. These units must be outside the Medicaid agency, generally in the state's attorney general office; normally must have both investigatory and prosecuting authority; and must be dedicated to Medicaid fraud control efforts.

handling drug diversion both within and outside the program, including the utilization of data available from the states' MMISs. We concentrated our review on data about providers—physicians and pharmacists—who may be diverting drugs through the Medicaid program, and we only performed limited work with respect to Medicaid recipient use of controlled substances.

We examined records and met with officials of state agencies involved in (1) administering Medicaid; (2) licensing, monitoring, and disciplining physicians and pharmacists; (3) administering the state MFCU; and (4) monitoring and enforcing laws relating to controlled substances. We obtained data from and met with officials of HHS and DEA who are involved with monitoring the Medicaid program and controlled substances. We also obtained data from and met with officials of private agencies, such as the American Medical Association (AMA). We concentrated our efforts on activities primarily during calendar year 1986.

As requested by the Committee's office, we did not obtain official comments on this report. We did discuss its contents with responsible federal and state officials and incorporated their views where appropriate. Our work was performed in accordance with generally accepted government auditing standards during the period March 1987 through February 1988.

Techniques and Data System Applications for Detecting Drug Diversion

While the federal government has the authority to enforce criminal laws against practitioners who divert drugs or controlled substances at the retail level, states have undertaken the primary responsibility for preventing controlled substance diversion at that level and for detecting and prosecuting cases when preventive efforts fail. Organizational structures vary, but within each state a number of agencies are usually involved. They typically include a controlled substances agency, which registers all individuals and organizations that are legally entitled to handle controlled substances; law enforcement agencies, such as state and local police forces; and agencies that license and monitor the activities of health care professionals.[1] These agencies use a number of techniques to detect diversion, ranging from standard criminal investigations, such as following up on tips and undercover operations, to analyses of wholesale drug purchases identifying pharmacies dispensing high volumes of controlled substances.

The primary focus of data analysis by the state Medicaid agencies is control of program costs through identification of overutilization of services and fraud against or abuse of the program. This focus is an appropriate one for Medicaid administrators. Because the Medicaid data base is often one of the most extensive in a state on drug prescribing and dispensing practices, we obtained information on how states use this data for drug diversion identification purposes.

Criminal Enforcement Efforts in Combating Drug Diversion

A primary source of information about drug diversion used by law enforcement agencies is tips from public complaints and informers. For example, citizens might report unusually high activity by outsiders at a pharmacy or physician's office. Or an informer might provide a tip about a particular physician's office where prescriptions for controlled substances are available for the asking. This information could lead to a criminal investigation of the involved providers and eventual enforcement action for drug diversion.

Another information source that is sometimes used is the data in DEA's Automated Reports and Consolidated Orders System (ARCOS). ARCOS contains information on the flow of the more dangerous controlled substances from their point of manufacture to their sale at the wholesale or other distribution level. Sales to the consumer are not tracked. The resulting reports are regularly provided to DEA field personnel, other federal agencies, state and local compliance and enforcement agencies,

[1] Details on how the four states we reviewed are organized for drug diversion control are in app. I.

and other state agencies. Reports help to identify the most heavily used controlled substances, plot usage trends, identify potential problem areas, and target potential purchasers of excessive amounts of controlled substances. Some limitations of the ARCOS data include: no coverage beyond the wholesale level, inclusion of only the more dangerous drugs, and the length of time from the occurrence of an activity until its inclusion in a usable report.

Law enforcement agencies in the four states placed varied emphasis on drug diversion. Louisiana has a Diversion Investigative Unit, which its commander believes has deterred diversion primarily because of the publicity associated with the arrest of physicians and pharmacists. New York's emphasis is focused primarily in New York City. The chief of Narcotics Services, Texas Department of Public Safety, said the service's main focus is on illicit drug manufacturing as opposed to the diversion of legal drugs. Similarly, the chief of the Wisconsin Bureau of Narcotics and Vice said the bureau is more involved in enforcement related to illicit drugs rather than to diversion.

