Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MULTIPLE COPY PRESCRIPTION PROGRAMS: STATE EXPERIENCES

Richard P. Kusserow
INSPECTOR GENERAL

JUNE 1992

OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services' (HHS) programs as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by three OIG operating components: the Office of Audit Services, the Office of Investigations, and the Office of Evaluation and Inspections. The OIG also informs the Secretary of HHS of program, and management problems, and recommends courses to correct them.

OFFICE OF AUDIT SERVICES

The OIG's Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations in order to reduce waste, abuse, and mismanagement and to promote economy and efficiency throughout the Department.

OFFICE OF INVESTIGATIONS

The OIG's Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil money penalties. The OI also oversees State Medicaid fraud control units which investigate and prosecute fraud and patient abuse in the Medicaid program.

OFFICE OF EVALUATION AND INSPECTIONS

The OIG's Office of Evaluation and Inspections (OEI) conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the Department, the Congress, and the public. The findings and recommendations contained in these inspection reports generate rapid, accurate, and up-to-date information on the efficiency, vulnerability, and effectiveness of departmental programs.

This report was prepared by Vicki A. Greene, of the Health Care Branch, Office of Evaluation and Inspections, Baltimore, Maryland, with the assistance of Mary Beth Clarke, R.Ph., Public Health and Human Services Branch, Washington, DC.

To obtain a copy of this report, call the Health Care Branch at (410) 966-3148.

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MULTIPLE COPY PRESCRIPTION PROGRAMS: STATE EXPERIENCES

Richard P. Kusserow
INSPECTOR GENERAL

OEI-12-91-00490

EXECUTIVE SUMMARY

PURPOSE

This report provides an overview of the operation and effectiveness of State Multiple Copy Prescription Programs.

BACKGROUND

The diversion of prescription drugs from legitimate distribution channels for illicit use is a serious national drug abuse and law enforcement problem. Estimates from the Drug Abuse Warning Network (DAWN) for 1990 indicate that legal, controlled substances are involved in approximately 32 percent of all drug-related emergency room visits.

In 1970, the Controlled Substances Act (CSA) established a tight system of controls on Scheduled prescription drug distribution from the manufacturer to distributor to the pharmacy. The controls implemented by the CSA greatly diminished the opportunity for diversion of drugs from legitimate wholesale channels.

However, once drugs leave the wholesale distribution network, there are few controls or monitoring systems. The weakest link in the distribution chain is at the retail level. The National Institute on Drug Abuse estimates that 80 to 90 percent of licit (legal) drugs diverted for non-medical use occurs at the retail (practitioner and pharmacy) level.

Several initiatives have emerged to combat diversion and abuse of licit drugs at the retail level, including third-party drug data review systems such as the Medicaid Abusable Drug Audit System (MADAS) developed by the Office of Inspector General. Another initiative, which is the subject of this report, is State-based multiple copy prescription programs (MCPPs). MCPPs have three major elements: (1) multiple (usually three) copies of the prescription are produced which are maintained by the physician, pharmacist, and State agency, (2) prescription forms are numbered sequentially and tinted so that they are hard to reproduce, forge, or erase, and (3) a retrospective data analysis is conducted to identify suspicious prescribing, dispensing, or patterns of use. Nine States have MCPPs in place.

METHODOLOGY

The information in this report was collected through an extensive literature review; interviews with national experts and interest groups in pharmacology, medicine, pain control, criminology; and interviews with officials in the States with MCPPs.

FINDINGS

- MCPPs reduce vulnerability to theft and forgery.
- MCPPs' effect on overall prescribing of scheduled drugs is difficult to assess from existing studies.
- MCPPs appear to have shown some effect on abuse of scheduled drugs, as measured by emergency room visits.
- Program officials associate MCPPs with better targeting of investigator resources and more successful prosecutions of offenders involved in drug diversion.
- Opponents of MCPPs express concerns about the program's effect on medical decisionmaking as well as confidentiality. MCPP States have attempted to respond to practitioner and community concerns in several ways.

TABLE OF CONTENTS

INTRODUCTION

BACKGROUND

The diversion of prescription drugs from legitimate distribution channels for illicit use is a serious national drug abuse and law enforcement problem. Estimates from the Drug Abuse Warning Network (DAWN) for 1990 indicate that legal, controlled drugs are involved in approximately 32 percent of all drug-related emergency room visits.[1] According to the 1988 National Household Survey on Drug Abuse by the National Institute on Drug Abuse (NIDA), 12 percent of the United States population over age 12 report using legitimate psychotherapeutic drugs for non-medical purposes.[2]

In 1970, the Controlled Substances Act (CSA) established a tight system of controls on Scheduled prescription drug distribution from the manufacturer to distributor to the pharmacy.[3] The Act also divides controlled substances into five Schedules and requires distributors and dispensers of drugs in these Schedules to register with the Drug Enforcement Administration.[4] The five Schedules are arranged so that the lower the Schedule number, the higher the abuse potential. Schedule I substances have a high potential for abuse and have no accepted medical use in the United States. Examples are heroin, LSD, and marihuana. Schedules II through V have currently accepted medical uses in the United States.

