Testimony
Before the Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
United States House of Representatives

The Use and Utility of Prescription Drug Monitoring Programs

Statement of

H. Westley Clark, M.D., J.D., M.P.H.

Director
Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 10:00 a.m.
Wednesday, October 24, 2007

Mr. Chairman and members of the Subcommittee, my name is Dr. H. Westley Clark, and I am the Director of the Center for Substance Abuse Treatment within the Substance Abuse and Mental Health Services Administration (SAMHSA), an agency of the Department of Health and Human Services (HHS). I am testifying on behalf of our Administrator, Terry Cline, Ph.D., who was not able to be here.

I am here to talk about electronic monitoring systems and how these systems have helped States and the Federal Government address non-medical use of prescription drugs.

Non-medical Prescription Drug Use

In February, John Walters, the Director of the White House's Office of National Drug Control Policy (ONDCP) stated, "Millions of Americans benefit from the tremendous scientific achievements represented by modern pharmaceutical products. But, when abused, some prescription drugs can be as addictive and dangerous as illegal street drugs."

Combined data from the Reports for 2002 to 2006 of SAMHSA's National Survey on Drug Use and Health (NSDUH) indicate that an annual average of 4.7 percent of persons aged 12 or older (an estimated 12.6 million persons) used a prescription pain reliever non-medically in the 12 months prior to the survey. In 2006, 2.1 percent of persons aged 12 or older (about 5.2 million persons) used a prescription pain reliever non-medically in the month prior to the survey. Current non-medical use of pain relievers between 2005 and 2006 was statistically unchanged. In the survey, "non-medical use" of these drugs was defined as use without a prescription of the

individual's own or simply for the experience or feeling the drugs caused. The 2006 survey found that males were more likely than females to have used a prescription pain reliever non-medically in the past year (6.1 vs. 4.3 percent). Young adults aged 18 to 25 had the highest rate of past year non-medical use, at 12.4 percent, compared to 7.2 percent for ages 12 to 17, 7.4 percent for ages 26 to 34, and 2.7 percent for ages 35 and above.

In addition, the NSDUH reported that in 2006, among persons aged 12 or older, 2.2 million **initiated** non-medical use of prescription pain relievers within the past year. That is about the same as the estimated number of initiates for marijuana.

Where are People Obtaining Their Drugs?

The 2006 NSDUH also revealed where people were obtaining their prescription drugs. Nearly 56 percent of the past year non-medical users of prescription pain relievers obtained the drugs free of charge from a friend or relative, 19.1 percent from a single doctor, 14.8 percent bought or took them from a relative or friend, 3.9 percent bought them from a drug dealer or other stranger, 1.6 percent got them from more than one doctor, less than 1 percent reported getting them from the internet, and 4.9 percent got them from other sources, including a fake prescription, or stole them from a doctor's office/clinic/hospital/pharmacy.

SAMHSA is responding, along with other agencies across the government, to address the non-medical use of prescription drugs, which now ranks second, only behind marijuana as the Nation's most prevalent illegal drug.

According to SAMHSA's Treatment Episode Data Set (TEDS), treatment admissions for abuse of opiates other than heroin, such as morphine, oxycodone, and hydrocodone, represented approximately 16,000 of all primary opiate admissions in 1995 and rose to about 68,000 in 2005. Opiates other than heroin represented 21 percent of all primary opiate admissions in 2005, up from 7 percent in 1995.

The emerging challenge of prescription drug abuse and misuse is a complex issue that requires epidemiological surveillance, distribution chain integrity, interventions, and more research by the private and public sectors. Thus, no organization or agency can address the problem alone; a coordinated response is required. The Federal Government, medical partners, public health administrators, State legislators, and international organizations all are needed to implement educational outreach and other strategies targeted to a wide swath of distinct populations, including physicians, pharmacists, patients (both intended and inadvertent), educators, parents, high school and college students, high risk adults, the elderly, and many others. Outreach to physicians and their patients and pharmacists needs to be complemented by education, screening, intervention, and treatment for those misusing or abusing prescription drugs.

Prescription drug monitoring programs (PDMPs) are among the most important components of government efforts to prevent and reduce controlled substance diversion and abuse. Prior to Fiscal Year (FY) 2002, there were 15 States operating PDMPs. Beginning in FY 2002, Congress appropriated funding to the Department of Justice (DOJ) to support PDMPs.

Since the inception of the DOJ program, called the Harold Rogers Prescription Drug Monitoring Program, (Rogers PDMP or Rogers Program), this funding opportunity has resulted in 21 States receiving new program grants and 13 States netting planning grants. There are now 25 States operating PDMPs and 8 States with legislation in place to establish a program. Nearly all of the 33 States have received funding through the Rogers Program. (Rhode Island has never applied for funding.) Out of the States that have enacted PDMP legislation, 24 States have legislative authority to provide reports to physicians or prescribers, 26 to licensing boards, 21 to pharmacies, and 29 to law enforcement. Currently, six States have established agreements with other States. As these programs mature, the number of States who are sharing information with other States continues to grow. It should be noted that some States collect more than only controlled substances information, and some States have different substances in their schedules than those set out in the Controlled Substances Act.

Although PDMPs vary from State to State, the majority of these types of programs are administered by a law enforcement agency in conjunction with a state board of pharmacy or through professional licensing boards. All States receiving Rogers PDMP funding are encouraged to exchange data. Collaboration is an important aspect of these activities, and grantees must develop a team of law enforcement and health care professionals and collaborate with other public and private agencies and organizations.

The Bureau of Justice Assistance (BJA) within DOJ's Office of Justice Programs administers the Rogers Program along with DEA's Office of Diversion Control and ONDCP. The National Alliance for Model State Drug Laws provides technical assistance to states that

either have a PDMP or intend to establish one. Every PDMP that receive funding through the Rogers Program must provide performance data on: reducing the rate of "inappropriate use of prescription drugs"; reducing the quantity of pharmaceutical controlled substances obtained by individuals attempting to engage in fraud and deceit (i.e., "doctor shopping"); and increasing coordination among PDMP partners (e.g., regulatory, health, law enforcement agencies).

All share the following common objectives:

- To educate and inform practitioners and the public;
- To develop and advance public health initiatives;
- To facilitate early identification and intervention in cases of drug misuse or abuse;
- To aid investigations and law enforcement; and
- To safeguard the integrity and access to the programs database.

Education and Information A major goal of many PDMPs is the provision of information and feedback to practitioners and the public. For example, data gathered through these systems is used to identify and analyze prescribing trends within geographic regions, medical specialties or drug classes permitting agencies to provide appropriate information or training at the right time.

Public Health Initiatives States use the information obtained from the review and analysis of monitoring data in the development of public health initiatives. Information on trends in prescribing and dispensing can be used to assist in addressing problems such as under- and over-utilization and inappropriate prescribing. Some States use monitoring information as the basis for initiation of education and prevention programs, formulation of laws and regulations,

development of controlled substances policies, and establishment of practice and treatment guidelines. One advantage of prescription drug monitoring is that initiatives can be targeted to selected subsets of healthcare practitioners.

Early Intervention and Prevention Another goal of these monitoring programs is early intervention and prevention of drug misuse. PDMPs can help physicians detect patients who may be abusing prescriptions sooner than would be possible with other forms of information gathering.

Investigations and Enforcement Existing DOJ-funded State programs have demonstrated a strong track record of assisting law enforcement and regulatory agencies to identify and respond to some illegal activity associated with prescription drugs. The systems make prescription records accessible at a single site, often computerized database, and thereby facilitate the gathering of evidence with minimal or no intrusion on practitioners and pharmacies. Similar to public health agencies, law enforcement can use information on trends in prescribing and dispensing to assist addressing problems such as identifying online Internet sales or finding suspicious prescribing patterns which may merit further investigation.

Confidentiality It is imperative that confidentiality protections are strictly enforced, so as to protect the patient, and that the systems work in conjunction with Health Insurance Portability and Accountability Act security and privacy provisions.

In recognition of the importance of the systems and the need for education and information, recently, the BJA within DOJ collaborates with SAMHSA through a multi-year grant to the SAMHSA-funded National Addiction Technology Transfer Center for an Educational Collaborative for Prescription Drug Monitoring Program Initiative. This initiative was created to enhance the linkages between the DOJ Prescription Drug Monitoring Programs and State-funded and -licensed addiction treatment systems. The goal of the project is to:

- create electronic profiles between the PDMPs and the State-funded treatment system;
- develop a guide for family practice physicians and pharmacists describing the signs and symptoms of prescription drug abuse;
- develop a guide for family practice physicians outlining the skills for screening, intervening and referring individuals to treatment for prescription drug use disorders; and
- develop a marketing plan to assure dissemination of these products and resources.

Although we do not yet have results from this grant, we are hopeful that the goals of the project will be met and will help with future efforts around establishing and enhancing PDMPs. Recognizing the fact that electronic monitoring systems are not the only answer, focus has expanded to the proper use of prescription drugs. Many individuals who receive prescriptions for pain because of surgeries, dental work, or back pain leave the drugs in their medicine cabinets or other places in the house for extended periods of time. The Federal Government in February of this year issued guidelines for proper disposal of prescription drugs. These guidelines urge Americans to:

- Take unused, unneeded, or expired prescription drugs out of their original containers;
- Mix the prescription drugs with an undesirable substance, like used coffee grounds or kitty litter, and put them in impermeable, nondescript containers, such as empty cans or sealable bags, further ensuring that the drugs are not diverted or accidentally ingested by children and pets;
- Throw these containers in the trash;
- Flush prescription drugs down the toilet only if the accompanying patient information specifically instructs it is safe to do so; and
- Return unused, unneeded or expired prescription drugs to pharmaceutical take-back locations that allow the public to bring unused drugs to a central location for safe disposal.

SAMHSA also works with ONDCP to provide outreach and disseminate educational materials efforts to various sectors of our society that encounter this class of drugs. On behalf of ONDCP, we administer grants to communities across the country to form local anti-drug community coalitions that coordinate prevention and intervention efforts. These coalitions bring together community leaders and professionals in health care, law enforcement, and education to provide local, grassroots solutions to the challenges drug and alcohol abuse pose to their neighborhoods.

The President's Fiscal Year (FY) 2008 budget request for SAMHSA includes $1.76 billion for the Substance Abuse Prevention and Treatment Block Grant, of which 20 percent is a mandatory set-aside for substance abuse prevention. These funds are directed to specialty

treatment providers, many of whom provide treatment for abuse and dependence of prescription drugs. The President's FY 2008 budget also includes nearly $504 million in prevention and treatment discretionary grants, including Access to Recovery (ATR) and Screening, Brief Intervention, Referral and Treatment (SBIRT) programs.

The Access to Recovery program was launched in August 2004 with the announcement of grants to 14 States and one tribal organization. Since then, more than 170,000 people with substance abuse problems have received treatment and/or recovery support services, exceeding the three-year target of 125,000 people. In September 2007, 24 new Access to Recovery grants were awarded to 18 States, five tribal organizations, and the District of Columbia to increase access to clinical treatment and recovery support services for an estimated 160,000 individuals over the three-year grant period.

The Screening, Brief Intervention, Referral and Treatment program was established to engage health professionals in the identification, counseling, referral, and ongoing medical management of persons with substance abuse disorders. Through SBIRT, States, territories, and tribal organizations are eligible to receive grants to provide effective early identification and observation in general medical settings. This program is based on research showing that by simply asking questions regarding future unhealthy behavior and conducting brief interventions, patients are more likely to avoid the behavior in the future and seek help if they believe they have a problem.

Conclusion

As I stated earlier in my testimony, the emerging challenge of prescription drug abuse and misuse is a complex issue that requires epidemiological surveillance, distribution chain integrity, interventions, and more research by private and public sectors. It requires a concerted effort by many, and electronic monitoring systems are a key part of the response along with treatment and prevention programs that include outreach and education. SAMHSA is committed to allowing its programs to give States and local authorities flexibility in meeting drug-related challenges their communities face, including the mounting problem of prescription drug abuse. Our strategies in prevention and treatment of prescription drug abuse are both targeted specifically to the prescription drugs themselves and to programs that enable prevention, intervention, and treatment of addictions, which can have a significant long-term impact on prescription drug abuse and misuse.

Thank you for this opportunity to present this information to you. I would be pleased to answer any questions you may have.

National All Schedules Prescription Electronic Reporting Act of 2005: A Review of Implementation of Existing State Controlled Substance Monitoring Programs

Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services

ACKNOWLEDGEMENTS

Numerous people contributed to the development of this report (see Appendix J). This report was produced by DB Consulting Group, Inc. (DB) and JBS International, Inc. (JBS) under the Center for Substance Abuse Treatment (CSAT) contract number 270-05-0109 (Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services).

Anton C. Bizzell, M.D., served as the CSAT Government Project Officer, Fred Carlini, Sharon Dow, M.S., and Douglas Rugh, Ph.D., served as DB Project Directors, Bonnie Wilford, M.S., served as JBS Project Director. Other DB personnel who contributed to this report included Richard Offner, Ph.D. Other JBS personnel included Ellen Dreyer, R.N., Mary A. Kelly, M.S.L.S., Erika Olsen, M.A., and Manu Singh, Ph.D.

The authors acknowledge with gratitude the input and advice provided by outside reviewers. However, the appearance of their names does not necessarily indicate that they have endorsed the findings and conclusions appearing in this report, for which the authors assume sole responsibility. A list of outside reviewers is listed in Appendix J.

ORIGINATING OFFICE

Division of Pharmacologic Therapies
Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services Administration
1 Choke Cherry Road
Rockville, MD 20857

TABLE OF CONTENTS

EXECUTIVE SUMMARY

INTRODUCTION

The report presents the findings of an assessment of existing State Controlled Substance Monitoring Programs (CSMPs) and other information related to the National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER; Public Law 109-60), which provides for the establishment of a CSMP in each State.

The non-medical use of prescription psychotherapeutic drugs in the United States has become a matter of increasing concern in recent years. According to the Substance Abuse and Mental Health Services Administration's (SAMHSA) 2005 National Survey on Drug Use and Health (NSDUH), an estimated 15.2 million persons aged 12 or older (6.2 percent of all persons in that age group) used prescription-type psychotherapeutic drugs non-medically in the past 12 months. In 2005, there were 6.4 million (2.6 percent) persons aged 12 or older who used prescription-type psychotherapeutic drugs non-medically in the past month. Of these, 4.7 million used pain relievers, 1.8 million used tranquilizers, 1.1 million used stimulants (including 512,000 methamphetamine users), and 272,000 used sedatives.