Licensing Efforts in Combating Drug Diversion

State licensing agencies have a role in combating drug diversion. Physicians and pharmacists are licensed by the state in which they practice. If providers personally abuse drugs or become involved in drug diversion, they are subject to sanctioning by the state licensing agency.

In cases of personal drug abuse that come to the attention of licensing agencies, an attempt is first made to get the involved provider to rehabilitate himself or herself. During the rehabilitation period, a restriction may be placed on the provider's license to prevent prescribing of drugs for himself or herself or the provider's license may be suspended. If rehabilitation efforts fail, the provider's license to practice may be revoked.

Sometimes providers unintentionally get involved in drug diversion. For example, through laxity a physician might prescribe excessive quantities of controlled substances or a pharmacist might not review the situation when persons present excessive numbers of prescriptions for controlled substances. If such cases come to the attention of licensing agencies, they normally try to educate the provider and get him/her to agree to a remedial course of action.

Complaints from the public and other providers to licensing agencies are a primary source of leads about problem providers, including their possible drug diversion. Information from law enforcement agencies is another important source. In addition, in some states a licensing agency is under the same umbrella agency as the controlled substance agency. Regulatory efforts used in carrying out the controlled substance agency function are discussed below.

Regulatory Efforts in Combating Drug Diversion

As an additional means in combating drug diversion, regulatory functions have also been assigned to state agencies. These functions are often vested in the licensing or law enforcement agencies discussed above. We will refer to these state agencies as the state controlled substance agencies. About half the states have made the controlled substance agency either the board of pharmacy or the state health department. The controlled substances acts in the four states we visited are administered by the Department of Health (New York), the Controlled Substances Board (Wisconsin), the Department of Public Safety (Texas), and the Department of Health and Human Resources (Louisiana).

Health care providers that prescribe and dispense controlled substances must register with DEA and, in many states, obtain a permit from the state controlled substances agency. If the controlled substance agency learns of a provider diverting controlled substances either through its own investigations or information provided from law enforcement and licensing agencies, the provider's state permit can be revoked and the information passed to DEA so that the provider's federal registration can be revoked.

States have adopted a number of regulatory approaches to combat controlled substance diversion by health care providers. Some of these approaches are discussed below.

Multiple-Copy Prescription Forms

Multiple-copy prescription form programs require the use of state-supplied official prescription forms for prescribing the most highly abused controlled substances. A copy of the form is filed with the state and provides a documented history of the prescribing and dispensing of these drugs. These data support the enforcement of the state's controlled substances act, can be helpful in conducting peer review of professional practices, and provide information for research.

Seven states, including New York and Texas, have a multiple-copy prescription program. These states include about one-third of all DEA registered practitioners. DEA reports that some states operating these programs had a 50 percent or more reduction in the amount of schedule II drugs prescribed and dispensed in the first 2 years of the programs.

An argument against multiple-copy prescription form programs is that they shift the diversion problem to the lower schedules of drugs. DEA reports that such a shift occurs, but the increase in lower schedule drugs is not as large as the reduction in schedule II drugs. Other arguments opponents have made against the programs include: (1) a loss of confidentiality in the practitioner-patient relationship because others will see what is being prescribed; (2) interference with medical practice because the practitioner may prescribe a less effective drug to avoid filling out the form; and (3) paperwork requirements that make the program less effective from a cost/benefit standpoint.

According to a New York State Department of Health official, the state's multiple-copy prescription form program is working well. In addition to being helpful in controlling drug diversion, data are used to identify physicians who have failed to keep up-to-date with good prescribing practices. When analyses show problems exist, local medical societies are asked by the state to provide the necessary education.

In Texas, the Department of Public Safety operates the multiple-copy prescription program. Statistics provided to us showed that the number of schedule II prescriptions written have dropped 64 percent since the inception of the program in 1981. Information obtained from the program has been used by the department and licensing agencies to initiate and conduct investigations.