Schedule II is the most restrictive of these four schedules. Schedule II drugs are subject to production and import quotas; other Schedules are not. All Schedule II drug transactions between suppliers and distributors must be reported routinely to the government; only the narcotic drugs in other schedules must be reported. Special physical security measures such as vault storage and special order forms using a unique Drug Enforcement Administration (DEA) registration number are required for Schedule II drugs while less-intensive measures apply to the drugs in other schedules. Prescriptions for Schedule II drugs may not be refilled. Prescriptions for drugs in the other schedules may be refilled up to five times within a certain time period. Finally, the maximum criminal penalties for unauthorized trafficking in Schedule II narcotics are greater than those for trafficking in other scheduled drugs.[5]

The controls implemented by the CSA have greatly diminished the opportunity for diversion of drugs from legitimate wholesale channels. However, once drugs leave the wholesale distribution network, there are few controls or monitoring systems. The weakest link in the distribution chain is at the retail level. The National Institute on Drug Abuse estimates that 80 to 90 percent of licit (legal) drugs diverted for non-medical use occurs at the retail (practitioner and pharmacy) level.[6] [7] Drug diversion cases consume a considerable amount of pharmacy boards' investigative resources.

Controlled prescription drugs are diverted from the retail (practitioner or pharmacy) level to illicit use by four main types of schemes or activities:

- theft, alteration, forgery, and counterfeiting of prescription forms;
- indiscriminate or careless prescribing and dispensing;
- purposeful misprescribing and dispensing by health care workers, frequently in collusion with a purported "patient"; and
- theft of drugs from a hospital, pharmacy, or physician's office.

Several initiatives have emerged to combat diversion and abuse of licit drugs at the retail level, including third-party drug data review systems such as the Medicaid Abusable Drug Audit System (MADAS) developed by the Office of Inspector General.[8] Another initiative is State-based multiple copy prescription programs (MCPPs). The OIG has previously recommended that States consider MCPP-type programs as a measure to combat drug diversion.[9] This report provides additional information on MCPPs, particularly their impact on the first three sources of drug diversion.

Nine States have some form of MCPP (see Figure 1): California, Hawaii, Idaho, Illinois, Indiana, Michigan, New York, Rhode Island, and Texas.[10] These nine States contain approximately 38 percent (307,148) of all practitioners registered with the Drug Enforcement Administration (DEA). Most European countries and four Canadian provinces have MCPPs in place.

MCPPs have three major elements: (1) multiple copies of the prescription are produced to provide checks and balances, (2) prescription forms which are prenumbered sequentially and tinted so that they are hard to reproduce, forge, or erase, and (3) a retrospective data analysis component to identify suspicious prescribing, dispensing, or patterns of use.

The forms have a minimum of two parts: one is retained by the pharmacist and the other is sent to the State by the pharmacist. In States with triplicate forms, the third part of the form is retained by the prescriber. MCPPs generally require that such records be maintained by physicians and pharmacists for at least two years.

MCPPs generally require that prescribers write prescriptions on these special forms for Schedule II substances. Schedule II drugs have a high potential for abuse and have highly addictive properties. Examples of Schedule II drugs are opium and codeine (narcotic analgesics), pentobarbital (a depressant), and methamphetamine (a stimulant).