Furthermore, the 2005 NSDUH found that 4.9 million young adults aged 18 to 25 (12.4 percent) used prescription pain relievers (analgesics) such as OxyContin® non-medically; in addition, 1.7 percent of the young adults met the criteria for dependence or abuse of prescription pain relievers in the past year. In 2005, the most common source from which recently used drugs were obtained among non-medical users of prescription-type drugs was "from a friend or relative for free."

States began to address the issue of prescription misuse and abuse more than 60 years ago by creating programs to monitor the dispensing of prescription drugs. By the 1980s, 10 States had adopted CSMPs, but they were quite diverse in features. These early programs required physicians to use special multiple-copy, two- or three-part prescription order forms.

Beginning in fiscal year 2002, Congress appropriated funding to the U.S. Department of Justice to support the Harold Rogers Prescription Drug Monitoring Program (U.S. Department of Justice Appropriations Act; Public Law 107-77). The purpose of the program is to enhance the capacity of regulatory and law enforcement agencies to collect and analyze controlled substance prescription data. The program focuses on providing help for States that want to establish new or enhance existing programs.

As part of a continuing effort to improve CSMPs, President Bush signed The NASPER Act on August 11, 2005. The Act authorizes the U.S. Department of Health and Human Services (HHS) to award grants to States to construct prescription drug monitoring programs and enhance existing ones. As of the time of this report's preparation, funding has not been provided for this activity.

NASPER provides a national plan and standardizes the program features in order to:

1. Foster the establishment of State-administered controlled substance monitoring systems to ensure that health care providers have access to accurate, timely prescription history information that can be used for the early identification of patients at risk for addiction. Early identification allows for early intervention of appropriate treatment to avert the tragic personal, family and community consequences of untreated addiction.
2. Establish, based on the experiences of existing State prescription monitoring programs, a set of best practices that can be used to guide the establishment of new State programs and the improvement of existing programs.

As a requirement of NASPER, SAMHSA presents findings of an assessment of existing State CSMPs and other relevant information in order to determine whether such programs have had a substantial negative impact on: 1) patient access to treatment, including therapy for pain or controlled substance abuse; 2) pediatric patient access to treatment; and 3) patient enrollment in research or clinical trials.

SOURCES OF INFORMATION

Four sources of information were used to complete the report. The sources included: 1) a literature review; 2) data analysis; 3) key informant questionnaires; and 4) publicly available information.

FINDINGS OF ASSESSMENT

The first major change in the design of CSMPs occurred in the 1990s when some States adopted electronic CSMPs that employed technology to capture prescribing information in ways similar to that pioneered by health insurers and other third-party payers. Such "electronic CSMPs" captured information more quickly, rendered it into usable form, allowed monitoring of a larger number of drug classes, and rendered results to State officials on a basis much close to real time (Alliance of States with Prescription Monitoring Programs and National Association of State Controlled Substance Authorities, 2002). As a result, some States switched from multiple-copy programs to electronic CSMPs, while other States that had not been able to afford a multiple-copy program established a CSMP for the first time.

We can provide "lessons learned" and strategies that States may find useful as they refine existing CSMPs and design and implement new programs. The findings of the analysis include:

- *ACCESS TO PAIN TREATMENT*. Evidence of a negative impact on patients' access to pain treatment was consistent across the literature reviewed, the data analyzed, and the information gathered from key informants. A negative effect was evidenced in jurisdictions where a CSMP required the use of a special prescription form, and/or where the CSMP covered Schedule II but not Schedule III analgesics.
- *ADDICTION TREATMENT*. The evidence as to whether or not CSMPs have had a significant negative effect on patients' access to opioid agonist therapies for addiction (e.g.,

treatment with methadone or buprenorphine) was not consistent across the literature review, the data analysis, and the key informants' responses.

- *PEDIATRIC CARE.* There are concerns about a potential effect of CSMPs on pain management in pediatric patients. Given that cancer is the second leading cause of death in children under age 12, this is a significant concern.
- *RESEARCH AND CLINICAL TRIALS.* There is little published literature and no data that address the effect of CSMPs on enrollment in clinical trials.

CONCLUSIONS

The results of the assessment are inconclusive and underscore the fact that further study is needed to determine the true impact of CSMPs on physicians' willingness to prescribe and patients' ability to access pharmacologic treatments.

---

[*] For the purpose of this report, Controlled Substance Monitoring Program (CSMP), Prescription Monitoring Program (PMP), and Prescription Drug Monitoring Program (PDMP) are used interchangeably.

INTRODUCTION

The report presents the findings of an assessment of existing State Controlled Substance Monitoring Programs (CSMPs) and other information related to the National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER; Public Law 109-60), which provides for the establishment of a CSMP in each State.

The non-medical use of prescription psychotherapeutic drugs in the United States has become a matter of increasing concern in recent years. According to the Substance Abuse and Mental Health Services Administration's (SAMHSA) 2005 National Survey on Drug Use and Health (NSDUH), an estimated 15.2 million persons aged 12 or older (6.2 percent of all persons in that age group) used prescription-type psychotherapeutic drugs non-medically in the past 12 months. In 2005, there were 6.4 million (2.6 percent) persons aged 12 or older who used prescription-type psychotherapeutic drugs non-medically in the past month. Of these, 4.7 million used pain relievers, 1.8 million used tranquilizers, 1.1 million used stimulants (including 512,000 using methamphetamine), and 272,000 used sedatives.

Furthermore, the 2005 NSDUH found that 4.9 million young adults aged 18 to 25 (12.4 percent) used prescription pain relievers (analgesics) such as OxyContin® non-medically; in addition, 1.7 percent of the young adults met the criteria for dependence or abuse of prescription pain relievers in the past year. In 2005, the most common source from which recently used drugs were obtained among non-medical users of prescription-type drugs was "from a friend or relative for free."

States began to address the misuse and abuse of prescription medications more than 60 years ago by creating programs to monitor the dispensing of prescription drugs. By the 1980s, 10 States had adopted CSMPs, but they were quite diverse in features. These early programs required physicians to use special multiple-copy, two- or three-part prescription order forms.

Beginning in fiscal year 2002, Congress appropriated funding to the U.S. Department of Justice (DOJ) to support the Harold Rogers Prescription Drug Monitoring Program (U.S. Department of Justice Appropriations Act; Public Law 107-77). The purpose of the program is to enhance the capacity of regulatory and law enforcement agencies to collect and analyze controlled substance prescription data. The program focuses on providing help for States that want to establish new or enhance existing programs.

As part of a continuing effort to improve CSMPs, President Bush signed the NASPER Act on August 11, 2005. The Act authorizes the U.S. Department of Health and Human Services (HHS) to award grants to States to construct prescription drug monitoring programs and enhance existing ones. As of the time of this report's preparation, funding has not been provided for this activity.

NASPER provides a national plan and standardizes the program features in order to:

1. Foster the establishment of State-administered controlled substance monitoring systems to ensure that health care providers have access to accurate, timely prescription history

information that can be used for the early identification of patients at risk for addiction. Early identification will allow for early intervention of appropriate treatment and avert the tragic personal, family and community consequences of untreated addiction.

2. Establish, based on the experiences of existing State prescription monitoring programs, a set of best practices that can be used to guide the establishment of new State programs and the improvement of existing programs.

As a requirement of NASPER, SAMHSA's Center for Substance Abuse Treatment (CSAT) presents findings of an assessment of existing State CSMPs and other information in order to determine whether such programs have had a substantial negative impact on (1) patient access to treatment, including therapy for pain or controlled substance abuse; (2) pediatric patient access to treatment; and (3) patient enrollment in research or clinical trials.

OVERVIEW AND CONTEXT

OVERVIEW: THE PRINCIPLE OF BALANCE

The abuse of controlled substances is one facet of America's drug problem that is particularly complex because access to these substances must be maintained for legitimate medical purposes. In fact, millions of persons are successfully treated each year with medications that have abuse potential, and the majority do not develop problems with misuse, abuse or addiction. Yet the use of such drugs is not without risk. The diversion of controlled substances to non-medical use is a public health and safety concern of considerable magnitude, which contributes to serious health consequences, including drug addiction and death.

The methods employed in drug diversion are deceptive and sometimes violent. They involve theft, forgery, and counterfeiting of prescription forms and the drugs themselves; illegal importation; frauds perpetrated against physicians, pharmacies, and patients; and deliberate misprescribing or illegal dispensing by a small percentage of physicians, pharmacists and other health care professionals (AMA, 1987; DEA, 2000).

To address the dichotomy between the medical usefulness of certain drugs and their potential for diversion and abuse, drug control programs traditionally are based on the principle of balance (a term introduced by Joranson and Dahl in 1989 and subsequently widely adopted). In essence, the principle of balance holds that the promotion of effective medical care and the reduction of drug misuse and abuse are equally important regulatory objectives, and that neither should be sacrificed in pursuit of the other (DEA, 2002).

In practice, the principle of balance means that physicians and pharmacists are required by Federal law to prevent the diversion of controlled substances and that they share with regulatory and enforcement authorities a responsibility to assure that controlled substance prescriptions are issued only for a legitimate medical purpose and within the usual course of professional practice (21 Code of Federal Regulations (C.F.R.) §1306.04, 2001).

The principle of balance has been endorsed in the official policies of a wide array of international and national agencies and organizations, ranging from the World Health Organization to the U.S. Drug Enforcement Administration (DEA); from the American Medical Association (1990) to the Federation of State Medical Boards (1998). In fact, in October 2001, the DEA released a joint statement with 21 health care organizations that called for a "balanced approach" to regulation of opioid analgesics. The statement affirmed that "[b]oth healthcare professionals and law enforcement and regulatory personnel share a responsibility for ensuring that prescription pain medications are available to the patients who need them and for preventing these drugs from becoming a source of harm or abuse" (DEA, 2001).

HISTORICAL CONTEXT

The current debate over how best to address the misuse and abuse of prescription medications has its origins more than a century ago, at a time when the most commonly abused drugs were freely available to any willing buyer (Musto, 1999). As DuPont (2005) describes the situation,

"heroin was sold over the counter as a soothing syrup for colicky babies and cocaine was the reason a then-new beverage invented in an Atlanta pharmacy was called 'Coke.'"

In the first two decades of the 20th Century, Congress adopted two seminal pieces of legislation to address this open market in dangerous drugs: the Pure Food and Drug Act of 1906 and the Harrison Narcotics Act of 1914. Enactment of these laws marked the adoption of a new social contract, which recognized that many of the most widely abused drugs also had important medical uses (DuPont, 2005).

The third bedrock of contemporary drug regulation – the Federal Controlled Substances Act (CSA) – was not adopted until 1970. In essence, the CSA established a "closed" distribution system – that is, one in which every step in drug manufacture and distribution was subject to reporting to and monitoring by Federal authorities. It also created a series of five schedules into which all drugs with a recognized potential for abuse could be classified. The schedules range from Schedule I (for drugs with high abuse potential and no accepted medical use) to Schedule V (for drugs such as paregoric, which have a demonstrated medical use and such minor abuse potential that they can be sold over the counter).

In the 1990s, prescription medications assumed a dramatically larger place in the treatment of many medical disorders, sometimes replacing surgery and frequently offering hope for the relief of conditions that previously had been untreatable. In the mental health arena, there was a new emphasis on use of pharmacologic treatments for psychotic disorders, mood and anxiety disorders (e.g., depression and panic disorder), and attention deficit/hyperactive disorder (ADHD). Even advances such as the development of effective treatments for cancer meant that patients, who in an earlier era would have rapidly succumbed to the disease, now could add months and years to their lives, although often increasing the need for ongoing pain management.

EXISTING CONTROL MECHANISMS

Parallel with these developments, Federal and State governments adopted a series of regulatory and enforcement mechanisms. Such approaches generally focus on one of two potential points of intervention. Demand reduction approaches seek to address the underlying causes of prescription diversion and abuse by treating the addicted population or educating the practitioners who prescribe or dispense the drugs. The majority of these approaches are sponsored by government agencies but executed by private-sector organizations. Supply reduction approaches involve efforts to monitor and control access to the drugs themselves, as well as to delimit the actions of those who are legally empowered to prescribe and dispense them. For the most part, these approaches rely on statutory authority and are employed by Federal and State governments.

Federal Responsibilities. Most Federal programs to address prescription drug abuse fall under the rubric of supply reduction. For example, to reach the market in the U.S., all prescription drugs – including controlled drugs – must be approved by the U.S. Food and Drug Administration (FDA) as safe and effective for human use under medical supervision. The FDA derives its authority from the Federal Food, Drug and Cosmetic Act of 1962. (It is important to note here that the FDA regulates approval and marketing of drugs for medical use, but not the medical practitioners who prescribe, administer and dispense them. Physicians generally are allowed to prescribe according to their best judgment [Federal Register, 1975, 1983].)

In addition to review and approval by the FDA, certain drugs and precursor chemicals are subject to additional requirements of the Federal Controlled Substances Act of 1970 (C.F.R., Title 21, Chapter 2), which consolidated more than 50 separate laws into a unified system of drug control. The CSA is intended to achieve both drug control and drug availability. The DEA is the lead Federal agency responsible for regulating controlled substances and enforcing the CSA.

Licensed physicians and other licensed health care professionals who wish to prescribe, dispense or administer controlled drugs must first register with the DEA (and usually also with the State) and be periodically renewed (DEA, 1990).

A prescription for a controlled drug is legal only if it is written for a legitimate medical purpose by a practitioner who holds a current license and DEA registration and who is acting within the usual course of professional practice. Most States have requirements that mirror (and occasionally exceed) the Federal rules.

State Responsibilities. In contrast to regulation of the drugs themselves, the regulation of the professionals who prescribe and dispense prescription medications falls primarily to the States. Physicians, pharmacists and other health professionals who prescribe or dispense controlled drugs must be licensed by the State in which they practice, have a current registration with the DEA, and maintain records of drugs prescribed, dispensed or administered in a manner that complies with State and Federal laws.

State legislatures have granted statutory authority to professional licensing boards (such as boards of medicine, pharmacy, or nursing) to license and discipline members of their respective professions. The boards also have the authority to review, suspend, or revoke licenses for cause.