Prescription Abuse Data Synthesis

Prescription Abuse Data Synthesis (PADS) is a model developed and financed by the American Medical Association. The model uses existing information to evaluate the extent of drug diversion within a state, the drugs involved, the sources of these drugs, and the consequences of such diversion. AMA offers PADS to states on a voluntary basis. An AMA technical consultant helps the states implement the model. The costs of implementing any changes in state practices or procedures resulting from PADS are financed by the state. Although it had not been used by the four

states we reviewed,[2] PADS has been used by 25 states and the District of Columbia.

According to an AMA consultant, one of the biggest successes of the PADS approach is getting the various agencies involved in preventing drug diversion to work together. A central tenet of PADS is that no single state agency has sufficient statutory authority and resources to deal with drug diversion problems by itself. Therefore, forming an interdisciplinary group of representatives of government agencies and professional associations is the first step in implementing PADS.

Another critical element in implementing PADS is the integration of all available information in order to identify the drug diversion problem as completely and accurately as possible. Combining information sources increases the probability that diversion will be detected. PADS mostly relies on ARCOS data and to a lesser extent on the Drug Abuse Warning Network (DAWN),[3] MMIS, multiple-copy prescription form programs, manufacturer/distributor sales records, special studies, reports on thefts of controlled substances, drug arrests, and death certificates giving drug overdose as the reason for death. MMIS data, since they focus on retail-level activity, are helpful in determining who is doing the prescribing and what drugs are being prescribed.

The AMA project director who oversees the PADS work stated that using PADS can result in a 10-percent reduction in a state's Medicaid drug costs. We did not verify this estimate. Recommendations resulting from PADS application involve changes, such as improvements in provider education and rehabilitation programs, and a continuing program to utilize existing data to detect drug diversion. According to PADS proponents, another beneficial result of PADS is a thorough understanding of the state's prescription drug abuse problem, which is more often than not a commonly perceived but undefined problem.

According to an AMA consultant, although the data used to implement PADS existed in the states where PADS had been used, none of those states had previously produced reports like those available through PADS. The PADS approach helped the states rearrange existing data in a more useful

[2]Wisconsin officials did, however, assist in the design and development of the model.

[3]DAWN is a data collection system sponsored by the National Institute on Drug Abuse. It captures data on drug incidents and deaths from emergency room and medical examiners' offices in selected metropolitan areas throughout the country representing approximately one-third of the U.S. population.

form to look at prescribers, dispensers, and dosage units of drugs throughout the state. In one state, the PADS data analysis even showed that a physician was diverting drugs by writing prescriptions while incarcerated in another state.

Use of ARCOS Data

Wisconsin was an early user of ARCOS data. The Wisconsin Controlled Substances Board, established by the state legislature, began using ARCOS data in the late 1970's to study statewide amphetamine use. The ARCOS data documented the locations where schedule II amphetamines were being dispensed. MMIS data were also used to identify practitioners receiving the largest Medicaid reimbursements for drugs. The data enabled the board to identify the small group of practitioners and pharmacies accounting for most of the statewide prescribing and dispensing of certain amphetamines. The data also showed that amphetamine use was particularly high in the Milwaukee area at the time. The board shared its ARCOS analyses with the state pharmacy and medical examining boards, which then initiated investigations of certain practitioners.

Wisconsin put several new policies into effect as a result of this effort. For example, the state prohibited Medicaid reimbursement for amphetamines unless prior authorization was granted. The Controlled Substances Board reviews the ARCOS data annually to detect trends in statewide drug use and decides which cases to refer to the various licensing boards. These referrals may result in a variety of actions ranging from a letter notifying the provider that his claims are being reviewed to disciplinary action. The board made over 80 referrals in 1986. We did not follow up on the final disposition of these referrals.

Techniques for Identifying Drug Diversion in the Medicaid Program

States use a number of techniques to maintain the integrity of Medicaid and assure that funds are spent only for allowable items and services. Most techniques are used as postpayment monitoring mechanisms or prepayment control devices. Generally, these techniques do not focus specifically on prescriptions for drugs but apply to all services. The techniques described below were cited by Medicaid officials as ways of dealing with drug diversion.