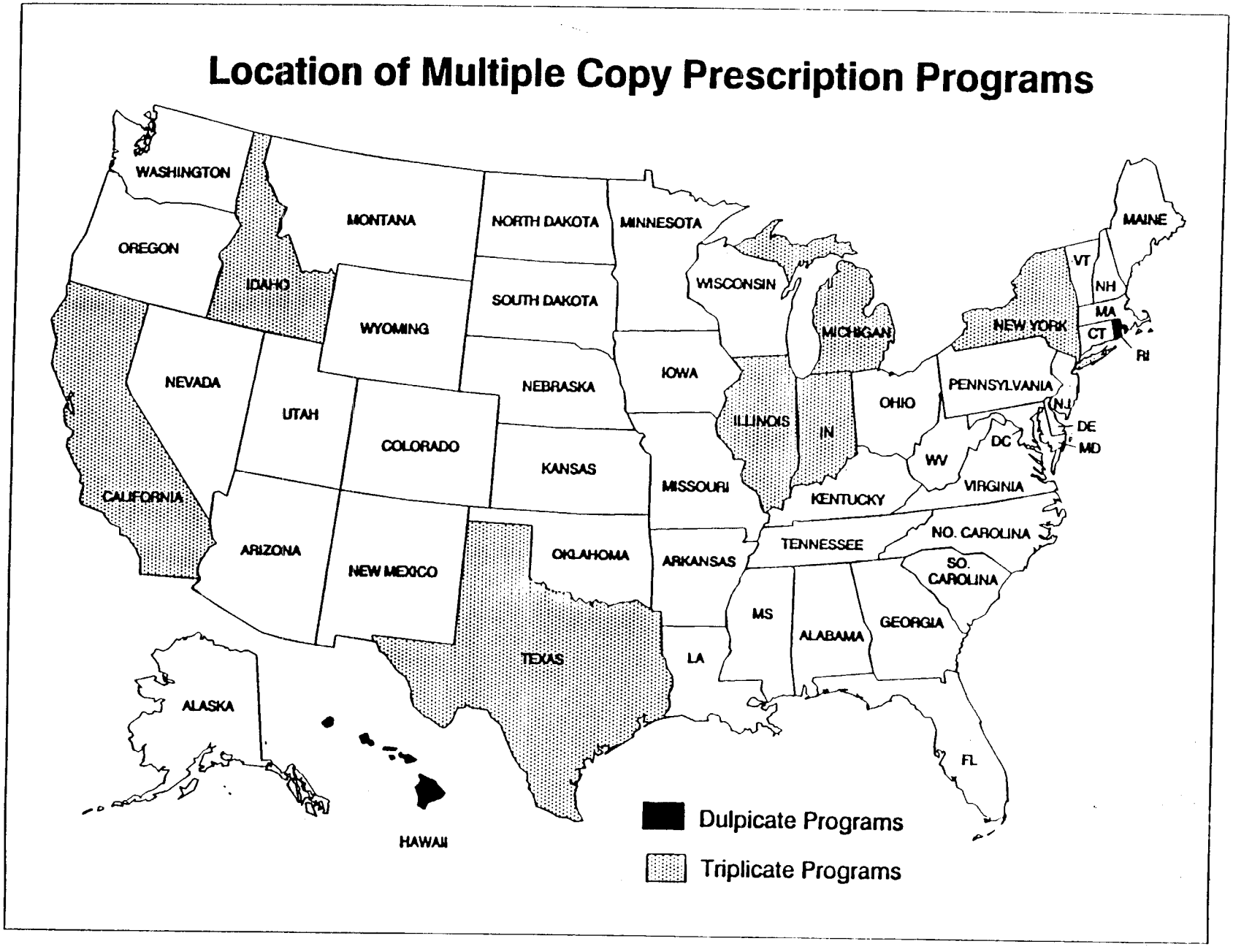
Location of Multiple Copy Prescription Programs
WASHINGTON
OREGON
CALIFORNIA
IDAHO
NEVADA
MONTANA
WYOMING
UTAH
ARIZONA
COLORADO
NEW MEXICO
NORTH DAKOTA
SOUTH DAKOTA
NEBRASKA
KANSAS
OKLAHOMA
TEXAS
MINNESOTA
IOWA
MISSOURI
ARKANSAS
LA
WISCONSIN
ILLINOIS
MICHIGAN
IN
OHIO
KENTUCKY
TENNESSEE
MS
ALABAMA
GEORGIA
FL
SO. CAROLINA
NO. CAROLINA
VIRGINIA
WV
PENNSYLVANIA
NEW YORK
VT
NH
MAINE
MA
CT
RI
NJ
DE
MD
DC
ALASKA
HAWAII
Dulpicate Programs
Triplicate Programs

Figure 1

MCPPs should be distinguished from electronic transmission programs such as the Oklahoma Schedule Two Abuse Reduction (OSTAR) program. OSTAR has been in effect since January 1991; it requires every pharmacy and dispensing physician to submit data electronically on all Schedule II substances dispensed. As with MCPPs, the State tracks the prescribing patterns using exception reports. Massachusetts will be initiating a similar electronic system in April, 1992. These electronic transmission programs do not require use of any special forms or multiple copies for prescribing.

A more detailed description of MCPPs and how they operate, and a summary chart with basic program characteristics is contained in appendix A.

METHODOLOGY

The information in this report was collected through interviews with national experts and interest groups in pharmacology, medicine, pain control, and criminology; interviews with officials in States and Canadian provinces with MCPPs, and an extensive literature review including the National Multiple Copy Prescription Survey conducted by the Michigan Triplicate Prescription Program.

FINDINGS

MCPPs REDUCE VULNERABILITY TO THEFT AND FORGERY.

Drug traffickers or "doctor shoppers"[11] obtain and cash fraudulent prescriptions using a variety of techniques: forgery and alteration of legitimate prescriptions, writing prescriptions on standard plain white prescription pads that have been stolen, or having fraudulent prescription pads printed at printing establishments.

The standard white single copy prescription form is relatively easy to print and/or reproduce. Undercover agents have successfully ordered forms printed at print shops with no identification, dressed in either casual or business attire.[12] Drug enforcement agents report that drug traffickers sell altered or clandestinely produced standard prescription forms to addicts for about $20.00 each.

A distinctive element of multiple copy prescription programs is the use of special State-issued forms for writing prescriptions for drugs covered under the MCPP. Of the States with MCPPs, only Hawaii does not have a State-issued form.[13] All of the forms have special features that make them difficult to clandestinely produce or photocopy. Features that make the form extremely resistant to various types of fraud include a color tint, design on the face of the form, water marks, invisible eradicator sensitive ink, and hidden pantograph that shows "VOID" if the form is copied. These characteristics are designed to have a sentinel effect to deter unscrupulous health care providers or patients from illicit activity.

In addition, the States preprint the prescriber's name and address on the form, and some preprint the prescriber's DEA number and/or controlled substances license number and other prescriber information. All States require the patient name and address to be entered on the form, and most require the patient age or date of birth.

A Rhode Island survey found that 77 percent of practitioners in Rhode Island agree that the MCPP makes forgery of prescriptions for Schedule II drugs more difficult. A Michigan survey of 2,000 prescribers found that 74 percent of respondents agreed that the MCPP could deter abuse and diversion of scheduled drugs.[14]

MCPPs' EFFECT ON OVERALL PRESCRIBING OF SCHEDULED DRUGS IS DIFFICULT TO ASSESS FROM EXISTING STUDIES.