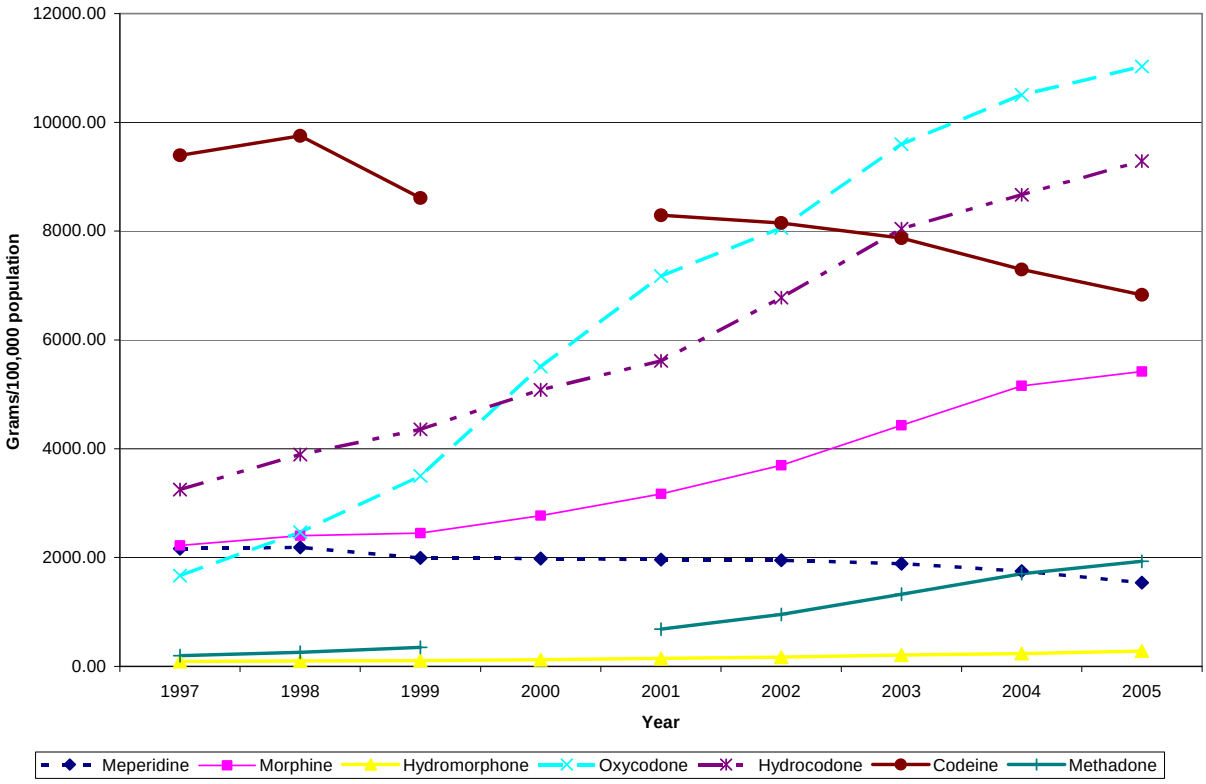
In addition to statutes governing professional practice, all States have adopted some version of the Federal Controlled Substances Act. It is under this authority that States have established CSMPs to facilitate the collection, analysis, and reporting of information on the prescribing, dispensing, and use of controlled substances (GAO, 2002).

IMPETUS FOR ADDITIONAL CONTROLS

For almost a century, the social contract governing the use of prescription drugs with abuse potential (as codified in the Harrison Narcotics Act) worked reasonably well to permit access to medically necessary drugs while protecting the public from their misuse. However, problems became evident in the 1990s and early 2000s, which saw the introduction of new medications and formulations to treat a variety of disorders, including ADHD, sleep disorders and pain (Curtis, Stoddard, et al., 2006a; DuPont, 2005). Technological developments loosened the existing controls over drug distribution by making it possible to purchase even controlled drugs over the Internet, often without a legitimate prescription (Wilford, Smith, et al., 2005). The resulting increase in distribution and use of medications was accompanied by increased problems with drug diversion and abuse (Exhibit 1), and experts concluded that expanded availability of psychotherapeutic medications was a significant factor in the increased rates of abuse (Dasgupta, Kramer, et al., 2006; Paulozzi, Budnitz, et al., 2006; Novak, Nemeth, et al., 2004; Jaffe and O'Keeffe, 2003).

Exhibit 1. U.S. Trends in Distribution and Problematic Use of Commonly Prescribed Pain Medications

Table 1. U.S. Trends in Distribution of Selected Opioid Analgesics, as Reported in Automation of Reports and Consolidated Orders Systems (ARCOS)



Source: Drug Enforcement Administration, ARCOS-2, 2006.
*Data were not available for codeine and methadone for 2000.

Table 2. Estimated Mentions of Selected Opioid Analgesics: 1997 – 2002 , as Reported in DAWN

Year	Meperidine*	Morphine*	Hydromorphone*	Oxycodone*	Hydrocodone*	Codeine*	Methadone
1997	864	1,300	604	5,012	11,570	7,869	3,832
1998	730	1,955	937	5,211	13,611	6,620	4,810
1999	882	2,217	1,313	6,429	15,252	4,974	5,426
2000	1,085	2,483	1,983	10,825	20,098	5,295	7,819
2001	665	3,403	2,003	18,409	21,567	3,720	10,725
2002	722	2,775	2,667	22,397	25,197	4,961	11,709

Table 2 includes “drug abuse.”
Values are expressed in number of estimated mentions.
ED visits includes dependence, drugs taken for psychic effects or suicide attempts.
*Combination products are included.

Source: Office of Applied Studies, SAMHSA, DAWN, 2003.

Table 3. Drug Abuse Warning Network: 2005
Nonmedical Use of Specified Opioid Analgesics Emergency Department Visits: 2004 and 2005

Drug category and selected drugs[1]	Estimated ED visits[2]		Rates[3]		Percent Change[4]
	2004	2005	2004	2005	2004, 2005
CNS Agents					
Opiates/opioid analgesics	158,284	196,225	53.9	66.2	24%
Codeine/combinations	5,836	5,550	2.0	1.9	
Hydrocodone/combinations	42,491	51,225	14.5	17.3	
Hydromorphone/combinations	2,779	5,344	0.9	1.8	92%
Meperidine/combinations	1,310	763	0.4	0.3	
Methadone	31,874	41,216	10.9	13.9	29%
Morphine/combinations	12,558	15,183	4.3	5.1	
Oxycodone/combinations	36,559	42,810	12.4	14.4	

Notes:
[1] The classification of drugs in DAWN is derived from the Multum Lexicon 2005, Multum Information Services, Inc. The classification was modified to meet DAWN's unique requirements (2006). The Multum Licensing Agreement governing use of the Lexicon is provided in Appendix A of DAWN, 2005: National Estimates of Drug-Related Emergency Department Visits and can be found on the internet at http://www.multum.com.
[2] These are estimates of ED visits based on a representative sample of non-Federal, short-stay hospitals with 24-hour EDs in the United States.
[3] ED visits per 100,000 population.
[4] This column denotes statistically significant ($p<0.05$) increases or decreases between estimates for the period shown.

Source: Office of Applied Studies, SAMHSA, DAWN, 2005 (2006 update).

Non-medical use of prescription-type psychotherapeutic drugs has become a matter of increasing concern in recent years (OAS, 2006), with the problem of prescription drug abuse characterized by Compton and Volkow (2006) as "staggering." One indication of the problem is found in a steady rise in the number of Americans aged 12 and older who have initiated use of a prescription medication nonmedically.

According to SAMHSA's 2005 NSDUH, 32.7 million persons (13.4 percent of the U.S. population) aged 12 or older had used prescription pain relievers non-medically at least once in their lifetime. This is up from 29.6 million persons (12.6 percent) in 2002, indicating an increase in the number of Americans using prescription medication other than under a physician's supervision.

Combined data from the 2002, 2003, and 2004 NSDUH indicate that an annual average of 14.8 million persons aged 12 or older (6.2 percent of all persons in that age group) had used prescription-type psychotherapeutic drugs non-medically in the past 12 months (OAS, 2006c). In 2005, 6.4 million or 2.6 percent of the U.S. population aged 12 or older were current nonmedical users of psychotherapeutic drugs. Of these, 4.7 million used pain relievers, 1.8 million used tranquilizers, 1.1 million used stimulants, and 272,000 used sedatives (OAS, 2006a).

Furthermore, the 2005 NSDUH found that 4.9 million young adults aged 18 to 25 (12.4 percent) used prescription pain relievers (analgesics) such as OxyContin® non-medically within the past year; in addition, 1.7 percent of the young adults met the criteria for dependence or abuse of prescription pain relievers in the past year (OAS, 2006a). Combined data for 2002 through 2004 revealed that young adults ages 18 to 25 had a higher prevalence of dependence or abuse for pain relievers, tranquilizers, and stimulants compared with the rates of dependence or abuse for these medications for persons in other age groups (OAS, 2006c).

In 2005, SAMHSA reports in the NSDUH that the most prevalent source from which recently used drugs were obtained among non-medical users of prescription-type drugs was "from a friend or relative for free." Among persons aged 12 or older who used pain relievers non-medically in the past 12 months, 59.8 percent reported that the source of the drug the most recent time they used was from a friend or relative for free. Another 16.8 percent reported they got the drug from one doctor. Only 4.3 percent got the pain relievers from a drug dealer or other stranger, and only 0.8 percent reported buying the drug on the Internet. Over half, or 57.6 percent, of past year non-medical users of stimulants aged 12 or older reported getting the drug from a friend or relative for free. Also, 6.5 percent bought the drug from a drug dealer or other stranger, and 7.2 percent bought it on the Internet (OAS, 2006a).

The NSDUH defines non-medical use as the use of prescription-type psychotherapeutic drugs not prescribed for the respondent by a physician or used for the experience or the feeling they cause (OAS, 2006a). The term encompasses all uses of prescription pain relievers, tranquilizers, stimulants, and sedatives other than those that are directed by a physician and used by a patient in a manner consistent with the prescribed regimen of treatment.

Nonmedical use of prescription drugs is associated with a variety of deleterious health consequences. The Drug Abuse Warning Network (DAWN) shows that nearly 1.3 million emergency department (ED) visits in 2004 were associated with drug misuse/abuse (OAS, 2006b). Nonmedical use of pharmaceuticals was involved in nearly 500,000 of the ED visits; over half of these ED visits involved multiple drugs. Opioid analgesics and benzodiazepines were each involved in more than 100,000 visits. According to DAWN, the most frequent diagnoses for the ED visits involving the nonmedical use of pharmaceuticals were overdose (in 38 percent of visits) and depression or another psychiatric condition (23 percent). Toxic effects were reported in 10 percent of visits (OAS, 2006b).

Of the half million ED visits involving non-medical use of pharmaceuticals in 2004, 31.9 percent involved opiates/opioids, 29.1 percent involved benzodiazepines, and 5.1 percent involved muscle relaxants (Exhibit 2).

DAWN's definition of non-medical use includes ED visits involving the misuse/abuse of pharmaceuticals, as well as visits where the patient took too much of his or her own medication or was given the drug by another person who intended to cause harm. DAWN's definition of nonmedical use does not include drug-related suicide attempts, adverse reactions, patients seeking drug rehabilitation, or accidental poisoning (OAS, 2006).

Reports on admissions to addiction treatment programs show that, in the decade between 1992 and 2002, admissions for problems with opioid analgesics more than doubled. (While such

treatment admissions increased for all age groups, the increase was especially notable among persons aged 20 to 30 [OAS, 2005]).

Exhibit 2. Emergency Department (ED) Visits Involving Nonmedical Use of Selected Pharmaceuticals, 2004

Drug	Estimated Visits	
	Number	Percentage
Opiates/opioids	158,281	31.9
Hydrocodone/combinations	42,491	
Oxycodone/combinations	36,559	
Methadone	31,874	
Benzodiazepines	144,385	29.1
Alprazolam	49,842	
Clonazepam	26,238	
Muscle relaxants	28,338	5.1
Carisoprodol	17,366	
Cyclobenzaprine	5,932	
All ED visits involving nonmedical use of pharmaceuticals	495,732	100

Source: Office of Applied Studies, SAMHSA, DAWN, 2004 (September 2005 update).

CONTROLLED SUBSTANCE MONITORING PROGRAMS (CSMPS)

CSMPs are among the most important components of State efforts to prevent and reduce prescription drug diversion and abuse. Such programs are used to monitor the prescribing of certain prescription drugs in an effort to detect patterns that suggest inappropriate actions on the part of physicians or patients. The primary goal of CSMPs is the detection and prevention of prescription drug diversion, although many programs also use the data for physician education and early intervention (Council of State Governments, 2004).

The first such program was adopted by California in 1939, followed by Hawaii in 1943 and Illinois in 1961. By the 1980s, seven more States had adopted CSMPs. These early programs required physicians to use special multiple-copy, two- or three-part prescription order forms. All were limited to drugs in Federal Schedule II (see Appendix B). Physicians generally were required to obtain the special multiple-copy prescription forms from a State agency, and some States charged a fee for the forms, thereby generating revenues to underwrite program costs. Pharmacists who dispensed the drugs were required to send one copy of the multiple-part order form to the State, where information from the forms was tallied and analyzed by State personnel (Brushwood, 2003).

The earliest CSMPs covered all drugs in CSA Schedule II. Some covered drugs in other schedules as well (the CSMP in New York State, for example, covered all drugs in Schedule II plus benzodiazepines, which are classified in Schedule IV). Typically, the States use various criteria (involving the total number of prescriptions written or volume of drugs prescribed, or prescribing medications in certain combinations, or the fact that a given patient is obtaining prescriptions for the same or similar medications from multiple physicians) to "flag" physicians or patients for further investigation. The information collected also could be used to monitor a

particular physician's prescribing patterns. For example, the CSMP in Washington State is used solely to monitor the activities of certain physicians adjudged to be engaged in problematic prescribing.

The potential of the multiple-copy programs was limited by the fact that the prescribing information was recorded on a paper form, and thus had to be manually entered into a database before it could be compiled and analyzed. This entailed considerable expense and meant that investigative staff could not obtain the resulting information in anything like "real time."

In the 1990s, some States adopted electronic CSMPs that employed technology to capture prescribing information electronically. Such "electronic CSMPs" captured information more quickly, rendered it into usable form with less intervening work, allowed monitoring of a larger number of drug classes, and rendered results to State officials in real time (Alliance of States with Prescription Monitoring Programs and National Association of State Controlled Substance Authorities, 2002). As a result, some States switched from multiple-copy programs to electronic CSMPs, while other States that had not been able to afford a multiple-copy program established a CSMP for the first time. A few States combined the features of the two approaches by continuing to require use of a special (usually State-issued and serialized) prescription form for certain classes of drugs, but also required that pharmacists input the data and transmit it to the State.

The change from paper-based to electronic monitoring marks "a significant paradigm shift in CSMPs' operations that began in the mid-1990s and is currently escalating. The core of this is the developing partnership between CSMPs and treating physicians and pharmacists; a partnership in which CSMPs provide ever-increasing volumes of information in response to direct requests from the practitioners and pharmacists to aid them in clinical care" (John Eadie, Personal communication, November 27, 2006).