Drug Use Restrictions

Some states place restrictions on the types and quantities of drugs that can be obtained from the Medicaid program to reduce opportunities for abuse. Several states do not allow payment for amphetamine or

amphetamine-like drugs, particularly when used for the treatment of obesity. Other limitations may also be placed on prescribing practices, such as specifying the number of refills over a given period. For example, Texas limits a Medicaid recipient to three prescriptions per month and no more than five refills in a 6-month period after the date of the prescription. Officials believe that the state's restrictions help limit the opportunity for diversion and abuse. Prior authorization is another technique that helps restrict the availability of drugs under the Medicaid program. When this technique is used, the Medicaid agency will not pay for specific services or items unless they were previously authorized. Wisconsin, for example, requires prior authorization for all schedule III and IV stimulant drugs.

Regional Pharmacists

Texas assigns regional pharmacists to its Medicaid agency for the purpose of insuring program integrity among pharmacies participating in Medicaid. Each of the state's 15 geographic regions has a regional pharmacist. Among the various reports that pharmacists receive and consider in their work is a monthly report that lists, for each pharmacy, total dollars paid for drug claims and the portion that represents controlled substances. Regional pharmacists routinely visit each pharmacy twice a year. If a problem is suspected, the regional pharmacist can request a special audit or fraud investigation.

Pharmacy Audits

In Texas, the Medicaid agency has an Inspector General Office that audits about 25 percent of Medicaid pharmacies each year. Audit steps relating to schedule II drugs include verifying prescriber signatures and testing for unauthorized refills.

Medicaid Management Information System

As discussed in chapter 1, MMIS must have a subsystem known as SURS, which was developed, in part, to identify providers and recipients most likely to be abusing the Medicaid program. MMIS contains a detailed computer history of paid claims, including such data items as provider and recipient identification numbers, dates and types of services, diagnoses, and amounts paid. SURS manipulates this information so that provider and recipient utilization patterns can be measured and compared to identify unusual patterns.

The following process is used to identify potential abusers: (1) utilization profiles for each provider/recipient are established using detailed claim data; (2) similar providers/recipients are grouped and average

utilization for selected services is computed for each group; (3) standard deviation or manually selected values are used as parameters to identify individual providers or recipients whose utilization patterns for selected services differ substantially from the average; (4) aberrant providers and recipients are considered potential abusers.

SURS staff then analyze detailed claims data on providers and recipients identified as potential abusers. Additional data may be obtained through various means. When it is determined that abuse has occurred, remedial actions are taken, ranging from education to terminating a provider from the Medicaid program or restricting a recipient's choice of provider (known as lock-in).

Louisiana, Texas, New York, and Wisconsin perform SURS exception reviews for providers on a regular basis. All four states have the capability to conduct provider utilization reviews focusing on controlled substances but none was routinely doing so. The types of analyses performed that at least consider controlled substance abuse are illustrated by the following New York example.

SURS Utilization Reviews in New York

Quarterly provider and recipient utilization reviews in New York are performed by the Program Analysis and Utilization Review unit of the Department of Social Services. All 2.3 million recipients and the approximately 50,000 providers (including nearly 22,000 physicians and 4,000 pharmacies) are reviewed on a quarterly basis.

SURS data items reviewed for pharmacies can number up to 250. Of the prescription drug data items in the 1986 utilization reviews of pharmacies,[4] 19 were controlled substance related and dealt mostly with the number of claims for all or specific controlled substances as well as amounts paid for some of these items. One of the controlled substances data items is used in the initial screening reviews of pharmacies to identify pharmacies with high utilization patterns within the peer groupings. These pharmacies are subject to further, more detailed review until, if deemed necessary, a review is made of the claims submitted. Pharmacies can be dropped from the review process if it can be determined that the high utilization pattern had some medical rationale or was not indicative of abusive practice.

[4]New York and Wisconsin did not perform analyses of physician prescribing patterns because many pharmacy claims did not include a prescribing physician identifier. Both states are taking steps to assure that all pharmacy claims have a valid and correct identifier for the prescribing physician.