Overall prescribing of prescription drugs generally declines following MCPP implementation.

In several States, there is a precipitous decline in the amount of Schedule II drugs prescribed after implementation of the MCPP. Texas experienced a 52 percent decrease in the number of prescriptions for Schedule II controlled substances during 1982, the first year of the program. In 1983, Schedule IIs declined another 13

percent.[15] After New York expanded its MCPP to include benzodiazepines (Federal Schedule IV tranquilizers), the number of benzodiazepine prescriptions fell approximately 65 percent from 1988 to 1989.[16]

In Rhode Island, the total number of Schedule II prescriptions written declined by 36.3 percent during the first year of the program.[17] To examine this phenomenon, the University of Rhode Island surveyed prescribers to assess their perspectives on changes in prescribing since institution of the MCPP. Interestingly, only 20 percent of the group in practice in the State before 1979 perceived that their prescribing practices had changed. Of these, 44 percent agreed that the availability of better therapeutic alternatives accounted for their decrease in prescribing. Forty four percent indicated that there was a better risk-benefit ratio for the patient by using Schedules III, IV, or V rather than II. Fourteen percent of the survey respondents said that they were aware of a colleague who had his or her license limited, suspended, revoked, or was placed in drug rehabilitation. Of this 14 percent, 23 percent (22 prescribers) felt that this awareness caused them to limit the number of Schedule II prescriptions that they write.[18]

In other States, prescribing for certain drugs has actually increased. For example, in Illinois, there have been increases in Schedule II prescriptions, especially in pain management therapy: morphine sulfate (a narcotic analgesic) prescriptions increased by 109 percent between FY 1985 and FY 1989, and oxycodone with acetaminophen prescriptions increased 58 percent.[19]

Since gross figures on increases or decreases in prescribing after implementation of MCPPs are unadjusted for patient and prescriber populations, or for other variables, it is difficult to interpret these numbers. Further evaluation of changes in prescribing of scheduled substances after MCPP is necessary to accurately assess the program's effect on prescribing patterns. Experimental designs with control and comparison groups could be used in non-MCPP States to provide such data. Interpretation of pre- and post-data in MCPP States, especially in light of divergent outcomes in the States, should be approached cautiously.

Two States show little or no substitution effect.

Two States, Michigan and New York, have attempted to assess if their MCPP has resulted in other drugs being prescribed in place of drugs which had to be prescribed on State issued triplicate forms.

According to analysis conducted by Blue Cross/Blue Shield of Michigan, a decline in Schedule II prescriptions was not accompanied by an increase in other scheduled drug prescriptions. Michigan BC analyzed prescribing of Schedules II through V week by week from August 1988 through December, 1989 and found decreases in the average weekly volume of prescriptions for each of Schedules III, IV, and V, along with the declines in Schedule II prescribing. This analysis suggests that the decline in Schedule

II prescribing following MCPP implementation in 1989 was not replaced by increased prescribing or "substitute prescribing" in other scheduled substances.

New York has performed a similar analysis for the Empire Plan and for Medicaid and found approximately a 21 percent "substitution effect" of "benzodiazepine substitute" drugs not on triplicate. Benzodiazepines were added to the New York MCPP in 1989.[20]

It is not clear what conclusions should be drawn about the existence or lack of a substitution effect. Specific medical reviews need to be conducted to determine if replacing a prescription requiring a MCPP form with one that does not is "good" or "bad" for the particular patients involved.

MCPPS APPEAR TO HAVE SHOWN A DECREASE IN ABUSE OF SCHEDULED DRUGS, AS MEASURED BY EMERGENCY ROOM VISITS.

The National Institute on Drug Abuse collects annual data to indicate the extent of drug abuse problems in the United States through the Drug Abuse Warning Network (DAWN). The DAWN is a drug abuse data collection system that targets 770 hospital emergency rooms in 21 metropolitan areas, and 87 medical examiners in 27 metropolitan areas. The data in DAWN are collected from reports submitted for each drug abuse patient who visits a DAWN emergency room (ER) and each drug abuse death encountered by an DAWN medical examiner (ME).[21]

DAWN data is used by analysts to study trends in drug abuse. In several cases, introduction of a MCPP has coincided with a decline in DAWN mentions. For example, emergency room mentions in Chicago for pentazocine (a narcotic analgesic) decreased from 477 in 1978 (when Illinois moved the drug up to Schedule II, thus requiring a MCPP form) to 38 in 1987 (a 92 percent drop). Total pentazocine DAWN mentions dropped 61 percent during the same time period.

In 1982, Illinois experienced diversion and abuse of glutethimide (a Federal Schedule IV sedative/hypnotic). The drug was reclassified under Schedule II of the Illinois Controlled Substances Act, thus requiring use of the multiple copy form. Chicago DAWN ER drug mentions for glutethimide decreased from 34 in 1982 to 6 in 1987, and ME drug mentions decreased from 16 to 0 during the same time period. Meanwhile, ER glutethimide mentions for the total DAWN network increased from 353 in 1982 to 592 in 1987.

In New York short acting barbiturates (sedative drugs) were placed under MCPP requirements in 1981 following Federal rescheduling to Schedule II. Just before that time approximately 33 percent of total ER mentions for these drugs were in New York (both Buffalo and New York City participate in DAWN). The New York DAWN emergency room mentions for barbiturates declined by 94 percent between 1980 and 1987, at which time the State accounted for only 10 percent of total U.S. DAWN ER mentions.