John Eadie, past President of the Alliance of States with Prescription Monitoring Programs (ASPMP) and of the National Association of State Controlled Substance Authorities (NASCSA) and former Director of the Division of Public Health Protection in the New York State Department of Health, adds that "Recent developments identify additional ways CSMPs are responding to the paradigm shift" (personal communication, November 27, 2006):

- In response to physicians' requests for rapid access to CSMP data, States are establishing web-based portals through which data users can request the data. This process began a few years ago with only one or two States, but it is now established in a majority of CSMPs.
- Physicians are now seeking real time access to the CSMP data. Kentucky, Maine, and Utah have established methods for practitioners and pharmacists to be authenticated; once authenticated, they are able to retrieve data regarding their patients (they must certify that the data sought is for their patients only).

As of December 1, 2006, 33 States have signed laws authorizing the creation of a CSMP, 25 States have active CSMPs, and 8 States have begun implementation of legislatively authorized programs. Other States are currently preparing legislation that would establish CSMPs.

CSMPs are administered by diverse government agencies, including professional licensing boards, health departments, human services agencies, or consumer protection agencies in 12 States; and by justice departments, public safety agencies, or State police in five more. States also vary markedly in terms of who has access to the information collected. In some States, for example, physicians and pharmacists can acquire a medication profile for a given patient from the administering agency (Peine, 2000). In other States, only regulatory or law enforcement personnel have access to the information (Alliance of States with Prescription Monitoring Programs and National Association of State Controlled Substance Authorities, 2001).

In practice, CSMPs take different forms because each State government determines the goals, structure, and organization of its program. The manner in which a program is implemented depends on its stated goals and the mission of the responsible agency (Peine, 2000). However, most State CSMPs articulate the following goals (Alliance for Model State Drug Laws and National Association of State Controlled Substance Authorities, 1999):

- To educate and inform practitioners and the public,
- To develop and advance public health initiatives,
- To facilitate early identification and intervention in cases of drug misuse or abuse,
- To aid investigation and law enforcement, and
- To safeguard the integrity and access to the programs' database.

A recent report sponsored by the U.S. Department of Justice (DOJ), Office of Justice Programs examined the interrelationship between the presence of a CSMP and the supply and abuse of prescription drugs (Simeone, 2006). The evaluation compares trends in abuse of prescription pain relievers and stimulants between States that have a CSMP and those that do not. The evaluation uses a series of models for estimating patterns of availability and abuse, applying a state-based ecological approach to evaluate the effects of the programs.

The principal findings of the evaluation suggest that: 1) the presence of a CSMP may reduce the per capita supply of prescription pain medications and stimulants and thereby reduce the probability of abuse of these drugs, and 2) States that are proactive in their approach may be more effective in reducing the per capita supply of prescription pain relievers and stimulants than States that are reactive in their approach to regulation.

The report attempts to quantify prescription drug abuse in the context of CSMPs, using the Treatment Episode Data Set (TEDS) treatment admissions data; examining drugs that are not in the top most misused or abused drugs; and restricting attention to Schedule II drugs. However, defining abuse based upon treatment admissions has several limitations. For example, many people who abuse drugs never seek treatment. Furthermore, restricting attention to Schedule II drugs leaves out some of the major drugs of abuse (Darvocet, Darvon, Tylenol with Codeine, Vicodin, Lortab and Lorcet). In addition, drugs in other schedules have a higher availability and are often abused more extensively that those in Schedule II.

The DOJ-sponsored study, along with the NASPER report, demonstrates the need for further evaluations of CSMPs for improved public health programming (Simeone, 2006).

THE NASPER ACT OF 2005

The NASPER Act was signed by President George W. Bush on August 11, 2005, as Public Law 109-60. NASPER authorizes the U.S. Department of Health and Human Services to issue a system of grants to the States for the purpose of establishing a new CSMP or improving an existing program. As of the time of this report's preparation, funding has not been provided for this activity. Furthermore, it creates a formula for determining the amount of such grants, which involves: 1) a minimum amount allocated to each approved State equal to 1.0 percent of the amount appropriated to carry out NASPER, and 2) an additional amount based on a ratio of the number of pharmacies in a State to the number of pharmacies in all States. It also requires that States establishing such programs be given preference in future competitive grant awards related to drug abuse.

The NASPER Act directs HHS to review whether the implementation of CSMPs had had a "substantial negative impact" on patient access to treatment or enrollment in research or clinical trials. This report summarizes the findings of this review.

The NASPER Act identifies several populations and areas of medical practices as topics of special concern. These include the care of patients in need of treatment for pain or addiction, the care of pediatric patients, and enrollment of patients in research and clinical trials.

Pain Treatment. Approximately 75 million persons in the United States suffer from severe pain. An estimated 50 million experience chronic pain, while 25 million suffer acute pain related to surgery, a medical disorder, or a traumatic injury. In fact, pain is the most common presenting complaint of patients who seek medical care (American Chronic Pain Association, 2002). It has been estimated that 40 to 90 percent of patients treated in specialized pain treatment facilities receive opioid analgesics for their pain (Manchikanti, Pampati et al., 2001; Turk and Okifuki, 1997; Flor, Fydrich, et al., 1992). The number of patients who receive similar medications from primary care providers is unknown. Joranson and Berger posit that only about one in four pain patients receives adequate pain relief (Joranson and Berger, 2000).

Addiction Treatment. Opioid agonist therapy (OAT), in which a prescribed drug is given to occupy the receptor sites that otherwise would respond to an illicit agent such as heroin, is a widely accepted medical treatment for opioid addiction whose efficacy has been documented in hundreds of studies (Center for Substance Abuse Treatment, 2004, 2005). The best-known and most widely used form of OAT involves methadone maintenance treatment. A second and newer form of OAT employs buprenorphine. Buprenorphine is able to block the effects of morphine and other opioids, while offering opioid-like effects that appear likely to encourage better patient adherence with the treatment regimen than would a non-opioid or antagonist drug (Vocci, Acri, et al., 2005).

Methadone is classified in Schedule II of the Federal Controlled Substances Act. The formulations of buprenorphine that are approved for the treatment of addiction (Subutex® and Suboxone®) are classified in CSA Schedule III.

Pediatric Care. Among the relatively few published reports on prescribing for pediatric patients, a large number address the treatment of cancer pain in children because cancer is the leading cause of non-accidental death in childhood (Joranson, Gilson, et al., 2003; Institute of Medicine, 2002; Gaughan, Hughes, et al., 2002). Although high-quality palliative care is now the standard during active treatment and at the end of life (American Medical Association, 2005; American Pain Society, 2004; Institute of Medicine, 2002), few studies have examined whether the care of children with cancer meets this standard (Goldman, 1998; Frager, 1996; Bossert, Van Cleve, et al., 1996; Collins, Grier, et al., 1995).

In an effort to address the issue of pediatric pain relief, Wolfe and colleagues (2000) interviewed the parents of children who had died of cancer and abstracted data from the children's charts to determine the patterns of care, the symptoms they experienced in the last month of life, the effectiveness of the pain and other palliative treatment offered, and any factors related to suffering from pain at the end of life. The majority of parents reported that their children experienced substantial suffering from at least one symptom in the last month of life. Among the most commonly reported symptoms was pain, which was actively treated in 76 percent of the children. However, based on the parents' reports, such treatment was successful in providing pain relief in only one child in three (Wolfe, Grier, et al., 2000).

Similar questions have been raised about the adequacy of pediatric care for attention-deficit/hyperactivity disorder (ADHD), which is estimated to affect about six percent of children and youth (Dey and Bloom, 2005; Secnik, Swenson, et al., 2004; Swensen, Birnbaum, et al., 2003).

Although the treatment of ADHD sometimes is categorized as either pharmacologic or non-pharmacologic, this is a somewhat artificial distinction because the two approaches are not mutually exclusive and often are used concurrently (Brown, Amler, et al., 2005; Remschmidt, 2005). Following an extensive review of the literature on ADHD, the Committee on Quality Improvement of the American Academy of Pediatrics (AAP) concluded that "the evidence strongly supports the use of stimulant medications for treating the core symptoms of children with ADHD and, to a lesser degree, for improving functioning" (Brown, Amler, et al., 2005).

Enrollment in Research and Clinical Trials. The conduct of research and clinical trials requires a distinct shift in attitudes and procedures from ordinary clinical practice, insofar as such trials require a proactive approach to the identification and recruitment of trial participants (Anderson, Kragstrup, et al., 2006; Greenhill, Vitiello, et al., 2003; Trauth, Musa, et al., 2000; Kiev, 1997; Howard and Beckwith, 1996). Any factor – such as a CSMP – that discourages physicians from referring patients to research or clinical trials, or that discourages patients from following through on such a referral, conceivably could exert a negative effect on the quality of the ensuing research.

ASSESSMENT

PURPOSE OF THE ASSESSMENT

In conformance with the language of the National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER; Public Law 109-60), the primary purpose of this assessment is to determine whether or not State CSMPs have had a "substantial negative impact" on patients' access to treatment.

The language of the NASPER requires that the assessment address the following questions:

- Have CSMPs negatively affected access to treatment for pain?
- Have CSMPs negatively affected access to treatment for addictive disorders?
- Have CSMPs negatively affected access to treatment for children and adolescents?
- Have CSMPs negatively affected enrollment in research and clinical trials?

According to the general directions contained in NASPER, this report focuses solely on the impact of CSMPs on access to care. Thus, information as to whether or not CSMPs in general, or a particular State's program, have been successful in reducing drug diversion and abuse was excluded from the assessment.

METHODOLOGY AND SOURCES OF INFORMATION

The assessment employed four approaches to information-gathering: literature review, data analysis, key informants, and publicly available information. The methods specific to each of the components of the assessment are described in the report (Appendix A).

ASSESSMENT FINDINGS

Because of the brief period of time afforded by NASPER and the relative recency of significant changes in CSMPs (i.e., conversion of CSMPs to electronic monitoring, the initiation of data-sharing with physicians and other practitioners, the establishment of web-based portals for practitioner access, and the elimination in all but one State of separate serialized prescriptions for certain controlled substances), it was not possible to gather sufficient data to support a robust conclusion as to whether or not current CSMPs have a substantial negative effect on access to treatment. However, the assessment did compile information that may be useful.

The information gathered for the assessment suggests that some CSMPs (largely the older multiple-copy programs), through their design or operation or both, have had a negative impact on some patients' access to accepted pharmacologic treatments. This effect is seen most clearly with patients' access to opioids for the treatment of pain, but may exist in subtler forms.

Access to Pain Treatment. Evidence that some CSMPs may exert a negative impact on patients' access to pain treatment was consistent across the literature review, the data analysis, and the information gathered from key informants. The negative effect was particularly pronounced in jurisdictions where a CSMP required the use of a special prescription form, and/or where the CSMP covered Schedule II but not Schedule III analgesics.

OPIOID ANALGESICS: All of the opioid analgesics used to control moderate to severe pain are classified as Schedule II drugs under the Federal Controlled Substances Act and thus are subject to the requirements of every State's CSMP. Results of the assessment suggest that some CSMPs may have an adverse effect on patients' access to analgesics used for pain relief. In addition, the literature makes clear that a large number of practitioners, policy analysts, and patient advocates have come to believe that CSMPs are an impediment to appropriate care.

For the assessment, nine States were identified that had enacted a CSMP between 1997 and 2004 (the period in which ARCOS data for drugs of interest were available online). The dosage units in grams per 100,000 population for oxycodone, hydromorphone, hydrocodone, and morphine then were graphed by year for the period preceding and following enactment of the CSMP. Similar data were graphed for control States (that is, States without a CSMP) for the same period of time.

To examine the possibility that the presence of a CSMP in one State might have an effect on prescribing and drug use activity in an adjacent State, ARCOS data for two of the most heavily distributed Schedule II drugs (hydrocodone and oxycodone) were arrayed in dosage units per 100,000, by quintiles, and multiple points of comparison were examined. The comparison showed no differences in the distribution of the study drugs between the CSMP and non-CSMP States during the period 1997-2004.

To determine whether the presence of a CSMP in one State had any effect on activity in an adjacent State, ARCOS data for hydrocodone and oxycodone were arrayed in dosage units per 100,000, by quintiles, and multiple points of comparison were examined. In all cases, the ARCOS data did not show any effect of a CSMP in one State on drug distribution to adjoining States.

In summary, the ARCOS data for CSMP and non-CSMP States showed virtually no differences in the prescribing of the study drugs, either in comparison to the control States or to national averages (Exhibit 3). Also using the ARCOS data, analysis showed little difference between CSMP and non-CSMP States in State rankings by per capita consumption of opioid analgesics (Exhibit 4).

However, these data need to be approached with caution for two reasons. First, as discussed by Brushwood (2003), the true measure of impact is in the difference between the amount of drug actually used and the amount that would have been used if a CSMP had not been in place. Unfortunately, we do not have a dataset that can provide that information, although some of the published comparisons of contiguous States are proxies for such a measure.

Second, ARCOS is an excellent indicator of drug distribution, but cannot track drug use. The differences are important, because hospitals, pharmacies and others order supplies of drugs (and DEA sets the quotas for their manufacture and distribution) based on past utilization.

Exhibit 3. Per Capita Distribution of Selected Opioid Analgesics to CSMP and Non-CSMP States, 2004*

	Morphine	Hydromorphone	Hydrocodone	Oxycodone
CSMP States				
Hawaii	8,047.58	170.49	5,169.88	10,042.17
Idaho	4,261.51	146.89	10,699.35	7,381.04
Illinois	2,858.31	158.66	6,304.06	3,521.68
Kentucky	3,962.39	180.73	16,989.12	11,030.94
Maine	7,796.42	262.23	6,628.91	16,771.24
Michigan	5,407.48	199.12	9,651.62	7,257.48
New York	3,347.83	285.86	5,801.14	6,884.52
Tennessee	12,821.03	292.36	17,654.78	17,304.90
Texas	3,364.40	167.95	11,874.07	4,299.17
Non-CSMP States				
Colorado	5,855.25	290.68	6,225.51	10,532.56
New Hampshire	5,769.75	312.54	3,543.24	14,516.92
Wisconsin	5,259.85	129.61	5,269.50	11,537.22
National Average	5,155.34	235.96	8,670.19	10,504.76

*In grams per 100,000 population

Source: Drug Enforcement Administration, ARCOS 2, 2005.