Pharmacies identified as exhibiting potentially abusive practices are referred by the review unit to the Office of Audit and Quality Control where detailed investigations are conducted. The office has the authority to disqualify or suspend a provider enrolled in the Medicaid program if the investigation indicates that the provider engaged in specified "unacceptable practices." In calendar year 1986, the office disqualified 225 providers from Medicaid, including 44 doctors and 80 pharmacists. Other SURS referrals may be sent to the MFCU or the Department of Health. Actions taken by these latter groups can include criminal prosecutions or license revocation/suspension. Available records were insufficient for us to determine if actions taken outside the Medicaid program were initiated due to SURS referrals.

Provider Reenrollment

A New York State Medicaid regulation, effective October 1986, required all Medicaid providers to reenroll in the program. The state's Medicaid agency investigated reenrollees and new applicants to verify application information and review their backgrounds. These investigations supplemented previous provider enrollment requirements, which consisted of possession of a valid license or operating certificate and current registration with the professional licensing agency. The reenrollment process is an attempt to impose tighter screening of providers participating in the program, according to state officials. Approximately 63,000 providers are expected to be reenrolled by December 1988.

Conclusions

States' approaches to detecting drug diversion take many forms and involve law enforcement agencies, health care licensers, regulatory agencies, and, to some extent, Medicaid agencies. These agencies use a number of techniques to determine if and where drug diversion is taking place. A critical element needed to make these techniques work is information on the extent of controlled substance activity in the state. Automated data bases, such as ARCOS and MMIS, can be useful in providing this information.

Although states make some use of MMIS data to identify drug diversion, the normal thrust of MMIS use is Medicaid program control. In the next chapter, we discuss possible expanded use of MMIS data to identify potential sources of drug diversion.

MMIS Could Be More Fully Utilized in Combating Drug Diversion

As requested by the Committee, we looked for ways Medicaid data could assist law enforcement, regulatory, and licensing agencies to identify drug diversion sources. We identified two ways MMIS data could be helpful. One involves detecting possible controlled substance diversion through more detailed analysis of MMIS data. The other involves more aggressive use of the data by sharing them with agencies outside the Medicaid program.

Laws related to Medicaid permit the disclosure of MMIS data to law enforcement agencies for use in criminal investigations and to state licensing and regulatory officials for use in disciplinary actions, provided certain confidentiality requirements are met. Overall, licensing and regulatory officials in the four states we visited said that the receipt of MMIS controlled substance data would be useful. Law enforcement officials were mixed in their reactions to receiving the data because their efforts are focused more on combating the flow of illicit drugs. Neither the licensing and regulatory officials nor the law enforcement officials were certain they would actually use MMIS data if they were routinely provided to them. Use would be dependent on the format (i.e., ease of use) of the data and the results obtained from using them. We agree with the state officials and believe testing of the concept is needed to determine the ultimate usefulness of routine sharing of Medicaid data.

More Detailed Analysis of Controlled Substance Data in MMISs

To examine the utility of controlled substances data items available in states' MMISs, we worked with Medicaid officials in Texas and New York to produce utilization data on pharmacies with high levels of drug dispensing. The same type of analyses could be performed for physicians.

In Texas we selected 20 pharmacies (2 from each of the state's 10 geographic regions) that had higher than average ratios of payments for controlled substances to total prescription payments during the period July 1 through November 20, 1987. With the assistance of a Texas Medicaid specialist, we selected 10 controlled substances—5 from schedule II, and 5 from schedules III and IV—to determine the extent of dispensing for these drugs. The selected drugs all had high abuse potential. We used MMIS to determine and list the total number of prescriptions filled for each selected drug and the recipient and prescriber identification numbers for each prescription. Texas Medicaid officials said that approaches like this could be a useful starting point for wider investigations.

In New York we selected for further analysis all pharmacies where 20 percent or more of their Medicaid claims involved controlled substances during 1986. Our analysis of the pharmacies focused on 20 data items—17 relating to controlled substances and 3 relating to overall Medicaid activity, such as total number of claims. The data elements for 11 of the pharmacies[1] were substantially above statewide averages. For example, one pharmacy dispensed controlled substances to 93 percent of its Medicaid customers. The statewide average was 27 percent. Seven of the 11 pharmacies had been disqualified from Medicaid during 1987, and at least one of these disqualifications was based, in part, on controlled substance activity. The remaining four were under investigation by the state at the time we completed our review.