The extent to which rescheduling of these substances accounted for declines in "mentions" of the drugs in emergency rooms is not known. Since Schedule II substances require tighter controls and carry harsher penalties for diversion, it is possible that ER mentions would have declined if the drugs had only been rescheduled and not placed on a MCPP.

However, in New York State, Schedule IV benzodiazepines (tranquilizers) were included under the MCPP in 1989 without rescheduling. In the first year benzodiazepines were on MCPP, ER mentions declined 46 percent in New York while declining 12 percent nationally.

PROGRAM OFFICIALS CITE A NUMBER OF ADVANTAGES ASSOCIATED WITH MCPPS, INCLUDING BETTER TARGETING OF INVESTIGATOR RESOURCES AND MORE SUCCESSFUL PROSECUTIONS OF OFFENDERS INVOLVED IN DRUG DIVERSION.

Better Targeting of Investigator Resources

In States without MCPPs, agents typically conduct audits of practitioners or pharmacies to track down forgeries, doctor shoppers, or other diversionary drug schemes. In an audit, inspectors usually select a random number of prescriptions to examine for forgeries. Absent any prescriber, pharmacist, or patient-based data, reviewers do not have an obvious starting point for research or inquiry. Reports that are produced through the MCPP significantly narrow down the range of possible drug diversion or abuse activity, and agents can more efficiently target cases or locations for review and investigation. Cases are targeted efficiently by identifying the top dispensers of controlled drugs, prescription writers, and abnormally high users.

Some situations in Texas illustrate this increased efficiency. In 1989, the Texas State Board of Medical Examiners had 14 investigators (including management) and approximately 26,000 licensees that were registered to handle controlled substances. working and average of 20 days per month and allowing 2 days per investigation, it would take 15 years to investigate all registered practitioners. Other licensees not registered would require additional time.

In 1980, the Texas State board of pharmacy had six investigators and two compliance officers to inspect and investigate 11,717 pharmacies and 4,078 pharmacies spread over 270,000 square miles.[22]

During the three-year period prior to implementation of the MCPP in Texas, 20 to 25 investigators conducted 127 investigations and successfully prosecuted one medical practitioner for diversion. Following implementation in 1982, 15 to 20 investigators conducted 289 investigations from January 1982 through June 1984. This is a 173 percent increase in investigations using 25 percent fewer investigators than was conducted over the prior three-year period.[23]

Los Angeles agents use triplicate program information in about 80 percent of their cases. The data provide concrete leads to sources of drug diversion by highlighting irregularities in patient filling, pharmacy dispensing, or physician prescribing. Agents in Los Angeles report that without the program, they would be operating in a "hit or miss" mode.

More Successful Prosecutions and Regulatory Sanctions

Program officials in MCPP States report that program data allows them to make better cases. According to Texas MCPP officials, information developed by the program leads to convictions as well as many out of court settlements due to the strong evidence presented by the data. Over the three year period following MCPP implementation, eighteen practitioners were indicted and/or convicted of diversion of controlled drugs. Seventeen prescribers surrendered prescribing privileges for Schedule II substances. Additionally, when Texas implemented its program, about 600 prescribers who had let controlled substance registrations lapse were immediately identified.[24]

In a specific Los Angeles 1989 case where program data were crucial, special agents were unable to make a direct buy from a suspected prescriber. However, data from the MCPP was responsible for the successful arrest of a doctor (and seizure of his assets) who had diverted Dilaudid (a narcotic analgesic) for an estimated profit of $1.4 million.

In 1989, the Illinois MCPP provided nearly 2,000 investigative profile reports leading to regulatory sanctions on the professional and controlled substances licenses of practitioners, pharmacists, and others that have violated the State Controlled Substances Act. Since 1985, the program has been involved in licensure sanctions of 71 medical practitioners, 28 pharmacists, and 23 pharmacies. Currently, the U.S. District Attorney's office is reviewing triplicate prescription information on 12 suspected doctor shoppers.

In New York, in 1989, 135 civil and criminal diversion cases were successfully prosecuted involving physicians, dentists, veterinarians, pharmacists, pharmacies, nurses, and others. Information from the MCPP was used in 85 of these cases.

OPPONENTS OF MCPPS EXPRESS CONCERNS ABOUT THE PROGRAM'S EFFECT ON MEDICAL DECISIONMAKING AS WELL AS CONFIDENTIALITY. MCPP STATES HAVE ATTEMPTED TO RESPOND TO PRACTITIONER AND COMMUNITY CONCERNS IN SEVERAL WAYS.

When initially implementing the programs, some States have encountered concerns and/or opposition among associations or groups such as pharmaceutical manufacturing companies, medical associations, and pharmaceutical associations. Some of the concerns expressed have been that 1) the program interferes in health care decisions

of practitioners, 2) confidentiality of patient information will be compromised, and 3) patients will not receive adequate pain medication due to the law.