Exhibit 4. Relative Ranking of CSMP and Non-CSMP States by Per Capita Distribution of Selected Opioid Analgesics, 2004*

	Morphine	Hydromorphone	Hydrocodone	Oxycodone
CSMP States				
Hawaii	7	40	40	30
Idaho	34	45	14	41
Illinois	51	44	31	51
Kentucky	38	35	3	26
Maine	10	21	29	8
Michigan	21	29	18	44
New York	46	18	36	45
Tennessee	1	16	2	7
Texas	45	41	10	50
Non- CSMP States				
Colorado	15	17	32	29
New Hampshire	16	13	46	15
Wisconsin	23	48	39	25

*In grams per 100,000 population

Source: Drug Enforcement Administration, ARCOS 2, 2005.

Occasionally, an event (such as the negative media reports about OxyContin, or implementation of a CSMP) changes prescribing behaviors in ways that are not immediately detectable. Also, pharmacies routinely resell unused drug supplies to "reverse distributors" and, for a variety of technical reasons, these transactions are not always reflected in the ARCOS data.

For these and other reasons, the Medical Expenditure Panel Survey (MEPS) is a better system than ARCOS for monitoring actual drug use because it tracks prescriptions as they are dispensed to consumers. MEPS is an ongoing survey by the Center for Financing Access and Cost Trends of the Agency for Healthcare Research and Quality (AHRQ) that collects nationally representative data on health care utilization, expenditures, sources of payment, insurance coverage, and health status for the U.S. civilian, non-institutionalized population.

In fact, data from MEPS did show an effect of CSMPs on prescriptions for opioid analgesics. For example, Exhibit 5 presents unadjusted mean purchases by persons living in States with and without a CSMP.

In the MEPS data, 2.90 percent of persons in non-CSMP States purchased at least one Schedule II opioid analgesic during each year of the study period. This was approximately twice the rate (1.16 percent) found in States that did have a CSMP. Differences between CSMP and non-CSMP States in purchases of Schedule III analgesics were not statistically significant.

Exhibit 6 presents coefficient estimates for Ordinary Least Squares (OLS) models. These coefficient estimates are similar to the estimates of means in Exhibit 5, but differ in two ways: first, the coefficients are estimates of differences over time in the means (rather than the actual means); second, the coefficients are adjusted for differences in individuals' demographic characteristics and health status, which may vary across States.

In most cases, the coefficients shown in Exhibit 6 present a very similar picture to the unadjusted means shown in Exhibit 5. However, an important difference between Exhibits 5 and 6 is seen in the data on non-Schedule II opioid analgesics. There, the study found a statistically significant difference between CSMP and non-CSMP States. Specifically, investigators found that persons living in a State with a CSMP are 0.95 percentage points more likely to use at least one non-Schedule II opioid analgesic during the year, and to have about 3.6 more purchases per 100 persons, than are persons living in States without a CSMP.

This suggests the type of "substitution effect" (that is, switching from a higher-scheduled drug covered by a CSMP to a lower-scheduled drug that is not covered) posited by Twillman (2006), based on an examination of retail drug distribution patterns in CSMP and non-CSMP States. Using ARCOS data for Schedule II and III drugs, Twillman found that distribution of Schedule II opioid analgesics was lower in CSMP States than in non-CSMP States (morphine and oxycodone appeared to be the most strongly affected), but that CSMP States reported significantly higher distribution of Schedule III analgesics, particularly combination products containing hydrocodone (Exhibit 7). Specifically, in States in which the CSMP monitored only Schedule II drugs, Twillman found significantly less prescribing of morphine and oxycodone than in States where the CSMP covered both Schedule II and III drugs. In fact, in the latter States, prescribing of Schedule II and Schedule III analgesics did not differ significantly from States without a CSMP in the distribution of any opioid analgesic *except* for Schedule II

hydrocodone combination products, which were prescribed at a much higher rate in the CSMP than the non-CSMP States.

The study by Curtis, Stoddard and colleagues (2006a, b) used the largest database and showed the clearest association – independent of all other variables – between the presence of a CSMP and reduced rates of opioid distribution. These investigators used the outpatient drug claims database of a national pharmacy benefit manager (Advance PCS, since acquired by Caremark Rx, Inc.) to examine geographic variations in outpatient prescriptions for opioid analgesics. They focused on geographic variation as a measure of the impact of State policies on use of opioid analgesics. Their work built on a 1996 study by Wastila and Bishop, which used data from the National Ambulatory Medical Care Survey to show that physicians in States in which the CSMPs required special prescription forms were less likely to prescribe opioids during an office visit than physicians in a non-CSMP State.

Exhibit 5. Average Number of Purchases Per Person of Schedule II Drugs in CSMP and Non-CSMP States, 1996-2003

	Percent of Population with Any Prescriptions								
	All Years 1996-2003			1996			2003		
State CSMP Category	With CSMP[1]	No CSMP		With CSMP	No CSMP		With CSMP	No CSMP	
Type of Drug									
All Schedule II Drugs	1.97	3.94	*	1.42	3.14	*	2.66	4.63	*
Schedule II:									
Opioid Analgesic	1.16	2.90	*	0.81	2.24	*	1.64	3.52	*
Stimulant	0.82	1.08	*	0.62	0.93		1.02	1.17	
Non-schedule II:									
Opioid Analgesic	7.56	7.46		8.05	8.07		7.93	8.12	
	Number of Prescriptions Per 100 Persons[2]								
	All Years 1996-2003			1996			2003		
State CSMP Category	With CSMP	No CSMP		With CSMP	No CSMP		With CSMP	No CSMP	
Type of Drug									
All Schedule II Drugs	9.4	16.2	*	6.2	10.1	*	13.5	20.3	*
Schedule II:									
Opioid Analgesic	4.7	9.0	*	2.2	4.5	*	6.9	11.9	*
Stimulant	4.7	7.2	*	3.9	5.6		6.6	8.4	
Non-schedule II:									
Opioid Analgesic	18.6	18.1		20.9	19.0		20.4	20.1	

[1] "With CSMP" indicates that States implemented a program to monitor Schedule II drugs prior to 1996. "No CSMP" indicates that States had not implemented a program to monitor schedule II drugs by 2003.
[2] Use is estimated across all persons in the non-institutionalized U.S. population, regardless of whether they had any drug purchases during the year.

*The difference between the "With CSMP" and "No CSMP" estimate is significant at $p < .05$, or better.

Source: Preliminary estimates are based on the 1996-2003 MEPS: Center for Financing, Access and Cost Trends, Agency for Healthcare Research and Quality.

Exhibit 6. Association of State CSMP Category with the Probability of Any Schedule II Drug Use and With the Number of Purchases of Schedule II Drugs, 1996-2003

Percent of Population with Any Prescriptions

	All Years 1996-2003			1996			2003		
State CSMP Category	With CSMP[1]	No CSMP		With CSMP	No CSMP		With CSMP	No CSMP	
Type of Drug									
All Schedule II Drugs	1.97	3.94	*	1.42	3.14	*	2.66	4.63	*
Schedule II:									
Opioid Analgesic	1.16	2.90	*	0.81	2.24	*	1.64	3.52	*
Stimulant	0.82	1.08	*	0.62	0.93		1.02	1.17	
Non-schedule II:									
Opioid Analgesic	7.56	7.46		8.05	8.07		7.93	8.12	

Number of Prescriptions Per 100 Persons[2]

	All Years 1996-2003			1996			2003		
State CSMP Category	With CSMP	No CSMP		With CSMP	No CSMP		With CSMP	No CSMP	
Type of Drug									
All Schedule II Drugs	9.4	16.2	*	6.2	10.1	*	13.5	20.3	*
Schedule II:									
Opioid Analgesic	4.7	9.0	*	2.2	4.5	*	6.9	11.9	*
Stimulant	4.7	7.2	*	3.9	5.6		6.6	8.4	
Non-schedule II:									
Opioid Analgesic	18.6	18.1		20.9	19.0		20.4	20.1	

[1] "With CSMP" indicates that States implemented a program to monitor Schedule II drugs prior to 1996. "No CSMP" indicates that States had not implemented a program to monitor schedule II drugs by 2003.

[2] Use is estimated across all persons in the non-institutionalized U.S. population, regardless of whether they had any drug purchases during the year.

*The difference between the "With CSMP" and "No CSMP" estimate is significant at $p < .05$, or better.

Source: Preliminary estimates are based on the 1996-2003 MEPS: Center for Financing, Access and Cost Trends, Agency for Healthcare Research and Quality.

Exhibit 7. Patterns of Retail Distribution of Opioid Analgesics in CSMP and Non-CSMP States Compared, 2003*

Drug	No CSMP Mean	CSMP Mean	Percent Change	*p*
Oxycodone	11,292	9,540	-15.5	0.167
Morphine	4,927	4,397	-10.8	0.359
Fentanyl	117	114	-2.6	0.657
Hydromorphone	216	197	-8.8	0.434
Meperidine	2,246	1,739	-22.6	0.184
Codeine	6,937	8,451	+21.8	0.026
Hydrocodone	6,938	10,076	+45.2	0.014

*All amounts expressed in grams/100,000 population.

Source: Adapted from Twillman R (2006). Impact of prescription monitoring programs on prescription patterns and indicators of opioid use. *The Journal of Pain* 7(4) Suppl 1:7.

In their study, Curtis, Stoddard et al. examined State-level prevalence of and variations in the prescribing of Schedule II opioid analgesics. They also examined the influence of a variety of factors – including CSMPs – on county-level rates of drug claims for all opioid analgesics and for controlled-release oxycodone (such as OxyContin®).

The data set used in the study included all prescription drug claims for more than 7 million persons who were enrolled continuously during calendar year 2000 and who filed at least one prescription drug claim for any drug in that year. A total of 1,171 health insurers – covering all 50 States, the District of Columbia, and the Virgin Islands – were represented in the data.

Based on 567,778 claims for oral opioid analgesics, the investigators calculated a national average of 74.2 opioid claims per 1,000 total claims; however, they found distinct geographic variations, with ratios ranging from less than 20 to more than 100 opioid claims per 1,000 total claims. The lowest rates were found in States with long-standing CSMPs (Exhibit 8).

The authors cautioned that the data do not allow an interpretation as to whether the association between CSMPs and lower rates of opioid claims should be attributed to a reduction in either appropriate or inappropriate prescribing. Instead, they recommended additional studies using individual-level data to make this important distinction (Curtis, Stoddard, et al., 2006a).

Exhibit 8: Rate of Claims for Opioid Analgesics Per 1,000 Total Drug Claims in CSMP and Non-CSMP States Compared, 2000

	Subjects	Total Claims	Total Claims* for All Oral Opioid Analgesics**
CSMP States			
Hawaii	1,202	3,299	244 (74.0)
Idaho	20,156	22,181	542 (24.4)
Illinois	613,439	734,358	6,608 (9.0)
Kentucky	159,516	195,977	16,576 (84.6)
Maine	18,253	21,345	1,908 (89.4)
Michigan	163,493	187,931	2,893 (15.4)
New York	298,827	282,339	4,730 (16.8)
Tennessee	454,005	568,110	59,194 (104.2)
Texas	498,039	594,619	8,640 (14.5)
Non-CSMP States			
Colorado	167,841	183,193	15,796 (86.2)
New Hampshire	19,132	24,378	2,498 (102.5)
Wisconsin	104,788	122,552	5,537 (45.2)

*Values are expressed as number (claims per 1,000 total claims).
**Opioid analgesics include codeine phosphate, codeine sulfate, hydromorphone, levorphanol, meperidine, meperidine and promethazine combination, methadone, morphine, oxycodone, oxycodone and acetaminophen combination, and oxycodone and aspirin combination.

Source: Adapted from ~~Curtis LH, Stoddard~~ J, ~~Radeva JI~~, et al. (2006a). Geographic variation in the prescription of schedule II opioid analgesics among outpatients in the United States. *Health Services Research* Jun; 41:837-855.

NON-OPIOID MEDICATIONS. In the peer-reviewed literature, the effect of CSMPs on medications other than opioids has not been examined closely; however, a pair of studies focusing on the addition of benzodiazepines to the New York triplicate prescription program yields interesting results. In 1989, New York State added benzodiazepines to its existing CSMP, which previously had been limited to Schedule II drugs. The result of the change was that, for the first time, New York physicians were required to write prescription orders for benzodiazepines on triplicate prescription forms, with one copy of each form forwarded by the dispensing pharmacy to a State surveillance unit.

To assess the impact of this policy change, Ross-Degnan et al. (2004) employed interrupted time series analyses of benzodiazepine prescriptions in the New York (intervention) and New Jersey (control) Medicaid programs for 12 months before and 24 months after New York added benzodiazepines to its CSMP.

In the year preceding the policy change, 20.2 percent of the New York cohort and 19.3 percent of the New Jersey cohort received at least one prescription for a benzodiazepine. In the 24 months after the effective date of the new requirement, there was a 54.8 percent reduction in benzodiazepine prescriptions in New York, but no change in benzodiazepine prescribing in New Jersey.

PERSISTENCE OF THE EFFECT: In a second study of the addition of benzodiazepines to New York's triplicate prescription program, which was designed to address the effects of the program change over time, the same group of investigators examined benzodiazepine prescribing in New York State at two and seven years after the program change. Again using interrupted time series and logistic regression analyses, they examined data from 124,867 non-institutionalized persons aged 18 years or older who had been enrolled continuously in New York's Medicaid program during the 12 months preceding, and at two and seven years following the addition of benzodiazepines to the State's CSMP (Pearson, Soumerai, et al., 2005).

The Medicaid data showed a sustained reduction in the number of benzodiazepine prescriptions even seven years after the program change. Moreover, even after adjusting for gender, Medicaid eligibility status, neighborhood poverty, and baseline use of the drug, the investigators found that black study subjects were more likely than white subjects to have had their use of benzodiazepines discontinued. Even though Medicaid enrollees in predominantly black neighborhoods had the lowest rates of benzodiazepine use at baseline, they also experienced the highest rates of discontinuation of therapy after introduction of the CSMP. This difference persisted over time.

The investigators concluded that, while the CSMP appeared to have reduced inappropriate prescribing of benzodiazepines, it also resulted in an unintended decrease in therapeutic use that disproportionately affected black populations (Pearson, Soumerai, et al., 2006).

Comparable results have been reported in other studies by the same group of investigators (Khandker and Simoni-Wastila, 1998), as well as in studies by Edwards, Fillingim and Keefe (2001), Bonham (2001), Cleeland, Gonin, et al. (1997), Fillenbaum, Horner, et al. (1996); and Fillenbaum, Hanlon, et al. (1993) and Green, Anderson, et al. (2003).