State Medicaid officials with whom we discussed the results of our analysis said that such data would be useful when reviewing pharmacies. They pointed out that it is often easier to prove a violation and obtain action against a pharmacy for other things, such as filing a false claim, than for diverting drugs, and added that a pharmacy involved in drug diversion is likely to be committing other illegal acts. Nevertheless, they agreed data such as we developed on controlled substance activity appear to be a good indicator of problem providers. The officials also pointed out that their primary concern is developing data to identify all types of recipient and provider fraud and abuse. To fully develop a controlled substance diversion case, a detailed and comprehensive claims analysis and, possibly, undercover work are generally required. We believe the state Medicaid officials' views are appropriate because Medicaid agencies' primary responsibilities are to assure recipients obtain needed services and that program costs are controlled.

In addition, we recognize that a provider with a suspiciously high level of controlled substances activity is not necessarily abusing the program. However, our review demonstrates that if a controlled substance focus is desired, the data exist within the system to do such an analysis. Although Medicaid agencies would not normally focus on controlling drug diversion, data developed from MMIS could be useful as the basis for investigations by law enforcement, licensing, and regulatory agencies.

[1]These pharmacies all had six or more data elements that exceeded the statewide averages by at least two standard deviations.

Using MMIS Controlled Substance Data Outside the Medicaid Program

We discussed the usefulness of MMIS controlled substance data with law enforcement, licensing, and regulatory agencies in the four states we visited. Overall, officials' reactions to the usefulness of the data were positive, particularly among the regulatory and licensing agencies. We also observed during our work that New York and Wisconsin had some experience with using MMIS controlled substance data outside the Medicaid program. Wisconsin had used the data in conjunction with a coordinated interagency approach to drug diversion, and the New York State Health Department is currently receiving selected controlled substances data.

Officials of state agencies that license and regulate physicians said MMIS data would be useful. Before our discussions with them, officials of New York's Department of Health had made arrangements with the Medicaid agency to receive MMIS data on the prescribing and dispensing of controlled substances. These data are used to supplement the department's efforts to develop drug usage trends and identify physicians who may be diverting controlled substances. In one instance, a MMIS report summarizing usage of Valium and benzodiazapines was used as part of the justification for proposing that these drugs be included in the state's multiple-copy prescription program. In another instance, the department used MMIS data to identify physicians who were dispensing a high percentage of controlled substances for Medicaid recipients. These data were used by the department to suspend several physicians' licenses, and provided the Bureau of Controlled Substances with leads on the prescribing practices of other physicians.

The New York Departments of Social Services and of Health have regular meetings to define user needs and system capabilities regarding the controlled substance data available from MMIS. A Department of Health official noted that while the state's multiple-copy prescription form program is working well, the MMIS data are useful in identifying diversion of drugs not covered by the program.

An official of Wisconsin's Medical Examination Board told us that MMIS data were used more in the late 1970's. The data are not used as much now because officials perceive less prescription drug abuse.

Agencies involved with the licensing and regulation of pharmacies were also positive about the potential usefulness of MMIS data. Pharmacy board officials in Texas and Louisiana said they thought the data could be used to indicate potential diversion by pharmacies. In New York, an official from the Office of Professional Discipline told us the data would

be useful, but noted that considerably more investigative work would be required after a suspect pharmacy was identified through MMIS data. An official of Wisconsin's Pharmacy Examining Board said that the data could be useful, but he had found reports he had seen in the past too voluminous and difficult to understand.

Law enforcement agencies generally thought that MMIS data could be useful in identifying potential sources of drug diversion but were not as certain they would use the data as licensing and regulatory officials were. In Texas and Louisiana, narcotics control officials said that they would use the information to identify physicians prescribing high volumes of scheduled drugs. Louisiana's Diversion Investigative Unit would use the data to focus on schedule II controlled substances because at the time of our review the state did not have a multiple-prescription program to capture this information. An official of the Texas Department of Public Safety said that based on his discussion with us, he planned to initiate a discussion with the Medicaid agency about the types of reports available.