MCPP States have attempted to address concerns expressed by various groups, and some States have continued to work closely with groups to obtain input. Many of the groups that had expressed initial opposition currently support the programs in their respective States.[25]

During implementation of their program in 1979, Rhode Island program officials worked to inform prescribers and pharmacists through pamphlets and presentations that the program would not interfere with legitimate medical practice and would maintain confidentiality of data. In developing its program, Michigan has worked closely with manufacturers and prescribers to develop uniform prescribing guidelines and to reassure them that the focus of the program is improper practices that lead to diversion and substance abuse. Additionally, the State has worked with the American Civil Liberties Union to develop patient data protections, as well as with several other groups to obtain input, answer questions, and alleviate misconceptions.

All MCPP States limit access to prescription information to program staff and authorized law enforcement and regulatory agencies. Data are not released without the authorization of the program director, pharmacy board, or other authorities. Penalties for unauthorized access to or distribution of data range from a misdemeanor (in Illinois) to a felony punishable by fine up to $30,000 and imprisonment up to 4 years (Michigan). The type of information that can be released to non-law enforcement agencies varies by State. New York and Indiana release only information that is deemed public knowledge, such as summary statistics not involving patient identity.

The MCPP States have various types of systems and techniques to protect the confidentiality of patient data. Examples include encrypting patient names, purging patient data, omitting patient identification from reports unless essential, and limiting access to system data base and hard copy information. Michigan destroys patient identifiers after one year, Rhode Island destroys all prescriptions not under investigation after 2 years, and Texas destroys or renders irretrievable all patient information after one year.

ENDNOTES

1. Suicides are subtracted from licit and total drug mentions.

2. National Institute on Drug Abuse, Division of Epidemiology and Statistical Analysis. 1988. National Household Survey on Drug Abuse: Rockville, MD.

3. Comprehensive Drug Abuse Prevention and Control Act of 1970, Public Law 91-513.

4. Title 21, CFR, Sections 1308.11 through 1308.15.

5. Controlled Substances Act, 84 Stat. 1242, P.L. 91-513 (1970), Title II.

6. Ibid. p.3

7. U. S. Department of Justice, Office of Justice Programs, Bureau of Justice Assistance, "Program Brief: Pharmaceutical Diversion Program," May 1987.

8. The MADAS is a data analysis program designed to identify outlier prescription drug patterns. It does not contain a data gathering component; it utilizes data supplied by a data collection system separate from the MADAS.

9. U. S. Department of Health and Human Services, Office of Inspector General, State Discipline of Pharmacists,
OAI-01-89-89020, July 1990.

10. Washington State has a Multiple Copy Prescription program that is used solely for monitoring and disciplinary action against physicians for abuse of drugs themselves or inappropriate prescribing. The program has been in place since 1989. Currently 13 physicians and 2 dentists are on the Washington Triplicate Prescription Program.

11. A doctor shopper is a purported patient who goes to several different doctors to obtain prescriptions. Each doctor is usually not aware that the "patient" is obtaining the same drugs from other physicians. Doctor shoppers are sometimes referred to as "professional patients."

12. Print shops are generally not required to obtain identification or verify information prior to filling orders for prescription pads. Agents conducting this type of undercover operation were simply attempting to determine how easy it would be to obtain the prescription blanks from print shops. Law enforcement officials and medical practitioners do not contend that instituting requirements to verify information at the print shop level is practical or desirable. The prescription forms would be very easy to produce without a print shop. This information was obtained through an interview

with John Santana, Director of the National Association of Drug Diversion Investigators.

13. In Hawaii, physicians may use any type of form for Schedule II prescriptions--even the traditional plain white type. They simply must make a duplicate of the form so that the pharmacist can keep one and send one to the State.

14. Prescriber Perceptions of Michigan's Triplicate Prescription Program. Michigan Department of Licensing and Regulation, July, 1991.

15. Department of Public Safety, Criminal Law Enforcement Division, Narcotics Service, "Texas Triplicate Prescription Program," April 1989.

16. U.S. Department of Justice, Drug Enforcement Administration. Multiple Copy Prescription Programs: Resource Guide. March 1990.

17. The Rhode Island Duplicate Prescription Program: The First Three Years, Hachadorian, Charles; D'Arezzo, Edward M., Campbell, Norman, Paper presented for the Association of Food and Drug Officials 86th Annual Conference. June 15, 1982, p. 8.

18. "The Impact of the Rhode Island Duplicate Prescription Law on Prescribing Practices for Schedule II Drugs," Bridgit A. Anness, Albert Taubman, and Cynthia Willey. Unpublished Masters Thesis, 1991.

19. Data sheets from the Illinois Department of Alcoholism and Substance Abuse, June 1989.

20. New York data sheets for the Triplicate Prescription Program.

21. Consult the National Institute on Drug Abuse Statistical Series: Data from the Drug Abuse Warning Network, Annual Data 1989, for a full discussion of data gathering methodology.

22. Department of Public Safety, Criminal Law Enforcement Division, Narcotics Service, "Texas Triplicate Prescription Program," April 1989.

23. Ironically, Texas MCPP officials point out that data from the program is utilized to exonerate an accused professional about as often as it is used to convict guilty parties. The data can be utilized to quickly and easily determine that nothing is amiss.

24. Department of Public Safety, Criminal Law Enforcement Division, Narcotics Service, "Texas Triplicate Prescription Program," April 1989.

25. National Multiple Copy Prescription Survey, statistics complied by: Michigan Triplicate Prescription Program, April 1991.