Addiction Treatment. The evidence as to whether CSMPs have had an adverse effect on patients' access to opioid agonist therapies for addiction (e.g., treatment with methadone or buprenorphine) was not consistent across the literature review, the data analysis, and the key informants' responses.

While the ARCOS data provide some evidence that the presence of a CSMP may have an adverse effect on the use of methadone to treat addiction, the number of confounding variables (including other Federal and State requirements, the gap between treatment need and availability, and practitioner and public attitudes toward methadone and addictive disorders) is too large to draw a definitive conclusion.

Pediatric Care. The evidence that CSMPs have an adverse effect on the prescribing of opioids for pain is sufficiently strong, and the history of undermedicating pain in children is so clear, as to raise concerns about a potential effect of CSMPs on pain management in pediatric patients. Given that cancer is (after traumatic injury) the second leading cause of death in children under age 12, this is a significant concern. Similarly, reports showing that children who are appropriately treated for ADHD are actually less likely to engage in later substance abuse than untreated or inadequately treated children argue for a closer look at the effect of CSMPs on access to such pharmacotherapies.

However, in the current study, the data analysis yielded little direct evidence as to whether CSMPs have had an adverse effect on pediatric patients' access to care. The difficulty of segmenting the pediatric population and the drugs prescribed for them are a particular impediment in this regard. As a result, no clear conclusion can be drawn, pending the results of additional studies. Of particular interest would be studies involving community-based practitioners and institutions, as well as institutions and practitioners who specialize in pediatric oncology and ADHD.

Research and Clinical Trials. The assessment found little published literature and no data sets that address the effect of CSMPs on enrollment in clinical trials.

Summary of Findings. There continues to be disagreement as to whether CSMPs exert a negative effect on prescribing for pain and other medical disorders.

With one exception, the assessment did not have access to an evaluation of this problem by the CSMP States themselves. Of the 11 reports obtained from CSMP States (Appendix D), only the report from Virginia addresses the question of a potential "chilling effect" on prescribing for pain. Virginia adopted an electronic CSMP in 2002 as a pilot program in the southwestern region of the State (Health Planning Region III). The CSMP became operational in September 2003. The report incorporates data on 2002, 2003, and 2004, and so captures the period immediately preceding and following implementation of the CSMP (Department of Health Professions and Virginia State Police, 2004). The executive summary of the report states "review of data collected thus far appears to show that implementation of the program has not had a 'chilling' effect on the legitimate prescribing of Schedule II controlled substances. The amount of oxycodone and hydrocodone being distributed in wholesale distribution channels continued to increase throughout Virginia at a rate of 9 percent and 8 percent respectively in 2002 and 2003. Information maintained by the Department of Medical Assistance Services (DMAS) shows that after a substantial drop in claims for oxycodone containing prescriptions in

the first and second quarters of 2002, the number of claims submitted in the first quarter of 2004 for these products are 21 percent higher than they were in the first quarter of 2001" (Department of Health Professions and Virginia State Police, 2004, pages iv-v).

CONCERN ABOUT DRUG DIVERSION AND ABUSE: Some experts have suggested that a significant barrier to the use of opioids to treat pain is that physicians, pharmacists, and other clinicians have difficulty discerning the difference between a patient who legitimately suffers pain and one who is pretending to be in pain for the sake of obtaining drugs (Brushwood, 2003; FSMB, 2001). This is based on the fact that chronic pain is a disorder that cannot be ruled out by an evaluation of laboratory values, radiological imaging, or a physical examination. Physicians must rely largely on patient interviews and histories to evaluate the presence and intensity of pain, and thus to determine a patient's need for pain medications (Patel and Ogle, 2000). This is a complex process that involves a large element of experience and judgment (NIDA, 2001).

Such factors were examined in a survey of Virginia physicians conducted in mid-2004 and compiled by the Survey and Evaluation Research Laboratory of Virginia Commonwealth University. In the survey, physicians were asked if in the preceding three years, they had prescribed fewer Schedule II medications. A little more than a third of the respondents said that, in fact, they had reduced their prescribing of Schedule II drugs. Of this group, 48 percent cited intense media coverage of drug diversion as the reason, while and 41 percent cited increased law enforcement activity. Almost a third (31 percent) acknowledged that prescribing fewer Schedule II drugs had a negative effect on helping patients manage their pain (Department of Health Professions and Virginia State Police, 2004, pages iv-v).

Access to care also may be impeded by policies that create confusion about the distinctions between addiction, tolerance and physical dependence (FSMB, 1998). For example, a physician who receives information from a CSMP showing that a patient has received pain medications from multiple physicians may incorrectly conclude that the patient is a "doctor-shopper" for whom pain medications should not be provided, rather than an individual whose pain has been inadequately treated (Brushwood, 2003; Passik and Kirsh, 2004).

LACK OF UNDERSTANDING OF THE CSMP: Physicians' lack of understanding of the goals and operations of CSMPs was cited by Barrett and Watson (2005) as a result of their 2003 survey of 672 physicians in southwest Virginia. Conducted during implementation of a pilot electronic CSMP in that part of the State, the mailed survey was designed to elicit physicians' knowledge of and attitudes toward the CSMP, as well as to assess its likely impact on their opioid prescribing behaviors. A total of 275 surveys were returned (a response rate of 41 percent). Less than half the responding physicians said they were aware of the CSMP before receiving the survey.

A total of 68 percent of the respondents said they expected the CSMP to be helpful in monitoring patients' prescription histories and reducing "doctor shopping," although only 11 percent had actually requested information from the prescription monitoring program database (Barrett and Watson, 2005).

Uncertainty about Standards of Care: Physicians' inadequate knowledge of pain control standards and protocols is a theme that runs through many current studies (Brushwood, 2003). In 1997, The American Academy of Pain Medicine and the American Pain Society identified the

following issues as sources of confusion to prescribing physicians and thus as potential impediments to adequate management of pain.

- *Addiction:* Misunderstanding of addiction and mislabeling of patients as addicts result in unnecessary withholding of opioid medications. Addiction is a compulsive disorder in which an individual becomes preoccupied with obtaining and using a substance, the continued use of which results in a decreased quality of life. Studies indicate that the *de novo* development of addiction when opioids are used for the relief of pain is a relatively infrequent event. Moreover, experience shows that even addicted individuals can benefit from the carefully supervised, judicious use of opioids for the treatment of pain resulting from cancer, surgery, traumatic injury, or illnesses such as sickle cell disease.
- *Respiratory Depression and Other Side Effects*: Fear of inducing respiratory depression is cited by physicians as a factor that limits the use of opioids in pain management. However, respiratory depression induced by opioids tends to be a short-lived phenomenon, generally occurs only in the opioid-naive patient, and is antagonized by pain. Therefore, withholding appropriate opioid analgesics from a patient who is experiencing pain because of respiratory concerns is unwarranted.
- *Tolerance*: Many physicians incorrectly believe that the development of tolerance to opioid analgesics limits the efficacy of such drugs for the long-term management of pain. Tolerance – which results in reduced pain relief with the same dose over time – has not proved to be a prevalent limitation to long-term opioid use. Experience with treating cancer pain has shown that what initially appears to be tolerance often is caused by progression of the disease.
- *Diversion:* Attention to patterns of prescription requests, as well as prescribing opioid analgesics as part of an ongoing relationship between a patient and a health care provider can reduce the risk of diversion without impeding patient care (AAPM and APS, 1997).

AVOIDANCE OF REGULATORY OVERSIGHT: In 1990, experts at the World Health Organization hypothesized that, in the presence of CSMPs, health care professionals may be reluctant to prescribe, stock or dispense opioids if they perceive a possibility that their professional licenses would be suspended, even though the medical need for such actions could be demonstrated (WHO, 1990). Similar concerns are found in the results of a survey by Barrett and Watson (2005), in which nearly 60 percent of the respondents said that Virginia's implementation of a CSMP would result in their prescribing behaviors being more closely monitored.

Concern about regulatory oversight also is evident in a survey of physicians by Weinstein and colleagues (2000), in which 23.8 percent of respondents agreed with the statement, "I give my patients a limited supply of pain medication to avoid being investigated." In the same survey, 26.4 percent of physicians said they were concerned about an investigation by regulators if they prescribed controlled substances for a chronic pain patient (Barrett and Watson, 2005).

Similar results have been found in surveys of family physicians in West Virginia (n = 186; Ponte and Johnson-Tribino, 2005), primary care physicians in California (n = 161; Potter, Schafer, et al., 2001), and even abroad. For example, in a telephone survey of Canadian physicians (Morley-Forster, Speechley et al., 2003, n = 100), 35 percent of general practitioners and 10

percent of palliative care specialists cited fear of regulatory sanctions as a barrier to opioid prescribing.

The impact of these attitudes was explored in a survey conducted in mid-2004 and compiled by the Survey and Evaluation Research Laboratory of Virginia Commonwealth University. In the survey, physicians were asked if in the preceding three years, they had prescribed fewer Schedule II medications. Almost a third (31 percent) acknowledged that prescribing fewer Schedule II drugs had a negative effect on helping patients manage their pain (Department of Health Professions and Virginia State Police, 2004, pages iv-v).

AVOIDANCE OF SPECIAL PRESCRIPTION ORDER FORMS: The administrative burden associated with obtaining, storing, and using multiple-copy or other special prescription forms may tend to suppress prescribing. However, only one State now requires use of a State-issued serialized form for a limited number of drugs and the future impact of the forms likely will lessen.

ANXIETY TRIGGERED BY HIGH-PROFILE CASES: High-profile arrests and prosecutions focus physicians' attention on the risks entailed in prescribing controlled substances in general, and have the specific effect of increasing physicians' and pharmacists' reluctance to prescribe, stock or dispense opioid analgesics (Brushwood, 2003; Fishman, 2006a).

NEGATIVE STEREOTYPES ASSOCIATED WITH PATIENTS' DEMOGRAPHIC OR ECONOMIC STATUS: A number of studies published over more than a decade report that CSMPs have had a disproportionately negative effect on access to care among certain patient populations (Payne, Medina, et al., 2003; Freeman and Payne, 2000; Morrison, Wallenstein, et al., 2000; Todd, Deaton, et al., 2000; Ng, Dimsdale, et al., 1996; Schneider, Zaslavsky, et al., 2002). The effect appears to be correlated most strongly with race and ethnicity, but some studies also have found correlations with age and gender, economic status, and certain stigmatized clinical diagnoses such as HIV.

Poverty also appears to be a factor. Medicaid eligibility is a widely accepted proxy for economic status, and one that has been used by a number of investigators to assess the effect of CSMPs on economically disadvantaged populations (Gornick, Eggers, et al., 1996; Khandker and Simoni-Wastila, 1998; Swartz, Landerman, et al., 1991). McNutt, Coles, et al. (1994), also examined the effect of income and found that low-income elderly in New York State received prescriptions for benzodiazepines at a rate less than that for the population as a whole.

What the data alone cannot do is explain the reasons for the differences. Morrison, Wallenstein, et al. (2000) examined this question, based on their observation that many black and Hispanic patients who were receiving palliative care at a major urban teaching hospital were unable to obtain prescribed opioids from their neighborhood pharmacies.

For their study, investigators calculated that 176 pharmacies (51 percent) did not carry sufficient supplies of opioids to treat patients with severe pain. In predominantly non-white neighborhoods, only 25 percent of pharmacies had opioid supplies sufficient to treat patients with severe pain. In predominantly white areas, by contrast, 72 percent of pharmacies had sufficient supplies.

Morrison and colleagues concluded that stereotypes about race and ethnicity contribute to pharmacists' or pharmacy owners' decisions as to what supplies of opioid analgesics to carry in stock. Patients' reports that local pharmacies do not carry certain medications in stock may be a factor physicians will take into account when deciding which drug to prescribe.

CONCLUSIONS

There is widespread agreement that diversion and abuse of prescription medications are large and growing problems. For example, in 2005, an estimated 33 million persons had used pain relievers nonmedically in their lifetime, 19 million had engaged in nonmedical use of stimulants, and 21 million used tranquilizers nonmedically in their lifetime (OAS, 2006a). Data from DAWN show that the most frequent diagnoses for ED visits involving the nonmedical use of pharmaceuticals were overdose (in 38 percent of the visits) and depression or another psychiatric condition (23 percent of visits). Toxic effects were reported in 10 percent of visits (OAS, 2006b). Reports on admissions to addiction treatment programs show that, in the decade between 1992 and 2002, admissions for problems with opioid analgesics more than doubled. (While such treatment admissions increased for all age groups, the increase was especially notable among persons aged 20 to 30 [OAS, 2004].)

CSMPs have been developed and refined over a period of 60 years to address this persistent problem. Yet some CSMPs appear to have some negative effects: information analyzed for the assessment suggests that some CSMPs – through their design or operation, or both – have exerted a negative impact on some patients' access to accepted pharmacologic therapies. This effect is seen most clearly with the older multiple-copy prescription programs, and the effect is most dramatic on patients' access to opioids for the treatment of pain, but there may be more subtle effects involving other medications and populations as well.

What the available information sources do not reveal are the reasons a CSMP would exert such an effect. Nor do the data clearly demonstrate what other factors might be at work. Only further research will provide these answers.

LESSONS LEARNED FROM THE ASSESSMENT

Suggestions have been offered by a variety of individuals and organizations to strengthen prescription monitoring programs. For example, the Council of State Governments (2004) has advised that, in order to alleviate any concern about the effect of CSMPs on sound medical practice, certain objectives should be met. These include:

- Providing the medical community with detailed information as to the purpose of the CSMP;
- Devising clear policies with regard to the management of pain and other debilitating conditions (such as the model policies endorsed by the Federation of State Medical Boards, which have been adopted by more than 20 States); and
- Evaluating resulting prescribing trends and program effectiveness.

In a June 2002, "Statement on State Prescription Monitoring Programs," the American Alliance of Cancer Pain Initiatives (AACPI) offered similar suggestions that appear to be consistent with

the intent of Congress in its passage of NASPER. AACPI, a national network of State, regional and Native American cancer pain initiatives, health care professionals, researchers, educators and patient advocates, recommended that CSMPs:

- Be administered by the State agency responsible for regulating healthcare;
- Adopt a number of design and organizational features to avoid the potential for CSMPs to suppress appropriate use of medications for patient care (e.g., avoiding the use of special prescription forms for certain drugs; monitoring of all medications in Schedules II, III, and IV; and incorporating safeguards to protect patient confidentiality);
- Establish an interagency diversion prevention and control program;
- Allow health care professionals access to CSMP data concerning their patients for use in evaluating the patients' use of controlled drugs;
- Allow law enforcement agencies to have access to the data when probable cause justifies such access in the course of investigating possible abuse or diversion;
- Establish a multidisciplinary medical review group (e.g., Nevada) to oversee the CSMP; and
- Provide educational programs to inform physicians and other health care professionals about the purpose of the CSMP (an approach that has been effectively employed in Michigan and Pennsylvania).