New York State Police officials said that the data may be useful, but they would have to examine it first. The chairman of the New York State Task Force on Narcotics and Medicaid Fraud in New York City was not sure such data would be used. He said he thought the data could probably be used more effectively by the Medicaid and regulatory agencies because a complex computer program is not necessary to identify the "pill mills" the task force is focusing on. Wisconsin Bureau of Narcotics and Vice officials said they were more involved in identifying sources of illegal controlled substances and that the data would more likely be used by regulatory agencies.

Providing controlled substances data analyses to outside agencies would involve some additional costs. After the necessary computer programs are prepared, these costs should be relatively small because the analyses would usually be run in conjunction with other SURS analyses, and the main cost would be whatever additional computer time was involved.

Conclusions

Opportunities exist for greater use of MMIS controlled substance data outside of the state Medicaid agencies to identify providers who divert controlled substances. These opportunities would involve analytical approaches focusing on controlled substances data already in MMIS. Because of the Medicaid program's size, the resultant data bases within

states' MMISs represent one of the largest sources on prescriptions and dispensing activity.

Regulatory and licensing agencies in all states expressed an interest in using MMIS controlled substance data for identifying where drug diversion may be taking place. Wisconsin has used the data in the past and the New York State Health Department is currently using the data to target abusive physicians. Law enforcement agencies were less certain about whether they would use MMIS data, but narcotics officers in Texas and Louisiana said the data could be used to identify physicians with a high volume of scheduled drugs.

The current MMIS utilization review process is designed to identify potential fraud and abuse throughout the spectrum of Medicaid provided services and items. However, the routine analysis of controlled substances activity among program providers could yield potential leads for interested agencies outside the Medicaid program. The laws related to Medicaid permit the disclosure of this data, and agencies outside of Medicaid said they would be interested in receiving it.

The ultimate usefulness of Medicaid data in assisting law enforcement, licensing, and regulatory agencies to identify sources of drug diversion, however, can only be determined by testing. Such testing should determine whether such efforts would be useful in combating drug diversion. However, because federal responsibilities for Medicaid and drug diversion are separately held by two departments and state responsibilities are placed in numerous different agencies, we believe that such testing is unlikely to occur without a federal agency taking the lead.

Recommendation to the Secretary of HHS

We recommend that the Secretary of HHS, in consultation with the Department of Justice in its role of assisting state and local law enforcement agencies, take the initiative and test the usefulness and cost of analyzing and providing MMIS controlled substances data to law enforcement, regulatory, and licensing agencies for identifying sources of drug diversion.

Selected Organizational Data on the Four States Reviewed

The licensing, regulation, and enforcement of prescription drug activity is shared among a number of agencies in the four states we reviewed. These organizational variations are briefly discussed below. As required, each state has a single agency for administering the Medicaid program. All four states have a certified MMIS and a certified MFCU.

Louisiana

Agencies having a role in licensing and regulating health care professionals are for the most part within the Department of Health and Human Resources and include:

- the Louisiana State Board of Medical Examiners,
- the Louisiana State Board of Pharmacy, and
- the Division of Licensing and Certification.

The State Board of Medical Examiners licenses, oversees, and disciplines physicians. The State Board of Pharmacy performs the same functions for pharmacists and pharmacies. The Division of Licensing and Certification is the state's registration agency for all persons, except pharmacies and pharmacists, who distribute, manufacture, or dispense controlled substances. Pharmacies and pharmacists are handled by the State Board of Pharmacy.

The Narcotics Section within the Department of Public Safety and Corrections has a Diversion Investigation Unit with four narcotics officers that work full time on drug diversion cases. The Narcotics Section chief said there is a good working relationship between the section, the Louisiana professional licensing boards, DEA, and the U.S. attorney in Louisiana.

The Department of Health and Human Resources also manages the Louisiana Medicaid program through the Office of Family Security. The office uses a fiscal agent to generate quarterly surveillance and utilization reviews of Medicaid data. The office also has a contract with a private firm to audit pharmacies that participate in Medicaid.