APPENDIX A

CHARACTERISTICS OF MULTIPLE COPY PRESCRIPTION PROGRAMS

MCPPS ARE PAPER SYSTEMS WITH ESTABLISHED AUDIT TRAILS.

MCPPs generally require that prescribers write prescriptions on State-issued, serialized, preprinted prescription forms for Schedule II substances. Schedule II drugs have a high potential for abuse and have highly addictive properties. Examples of Schedule II drugs are opium and codeine (narcotic analgesics), pentobarbital (a depressant), and methamphetamine (a stimulant).

The State-issued forms are prenumbered, colored (similar to a payroll check), and printed with the physician name and address. The forms have a minimum of two parts, one which is retained by the pharmacist and the other sent to the State by the pharmacist. In States with triplicate forms, the third part of the form is retained by the prescriber. MCPPs generally require that such records be maintained by physicians and pharmacists for at least two years.

As computer technology advances, some States are considering new ways of transmitting prescription data. Texas is considering permitting prescriptions to be faxed from prescriber to pharmacy. Michigan is mandated by law to establish a standardized database system to facilitate electronic or storage media (tapes or diskettes) transfer of multiple copy data from pharmacies to the State. New York is also considering development of electronic transfer of data from pharmacist to State as well as from State to pharmacy.

Although electronic submission reduces administrative burdens and speeds collection of data, the paper copy has certain advantages. In triplicate form States, a nurse or receptionist can verify information for a pharmacist since a copy is retained by the doctor's office. Since the physician retains a written record of the prescription, the physician will not have to rely on memory, or potentially incomplete patient records, to answer questions regarding a patient's prescription. Additionally, as discussed above, the special qualities of the form deter drug diversion via fake or altered prescriptions.

INCOMING DOCUMENTS ARE EXAMINED FOR ALTERATION, FRAUD, INCOMPLETENESS AND INACCURACY.

MCPP States have staff that examine the incoming documents for accuracy, completeness, and compliance with State information requirements. Action taken if there is missing information on the forms varies among the States: most of the nine

States contact the prescriber and/or pharmacist if information is missing (such as strength of substance prescribed, name of person for whom the controlled substance was prescribed, or date the prescription was filled). California's MCPP returns the form to the pharmacy if crucial information is missing.

In most MCPP States, the same personnel that examine the incoming forms for accuracy and completeness are responsible for identifying altered or fraudulent prescriptions. In New York other staff specially trained to detect fraud are used for this purpose.

STATES GENERATE REPORTS TO IDENTIFY PATTERNS AND POSSIBLE PROBLEMS.

States produce standard reports based on MCPP data.

States generally produce monthly reports arranged by prescriber, patient, selected substances, prescription series number, as well as other special reports. Some States do not analyze drug usage by patient. These reports are analyzed for unusual or suspicious prescribing, dispensing, or patient use activity.

California generates several monthly reports for diversion agents and the Medical Board. These include exception reports on particular substances (oxycodone, Dilaudid, barbiturates, amphetamines, etc.), prescribers, patients, dosage prescribed, and others. A monthly report is produced for departmental agents sorted by stolen, lost, found, and never received serial numbers.

Michigan generates standard reports displaying summary statistics on all prescriptions and on all drugs prescribed. Other reports are produced as required, such as: Pharmacy Summary Report listing information for a specific pharmacy for particular time periods; Practitioner's Summary Report, and various other summary reports. Michigan's system allows them to link all data fields in any combination desired.

New York produces daily update reports to track processing and verify record counts and filled prescriptions, a monthly report to monitor number of prescriptions, prescribers, and doctor shoppers; a quarterly report for professional oversight and enforcement by the county medical societies; and a report to review triplicate prescription activity by pharmacy, patients and doctors sorted by various fields.

Texas produces a monthly statistical report indicating how many prescriptions were ordered, stolen, flagged as filled and stolen, as well as monthly intelligence reports of the top prescribers and dispensers, and specialists prescribing substances outside of their practice. Texas does not produce a summary analysis of the prescription data. The program can respond to requests for specific information within a few days.

States use guidelines and threshold levels for initiating further analysis.

MCPP States use different measures, with varying degrees of sensitivity, to follow-up on patterns they identify. For example, California flags prescribers who have written in excess of 25 prescriptions during the reporting period. Indiana flags its top 75 prescribers, patients receiving prescriptions from three or more doctors, and patients visiting two or more pharmacies. Michigan flags its 100 most active pharmacies, pharmacists, and prescribers. Rhode Island flags its top ten prescribers and top five pharmacies.

Actions taken based on these reports and screens varies depending on State policies and the extent to which drugs or individuals exceed expected patterns.

Based on this first level of analysis, States may invest further resources to develop an understanding of the patterns they have identified.

While States differ in the credentials of personnel used to conduct their analysis of practice patterns, the elements of analysis are quite similar from State to State. Physician prescribing patterns, for example, are analyzed in light of specialty. An oncologist, surgeon, or other specialist may prescribe greater amounts of certain substances than a general practice practitioner. If analysis determines that a practitioner has a specialty that is associated with prescribing relatively large amounts of Scheduled substances, or has a unique situation, such as treatment of high numbers of cancer patients, the prescriber is not scrutinized.