In another example, the American Academy of Pain Medicine (AAPM) and the American Pain Society (APS) jointly released a statement in 1997 that articulated a number of reasons for physicians' failure to adequately treat pain. These included concerns about addiction, respiratory depression and other side effects of opioid analgesics, the development of tolerance, worries about diversion, and fear of regulatory actions. To address these concerns, AAPM and APS recommend that practice guidelines be developed to help physicians appropriately manage acute and chronic pain as "an extension of the basic principles of good professional practice" (AAPM and APS, 1997). The societies endorsed the following content areas for such guidelines:

PATIENT EVALUATION: Evaluation should initially include a pain history and assessment of the impact of pain on the patient, a directed physical examination, a review of previous diagnostic studies, a review of previous interventions, a drug history, and an assessment of coexisting diseases or conditions.

TREATMENT PLANNING: Treatment planning should be tailored to both the individual and the presenting problem. Consideration should be given to different treatment modalities, such as a formal pain rehabilitation program, the use of behavioral strategies, the use of noninvasive techniques, or the use of medications, depending upon the physical and psychosocial impairment related to the pain. If a trial of opioids is selected, the physician should ensure that the patient or the patient's guardian is informed of the risks and benefits of opioid use and the conditions under which opioids will be prescribed. Some practitioners find a written agreement specifying these conditions to be useful. An opioid trial should not be done in the absence of a complete assessment of the pain complaint.

CONSULTATION AS NEEDED: Consultation with a specialist in pain medicine or with a psychologist may be warranted, depending on the expertise of the practitioner and the complexity of the presenting problem. The management of pain in patients with a history of addiction or a comorbid psychiatric disorder requires special consideration, but does not necessarily contraindicate the use of opioids.

PERIODIC REVIEW OF TREATMENT EFFICACY: Review of treatment efficacy should occur periodically to assess the functional status of the patient, continued analgesia, opioid side effects, quality of life, and indications of medication misuse. Periodic reexamination is warranted to assess the nature of the pain complaint and to ensure that opioid therapy is still indicated. Attention should be given to the possibility of a decrease in global function or quality of life as a result of opioid use.

DOCUMENTATION: Documentation is essential for supporting the evaluation, the reason for opioid prescribing, the overall pain management treatment plan, any consultations received, and periodic review of the status of the patient.

The societies also suggested that regulators would find practice guidelines helpful in targeting their investigative, educational, and disciplinary resources so as to address prescription drug diversion and abuse while avoiding interference with legitimate medical care (AAPM and APS, 1997).

KEY INFORMANT SUGGESTIONS

Key informants also offered suggestions to enhance the effectiveness of CSMPs and to minimize any adverse impact on patients' access to treatment. Their comments follow:

PROGRAM ADMINISTRATION:
"Programs should be administered by a State agency responsible for health matters and not by a law enforcement agency."

"Medical review groups should be created to assist in analysis of the data obtained and therefore to assure protection of legitimate prescribing and dispensing of controlled substances."

PROGRAM DESIGN:
"Programs should adequately address the differences between adults and children. 'One size fits all' doesn't apply here and we continue to advocate for a separate list and discussions for the pediatric population."

"Using a security prescription form for all schedules of medications should avoid the chilling effect that has characterized CSMPs historically."

"Eliminate inconsistencies – have the same rules and access across State lines."

ACCESS TO PROGRAM DATA:
"Prescribers should have timely access to data about their individual patients so they can use it in making critical clinical decisions."

"Data from CSMPs must be made available to clinicians at the point of care."

"Law enforcement agencies should only have access to the data when justified by probable cause; for example, when investigating possible diversion and abuse."

"The confidentiality of patients should be vigorously guarded."

PROVIDER EDUCATION AND COMMUNICATION:
"Educational programs should be developed to address health care professionals' perceptions about the risks of regulatory scrutiny and to assure that there is understanding of the laws and regulations that govern the prescribing and dispensing of controlled substances."

"Providing adequate pain management and preventing diversion and abuse of prescription controlled substances are both important public health goals. Achieving both goals requires exchange of information and perspectives, identification of issues, and concerted action. Increased communication and cooperation between regulatory and pain groups can contribute to a good balance between drug control and drug availability."

OUTCOMES EVALUATION:
"[There has been] little if any outcomes evaluation for efficacy and safety. If efficacy is evaluated, the outcome should be a reduction in diversion, but is usually the extent that prescriptions are reduced, which can have a detrimental impact on medication availability."

"There should be regular (ideally annual) assessment of health care professionals to determine the impact of CSMPs on their use of controlled substances for the treatment of pain, anxiety, insomnia, ADHD. How are CSMPs impacting the quality of patient care? Medical decisions should be based on appropriate assessment of patient needs, not on fears of regulators."

REFERENCES

Alliance for Model State Drug Laws (2006). *State Prescription Monitoring Statutes and Regulations Citation List*. Alexandria, VA: The Alliance.

Alliance of States with Prescription Monitoring Programs and National Association of State Controlled Substances Authorities (2002). *Background Information on the Prescription Monitoring Program Model Act.* Troy, NY: The Alliance and the Association, October.

Alliance of States with Prescription Monitoring Programs and National Association of State Controlled Substances Authorities (1999). *The Goals of Prescription Monitoring*. Troy, NY: The Alliance and the Association.

Alliance of States with Prescription Monitoring Programs (2006). *Alliance of States with Prescription Monitoring Programs Web site.* [On-line]. Retrieved October 16, 2006 from the World Wide Web: http://www.nascsa.org.

Amato L, Davoli M, Perucci CA et al. (2005). An overview of systematic reviews of the effectiveness of opiate maintenance therapies: Available evidence to inform clinical practice and research. *Journal of Substance Abuse Treatment,* 28: 321-329.

American Academy of Pain Medicine and American Pain Society (1997). *The Use of Opioids for the Treatment of Chronic Pain*. Glenview, IL.

American Academy of Pain Medicine, American Pain Society, and the American Society of Addiction Medicine (2001). *Definitions Related to the Use of Opioids in the Treatment of Chronic Pain.* Glenview, IL: American Pain Society.

American Alliance of Cancer Pain Initiatives (2002). *AACPI Statement on State Prescription Monitoring Programs*. Madison, WI: The Alliance, June.

American Bar Association (ABA) Commission on Legal Problems of the Elderly (2000). *Report to the House of Delegates — Proposed ABA Policy on Legal Obstacles to Effective Pain Management.* Chicago, IL: The Association, April (accessed at: www.abanet.org/ftp/pub/elderly/painmanagement.pdf).

American Chronic Pain Association (2005). *Medications and Chronic Pain: Supplement 2005.* Rocklin, CA: The Association.

American Geriatrics Society (AGS) Panel on Persistent Pain in Older Persons (2002). The management of persistent pain in older persons. *Journal of the American Geriatrics Society,* 50(6S):S205-S224 (accessed at: http://www.americangeriatrics.org/education/manage_pers_pain.shtml).

American Medical Association (1999). Use of Opioids in Chronic Noncancer Pain (Report 11 of the Council on Scientific Affairs). *Proceedings of the House of Delegates of the American Medical Association.* Chicago, IL: The Association (accessed at: www.amaassn.org/ama/pub/category/11541.html).

American Medical Association (2005). Pain Management Using Opioid Analgesics. *Proceedings of the House of Delegates of the American Medical Association.* Chicago, IL: The Association (accessed at: www.ama-assn.org/ama/pub/category/11541.html).

American Methadone Treatment Association (1998). *Survey of Methadone Treatment Programs*. New York, NY: The Association.

American Pain Society (1999). *Guideline for the Management of Acute and Chronic Pain in Sickle Cell Disease (Clinical Practice Guideline Number 1).* Glenview, IL: The Society.

American Pain Society (1999). *Guideline for the Management of Cancer Pain in Adults and Children (Clinical Practice Guideline Number 2).* Glenview, IL: The Society.

American Pain Society (2004). *Guideline for the Management of Acute and Chronic Pain in Sickle Cell Disease (Clinical Practice Guideline Number 1).* Glenview, IL: The Society.

American Pain Society (APS) (1999). *Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain, 4th Edition*. Glenview, IL: The Society.

American Psychiatric Association (1994). *Diagnostic and Statistical Manual of Mental Disorders, 4th Edition*. Washington, DC: American Psychiatric Press.

Anderson KO, Mendoza TR, Valero V, et al. (2000). Minority cancer patients and their providers: Pain management attitudes and practice. *Cancer,* 88(8): 1929-1938.

Anderson M, Kragstrup J and Sandergaard J (2006). How conducting a clinical trial affects physicians' guideline adherence and drug preferences. *Journal of the American Medical Association,* 295(23): 2759-2764.

Barrett K and Watson A (2005). Physician perspectives on a pilot prescription monitoring program. *Journal of Pain and Palliative Care Pharmacotherapies,* 19(3): 5-13.

Bearn J, de Wet C and Reed L (2005). Trends in prescribing buprenorphine (letter). *Addiction,* 100(9): 1374-1375.

Bernabei R, Gambassi G, Lapane K, et al. (1998). Management of pain in elderly patients with cancer. *Journal of the American Medical Association,* 279(23): 1877-1882.

Bjornstad G and Montgomery P (2005). Family therapy for attention-deficit disorder or attention-deficit/hyperactivity disorder in children and adolescents. *Cochrane Database System Review,* 18(2): CD005042.

Bonham V. (2001). Race, ethnicity and pain treatment: Striving to understand the causes and solutions to the disparities in pain treatment. *Journal Law Medical Ethics,* 29(1): 52-69.

Bossert EA, Van Cleve L and Savedra MC (1996). Children with cancer: The pain experience away from the health care setting. *Journal of Pediatric Oncologic Nursing,* 13(3): 109-120.

Breitbart W and Dibiase L (2002a). Current perspectives on pain in AIDS: Part 1. *Oncology,* 16(6): 818-835.

Breitbart W, Passik S, McDonald MV, et al. (1998). Patient-related barriers to pain management in ambulatory AIDS patients. *Pain,* 76, 9-16.

Brown RT, Amler RW, Freeman WS, et al., for the American Academy of Pediatrics Committee on Quality Improvement; Subcommittee on Attention-Deficit/Hyperactivity Disorder (2005). Treatment of attention-deficit/hyperactivity disorder: Overview of the evidence. *Pediatrics,* 115(6): 749-757.

Brushwood DB (2003). Maximizing the value of electronic prescription monitoring programs. *Journal of Law, Medicine and Ethics,* 31: 41-54.

CASA (2005). The National Center on Addiction and Substance Abuse at Columbia University. *Under the counter: The diversion and abuse of controlled prescription drugs in the U.S.*

Center for Substance Abuse Treatment (1999). *Treatment for Stimulant Use Disorders.* Treatment Improvement Protocol (TIP) Series 33. DHHS Publication No. (SMA) 99-3296, Rockville, MD: Substance Abuse and Mental Health Services Administration.

Center for Substance Abuse Treatment (2004). *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*. Treatment Improvement Protocol (TIP) Series 40. DHHS Publication No. (SMA) 04 -3939. Rockville, MD: Substance Abuse and Mental Health Services Administration.

Center for Substance Abuse Treatment (2005). *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*. Treatment Improvement Protocol (TIP) Series 43. DHHS Publication No. (SMA) 05-4048. Rockville, MD: Substance Abuse and Mental Health Services Administration.

Clark HW and Bizzell AC (2005). Federal perspective on the abuse of prescription stimulants. *Psychiatric Annals*, 35: 261-263.

Cleeland CS, Gonin R, Baez L et al. (1997). Pain and treatment of pain in minority patients with cancer. *Annals of Internal Medicine,* 127: 813-816.

Collins JJ, Grier HE, Kinney HC, et al. (1995). Control of severe pain in children with terminal malignancy. *Journal of Pediatrics*, 126(4): 653-657.

Compton WM and Volkow ND (2006). Abuse of prescription drugs and the risk of addiction. *Drug and Alcohol Dependence* (online; accessed May 26, 2006).

Cooper JR, Czechowicz DJ, Molinari SP, et al., eds. (1993*). Impact of Prescription Drug Diversion Control Systems on Medical Practice and Patient Care (NIDA Research Monograph 131).* Rockville, MD: National Institute on Drug Abuse, National Institutes of Health.

Council of State Governments (2004). Drug abuse in America – Prescription drug diversion. *Trends Alert.* Lexington, KY: The Council, April.

Curtis LH, Stoddard J, Radeva JI, et al. (2006a). Geographic variation in the prescription of schedule II opioid analgesics among outpatients in the United States. *Health Services Research*, 41: 837-855.

Curtis LH, Stoddard J, Radeva JI, et al. (2006b). Correction to "Geographic variation in the prescription of schedule II opioid analgesics among outpatients in the United States." *Health Services Research*, 41: 856-859.

Dasgupta N, Kramer ED, Zalman MA, et al. (2006). Association between non-medical and prescriptive usage of opioids. *Drug and Alcohol Dependence*, 82(2): 135-142.

Department of Health Professions and Virginia State Police (2004). *Prescription Monitoring Program.* Richmond, VA: Department of Health Professions and Virginia State Police.

Dey AN and Bloom B (2005). Summary: Health statistics for U.S. children: National Health Interview Survey, 2003. *Vital Health Statistics*, 223: 1-78.

Doyle AE, Willcutt EG, Seidman LJ et al. (2005). Attention-deficit/hyperactivity disorder endophenotypes. *Biological Psychiatry*, 57(11): 1324-1335.

Drayer RA, Henderson J, Reidenberg M (1999). Barriers to better pain control in hospitalized patients. *Journal of Pain and Symptom Management*, 17(6), 434-440.

Drug Enforcement Administration (DEA), Office of Diversion Control (2001). *21 Health Groups Call for Balanced Policy on Prescription Pain Medication Like OxyContin,* October 23 (accessed at: http://www.deadiversion.usdoj.gov/pubs/pressrel/newsrel_102301.pdf.

Drug Enforcement Administration (DEA), Office of Diversion Control (1990). *Physician's Manual: An Informational Outline of the Controlled Substances Act of 1970*. Washington, DC: U.S. Department of Justice, Drug Enforcement Administration.

Drug Enforcement Administration (DEA), Office of Diversion Control (2002). *Working to Prevent the Diversion and Abuse of OxyContin*® (accessed at: www.deadiversion.usdoj.gov/pubs/brochures/alert_oxycontin/alert_oxy.htm).