New York

Licenses for doctors and pharmacists are obtained through the Department of Education. A medical board and a pharmacy board assist the department's Board of Regents on matters of professional licensing, practice, and conduct. Investigations of and recommended disciplinary actions against pharmacies are handled by the department's Office of

Professional Discipline. Similar responsibilities for doctors and physicians assistants are handled by the Office of Professional Medical Conduct within the Department of Health. Final action on the disciplinary recommendations of both offices is taken by the Department of Education's Board of Regents.

The Bureau of Controlled Substances within the Department of Health administers the regulations of the Controlled Substances Act. The bureau develops and implements the regulatory and preventative programs involving controlled substances and abuse, including the triplicate prescription program. Licensure and drug receipt/destruction are among many of the functions performed by the bureau.

The Medicaid program is administered by the Department of Social Services. Several organizational components of this department set policy, operate, monitor, and complete reporting requirements for the program. Two organizational components of the department are noteworthy—the Office of Audit and Quality Control and the Bureau of Program Analysis and Utilization Review. The Office of Audit and Quality Control is an audit/investigative arm responsible for, among other things, detecting and controlling Medicaid fraud and abuse. The Bureau of Program Analysis and Utilization Review conducts surveillance and utilization reviews.

Texas

Licensure of physicians is performed by an independent executive agency called the Texas Board of Medical Examiners. The State Board of Pharmacy is also an independent state agency and is responsible for pharmacy and pharmacist registrations. The Board of Medical Examiners investigates complaints and disciplines violators of laws pertaining to the practice of medicine. Board actions range from warnings to revocations of physicians' licenses. The State Board of Pharmacy has similar responsibilities and takes similar actions.

The Texas Department of Public Safety is the controlled substance registration agency for the state and also operates the state's triplicate prescription program. The Narcotics Services within the department performs some drug diversion investigations; however, a drug diversion unit was dissolved in 1985 after DEA funds were discontinued.

The Medicaid program is administered by the Department of Human Services. Within the department, the vendor drug program develops statewide Medicaid policy and procedures for drugs. The program also

provides technical support to the department's Pharmacy Enrollment and Billing Division and supervises the regional pharmacists. Regional pharmacists help insure Medicaid program integrity by visiting each participating pharmacy in the state twice a year. The primary purpose of the visits is educational, but the regional pharmacists are also alert for problems as they review pharmacy records.

Utilization reports on the Texas Medicaid program are routinely provided for the use of regional pharmacists, and the department's Fraud and Abuse Division. The MFCU also uses MMIS data in prosecuting Medicaid providers.

Wisconsin

The Department of Regulation and Licensing is an umbrella agency providing administrative and regulatory services to a number of professional boards, including the Boards of Medicine and Pharmacy.

A Controlled Substances Board, located within the Department of Health and Social Services, administers the regulations of the Controlled Substances Act, has the authority and the responsibility for the proper placement of psychoactive drugs with abuse potential into the schedules of the act, grants special use authorizations to possess controlled substances, and coordinates an interagency drug diversion prevention and control program. The board was established in 1970, and was assigned its diversion coordination responsibilities in 1982. The board also serves as an advisor, and provides technical assistance on drug abuse and controlled substances matters to numerous agencies and individuals. The six-member board has representatives from the State Attorney General's Office and the Department of Health and Social Services, as well as the Chairman of the Pharmacy Examining Board; the Secretary of Agriculture, Trade, and Consumer Protection; a pharmacologist; and a psychiatrist.

The Department of Health and Human Services is the single state agency for administering the Medicaid program in Wisconsin. Within the department, the Bureau of Health Care Financing has a Surveillance and Utilization Review unit that investigates fraud and abuse by recipients and providers. The bureau also has a medical consultants section that provides assistance and consultation to bureau staff and providers on policy matters and claims-processing problems. This latter section is staffed by several professional medical personnel, including a pharmacy consultant. The department also has a contract with the University of Wisconsin to operate the Medical Evaluation Program. This program

provides services for Medicaid's program control (fraud and abuse), policy analysis, and policy evaluation functions. Part of the program's work includes monitoring provider utilization and developing profiles of aberrant medical practice.

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