In Rhode Island, the Division of Diversion Control, the Rhode Island Medical Society, and the Director of Health established a three-member physician advisory committee to assist the Division in its analysis. The committee reviews cases to determine whether the prescribing circumstances are in good faith and in the normal course of professional practice. Cases requiring further study are carried out by pharmacists, narcotics inspectors, or other health professionals with experience in the particular area of health involved. In developing cases flagged by pharmacy/pharmacist data, Rhode Island officials recognize that their set guidelines may be exceeded for legitimate reasons, such as a pharmacy contract with one or more nursing homes to supply prescription drugs.

STATES USE DATA FROM THEIR MCPP PROGRAMS TO BOTH EDUCATE PROVIDERS AND TAKE REMEDIAL ACTION TO ADDRESS PROBLEMS IDENTIFIED THROUGH THEIR ANALYSIS.

States use MCPP data to educate the provider community.

MCPP officials work with and assist health care professionals in various ways: providing data for peer review; providing information to prescribers on potential doctor-shoppers; offering educational in-service programs; and providing information and answering questions about program policies, State law, ordering forms, etc. The

extent to which MCPPs have "outreach" or actively educate and work with medical societies and other groups in the States varies considerably.

Many of the MCPPs are currently undertaking or plan cooperative ventures with prescriber or pharmacist associations. New York, in addition to its current physician peer review program, is planning educational efforts with State and local medical societies and pharmaceutical manufacturers to try to increase understanding and flow of information.

Illinois, Michigan, and New York assist their State medical societies and pharmacist associations by providing educational programs to inform them about prescribing patterns and dispensing and administering of controlled substances. New York is also considering sending prescribers and pharmacies, upon request, their own data to self evaluate prescribing and dispensing. Illinois and Indiana are working with medical schools to develop curricula to educate prospective practitioners on prescribing, pain control, and other prescription drug issues.

In some States, MCPP officials might use the information generated from the program to inform practitioners that their prescribing practices differ from that of their peers. In California, if there is an apparent violation of law, the MCPP may send the practitioner a letter stating what they are doing wrong, citing the law.

Based on analysis and investigation, States may refer practitioners to licensing boards or refer practitioners and users for criminal prosecution.

As mentioned above, MCPP officials gather additional detailed information, such as physician specialty, and analyze patient profiles and prescribing practices to see if there is a logical explanation for any deviation. MCPP officials will try to determine if a real problem exists prior to turning the investigation over to field agents. They do a considerable amount of background work "from the desk," attempting to determine if patterns of prescribing, dispensing, or use are due to legitimate medical reasons or the nature of a physician's or pharmacist's practice.

When patterns are unexplained by information review and medical practitioners are unable to account for deviation, the case is referred to investigators or field agents. Based on the results of investigations, cases may be referred to licensing boards, who may institute a restriction on what type of drugs the prescriber may prescribe, revoke or suspend a license, or require the practitioner to attend certain educational classes. There may also be referral to enforcement authorities for prosecution under Federal and State statutes involving penalties such as fines, restitution, or prison.

The activities in case development and investigation are decided on a case by case basis depending on the nature of the suspected violation or illicit activity. During the course of an investigation, agents might visit pharmacies and check for any current complaints or other ongoing investigations. There are times that an undercover operation may be initiated. If investigation shows that a prescriber may be prescribing

indiscriminately, agents might try to obtain a prescription undercover from the prescriber without a medical reason. Agents also may conduct surveillance. Investigative work may simply consist of talking to the practitioner and reviewing medical records. If a prescription looks like it has been altered, MCPP officials follow up with the prescriber or pharmacy to verify whether the prescription is valid.

MCPP information may also be used to support an ongoing investigation. Law enforcement officials may request specific pharmacy, patient, or prescriber information if street intelligence or a complaint indicate some sort of suspicious activity.

ALL NINE STATES ALLOW FOR EMERGENCY TELEPHONE PRESCRIPTIONS.

As required by the Federal law[1], all of the MCPP States allow an emergency prescription to be given over the telephone. The verbal prescription must be followed up within 72 hours with the written triplicate prescription.

[1] 21 Code of Federal Regulations 1306.11(d)(4).

TABLE OF MCPP CHARACTERISTICS

STATE	RESPONS. STATE AGENCY	DRUGS INCLUDED	NO.YRS IN OPER. (1992)	TRIPL OR DUPL.	# SCRIPT PROCESS PER YEAR *
CALIF.	Bureau of Narcotic Enforcmt.	Schedule II	52	tripl.	960,000
HAWAII	Office of Narcotics Enforcmt.	Schedule II	49	dupl.	90,000
IDAHO	Board of Pharmacy	Schedule II	25	tripl.	50,400
INDIANA	Health Professns Bureau	Schedule II	3	tripl.	197,296
ILLINOIS	Dept. of Alcoholsm & Subst. Abuse	designated Schedule II	31	tripl.	200,000
MICH.	Dept. of Commerce	Schedule II, Selected Steroids	3	tripl.	500,000
NEW YORK	Dept. of Health, Bureau of Prescripn Analysis	Schedule II, Steroids, Benzos.	15	tripl.	2.9 mill
RHODE ISLAND	Dept. of Health, Drug Con-trol Divn	Schedule II, Syringes	13	dupl.	54,940
TEXAS	Dept. of Public Safety	Schedule II	10	tripl.	639,331

* Source: Michigan Multiple Copy Prescription Program Survey, 1991.