DuPont RL, chair (2005). *Non-Medical Use of Methylphenidate: Defining the Problem, Creating Solutions – Report of an Advisory Committee to the Institute for Behavior and Health.* Bethesda, MD: Institute for Behavior and Health.

Eadie J, personal communication, November 27, 2006.

Edwards CL, Fillingim RB and Keefe F (2001). Topical review: Race, ethnicity and pain. *Pain,* 94: 133–137.

Faraone SV, Perlis RH, Doyle AE, et al. (2005). Molecular genetics of attention-deficit/ hyperactivity disorder. *Biological Psychiatry,* 57(11): 1313-1323.

Federation of State Medical Boards of the United States, Inc. (1998). *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* (adopted May 2). Dallas, TX: The Board (accessed at: http://www.medsch.wisc.edu/painpolicy/domestic/model.htm).

Fiellin DA, Kleber H, Trumble-Hejduk JG et al. (2004). Consensus statement on office-based treatment of opioid dependence using buprenorphine. *Journal of Substance Abuse Treatment,* 27: 153-159.

Fillenbaum GG, Hanlon JT, et al. (1993). Prescription and nonprescription drug use among black and white community-residing elderly. *American Journal of Public Health*, 83(11): 1577-82.

Fillenbaum GG, Horner RD, Hanlon JT, et al. (1996). Factors predicting change in prescription and nonprescription drug use in a community-residing black and white elderly population. *Journal of Clinical Epidemiology,* 49: 587-593.

Fishman SM (2005). From balanced pain care to drug trafficking: The case of Dr. William Hurwitz and the DEA. *Pain Medicine,* 6(2): 162-164.

Fishman SM (2006a). Pain and politics: DEA, Congress and the courts (editorial). *Pain Medicine,* 7(1): 87-88.

Fishman SM (2006b). The DEA and pain medicine (editorial). *Pain Medicine* 7(1).

Flor H, Fydrich T and Turk DC (1992). Efficacy of multidisciplinary pain treatment centers: A meta-analytic review. *Pain,* 49: 221-230.

Frager G (1996). Pediatric palliative care: Building the model, bridging the gaps. *Journal of Palliative Care,* 12: 9-12.

Freeman HP and Payne R (2000). Racial injustice in health care. *New England Journal of Medicine,* 342: 1045-1047.

Fudala PJ and Woody GW (2004). Recent advances in the treatment of opiate addiction. *Current Psychiatry Reports,* 6: 339-346.

Gallagher R, Hawley P and Yeomans W (2004). A survey of cancer pain management knowledge and attitudes of British Columbian physicians. *Pain Research and Management* Winter; 9(4): 188-194.

Gaughan DM, Hughes MD, Seage GR, et al. (2002). The prevalence of pain in pediatric human immunodeficiency virus/acquired immunodeficiency syndrome as reported by participants in the Pediatric Late Outcomes Study. *Pediatrics,* 109(6): 1144-1152.

General Accounting Office (2002). *Prescription Drugs: State Monitoring Programs Provide Useful Tool To Reduce Diversion.* Washington, DC: GAO (GAO-02-634), May 17.

Gilson AM and Joranson DE (2002). U.S. policies relevant to the prescribing of opioid analgesics for the treatment of pain in patients with addictive disease. *Clinical Journal of Pain,* 18(4 Suppl): S91-S98.

Gilson AM, Joranson DE, Maurer MA, et al. (2005). Progress to achieve balanced state policy relevant to pain management and palliative care: 2000-2003. *J Pain Palliat Care Pharmacotherapy,* 19(1): 7-20.

Gilson AM, Maurer MA, and Joranson DE (2005). State policy affecting pain management: Recent improvements and the positive impact of regulatory health policies. *Health Policy,* 74(2), 192-204. (http://www.painpolicy.wisc.edu/publicat/05hlthpol/05hlthpol.pdf).

Goldman A (1998). ABC of palliative care: Special problems of children. *British Medical Journal,* 316: 49-52.

Gornick ME, Eggers PW, Reilly TW, et al. (1996). Effects of race and income on mortality and use of services among Medicare beneficiaries. *New England Journal of Medicine,* 335: 791-799.

Green CR, Anderson KO, Baker TA, et al. (2003). The unequal burden of pain: Confronting racial and ethnic disparities in pain. *Pain Medicine,* 4(3): 277-294.

Green CR, Baker TA, Smith EM, et al. (2003). The effect of race in older adults presenting for chronic pain management: A comparative study of black and white Americans. *Journal of Pain,* 4(2): 82-90.

Greenhill LL, Vitiello B, Abikoff H et al. (2003). Developing methodologies for monitoring long-term safety of psychotropic medications in children: Report on the NIMH conference, September 25, 2000. *Journal of the American Academy of Child and Adolescent Psychiatry,* 42(6): 651-655.

Heit HA (2006). The DEA and pain medicine: Trying to get back in balance. *Pain Medicine,* 7(1): 72-74.

Hollen CJ, Hollen CW, and Stolte K (2000). Hospice and hospital oncology unit nurses: A comparative survey of knowledge and attitudes about cancer pain. *Oncology Nursing Forum,* 27(10), 1593-1599.

Howard J and Beckwith L. (1996). Issues in subject recruitment and retention with pregnant and parenting substance abusing women. *NIDA Research Monograph, 166: 68-86.*

Huang, N., Cunningham, F., Laurito, C., and Chen, C. (2001). Can we do better with postoperative pain management? *American Journal of Surgery*, 182(5), 440-448.

Institute of Medicine (2002). *When Children Die: Improving Palliative Care and End-of-Life Care for Children and Their Families.* Washington, DC: National Academy Press (accessed at: http://www.nap.edu/books/0309084377/html/index.html).

Institute of Medicine (1996). *Pathways of Addiction: Opportunities in Drug Abuse Research.* Washington, DC: National Academy Press.

Jaffe JH and O'Keeffe C (2003). From morphine clinics to buprenorphine: Regulating opioid agonist treatment of addiction in the United States. *Drug and Alcohol Dependence* 70:S3-S11.

Joranson DE and Dahl JS (1989). Achieving balance in drug policy: The Wisconsin Model. In CS Hill, Jr. and WS Fields (eds.) *Advances in Pain Research and Therapy, Vol. 11*. New York, NY: Raven Press.

Joranson DE and Gilson AM (2002). Pain management and prescription monitoring. *Journal of Pain and Symptom Management,* 23: 231–238.

Joranson DE and Gilson AM (2003). Legal and regulatory issues in the management of pain. In AW Graham, TK Schultz, MF Mayo-Smith, RK Ries and BB Wilford (eds.) *Principles of Addiction Medicine, Third Edition*. Chevy Chase, MD: American Society of Addiction Medicine, Inc., 1465-1474.

Joranson DE and Payne R (2003). Will my pain be managed? In WAD Edmondson (ed.) *Improving End-of-Life Care: The Role of Attorneys General*. Washington, DC: National Association of Attorneys General, 27-34.

Joranson DE, Carrow GM, Ryan KM, et al. (2002). Pain management and prescription monitoring. *Journal of Pain and Symptom Management,* 23(3): 231-238.

Joranson DE, Gilson AM, Ryan KM, et al. (2003). Availability of opioid analgesics for cancer pain relief in children. In: McGrath PJ, Finley GA (eds.) *Pediatric Pain: Biological and Social Contex*t. Seattle, WA: IASP Press; 201-216.

Kalivas PW, Volkow ND (2005). The neural basis of addiction: A pathology of motivation and choice. *American Journal of Psychiatry,* 162: 1403-1413.

Khandker RK and Simoni-Wastila LJ (1998). Differences in prescription drug utilization and expenditures between Blacks and Whites in the Georgia Medicaid population. *Inquiry*, 35: 78-87.

Kiev A (1997). Management of clinical trials with new medications for cocaine dependence and abuse. *NIDA Research Monograph 175*. Rockville, MD: National Institute on Drug Abuse, 96-117.

Kreek MJ, Bart G, Lilly C, LaForge KS, Nielsen DA. (2005). Pharmacogenetics and human molecular genetics of opiate and cocaine addictions and their treatments (Review). *Pharmacol Reviews* Mar, 57(1): 1-26.

Larue F, Colleau SM, Fontaine A, et al. (1995). Oncologists and primary care physicians' attitudes toward pain control and morphine prescribing in France. *Cancer,* 76(11): 2375-2382.

Legal Action Center (2004). *Of Substance* (newsletter). March/April.

Manchikanti L (2006). Prescription drug abuse: What is being done to address this new drug epidemic? Testimony before the Subcommittee on Criminal Justice, Drug Policy and Human Resources. *Pain Physician,* 9(4): 287-321 (epub in advance of print).

Manchikanti, L., Whitfield, E., and Pallone F. (2005). Evolution of the national all schedules prescription electronic reporting act (NASPER): A public law for balancing treatment of pain and drug abuse and diversion. *Pain Physician,* 8, 335-347.

Marsch LA, Bickel WK, Badger GJ, et al. (2005). Comparison of pharmacological treatments for opioid-dependent adolescents. *Archives of General Psychiatry,* 62: 1157-1164.

McNutt LA, Coles FB, McAuliffe T, et al. (1994). Impact of regulation on benzodiazepine prescribing to a low income elderly population, New York State. *Journal of Clinical Epidemiology,* 47: 613-625.

Miaskowski C, Cleary J, Burney R, et al. (2005). Guideline for the Management of Cancer Pain in Adults and Children. *APS Clinical Practice Guidelines Series, No. 3*. Glenview, IL: American Pain Society.

Morley-Forster PK, Clark AJ, Speechley M, et al. (2003). Attitudes toward opioid use for chronic pain: A Canadian physician survey. *Pain Research and Management* Winter; 8(4): 189-194.

Morrison RS, Wallenstein S, Natale DK, Senzel RS, and Huang L. (2000). "We don't carry that"--Failure of pharmacies in predominantly nonwhite neighborhoods to stock opioid analgesics. *New England Journal of Medicine,* 342(14), 1023-1026.

Musto D (1999). *The American Disease,* 3rd Edition. New York, NY: Oxford University Press.

National Association of State Controlled Substance Authorities (1996). *Model Prescription Accountability Act.* Richmond, VA: The Association.

National Conference of Commissioners on Uniform State Law (1994). *Uniform Controlled Substances Act*. Chicago, IL: NCCUSL; July 29-August 5, p. 13.

National Institute on Alcohol Abuse and Alcoholism (2005). *Helping Patients Who Drink Too Much: A Clinician's Guide, 2005 Edition.* Bethesda, MD: National Institutes of Health.

National Institute on Drug Abuse (2001). *Prescription Drugs: Abuse and Addiction (*NIH Pub. No. 01-4881). Bethesda, MD: National Institutes of Health.

Ng B, Dimsdale JE, Rollnik JD, et al. (1996). The effect of ethnicity on prescriptions for patient-controlled analgesia for post-operative pain. *Pain* 66:9-12.

Noah L (2003). Challenges in the Federal regulation of pain management technologies. *Journal of Law, Medicine and Ethics*, 31(1): 55–74.

Novak S, Nemeth WC and Lawson KA (2004). Trends in medical use and abuse of sustained-release opioid analgesics: A revisit. *Pain Medicine* Mar, 5(1): 59-65.

Oberlander TF, Symons F, van Dongen K, et al. (2003). Pain in individuals with developmental disabilities: Challenges for the future. In JO Dostrovsky, DB Carr and M Koltzenburg (eds.) *Proceedings of the 10th World Congress on Pain*. Seattle, WA: IASP Press, pages 705-723.

Office of Applied Studies (2003a). *NHSDA Report: Non-Medical Use of Prescription-Type Drugs Among Youths and Young Adults*. Rockville, MD: Substance Abuse and Mental Health Services Administration, January 16, page 2.

Office of Applied Studies (2003b). *Emergency Department Trends From the Drug Abuse Warning Network, Final Estimates 1995-2002*. Rockville, MD: Substance Abuse and Mental Health Services Administration.

Office of Applied Studies (2005a). *National Survey of Substance Abuse Treatment Services (N-SSATS), 2000, 2002-2005*. Rockville, MD: Substance Abuse and Mental Health Services Administration.

Office of Applied Studies (2005b). *Treatment Episode Data Set (TEDS) Report: Admission to Treatment Programs, 2004.* Rockville, MD: Substance Abuse and Mental Health Services Administration.

Office of Applied Studies (2006a). *Results from the 2005 National Survey on Drug Use and Health: National Findings.* Rockville, MD: Substance Abuse and Mental Health Services Administration.

Office of Applied Studies (2006b). *Drug Abuse Warning Network, 2004: National Estimates of Drug-Related Emergency Department Visits*. DAWN Series D-28, DHHS Publication No. (SMA) 06-4143, Rockville, MD.

Office of Applied Studies (2006c). *Misuse of Prescription Drugs: Data From the 2002, 2003 and 2004 National Surveys on Drug Use and Health*. Rockville, MD: Substance Abuse and Mental Health Services Administration.

Office of Applied Studies (2007). *Drug Abuse Warning Network, 2005(4/2006 update).* Rockville, MD: Substance Abuse and Mental Health Services Administration.

Pain and Policy Studies Group (2003). *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation*. (Madison, WI: University of Wisconsin Comprehensive Cancer Center).

Passik SD and Kirsh KL (2004). Opioid therapy in patients with a history of substance abuse. *CNS Drugs,* 18(1): 13-25.

Paulozzi LJ, Budnitz DS and Yongli X (2006). Increasing deaths from opioid analgesics in the United States. *Pharmacoepidemiology and Drug Safety* (epub ahead of print).

Payne R, Medina E and Hampton JW (2003). Quality of life concerns in patients with breast cancer: Evidence for disparity of outcomes and experiences in pain management and palliative care among African-American women. *Cancer,* 97(1S): 311-317.

Pearson SA, Soumerai S, Mah C et al. (2006). Racial disparities in access after regulatory surveillance of benzodiazepines. *Archives of Internal Medicine,* 166, 572-579.

Peine SI, ed. (2000). *A Closer Look at State Prescription Monitoring Programs*. Washington, DC: Drug Enforcement Administration (accessed at: http://www.deadiversion.usdoj.gov/pubs/program/rx_monitor/index.html).

Pliszka SR (2005). The neuropsychopharmacology of attention-deficit/hyperactivity disorder. *Biological Psychiatry* 57(11):1385-1390.

Ponte CD and Johnson-Tribino J (2005). Attitudes and knowledge about pain: An assessment of West Virginia family physicians. *Family Medicine* Jul-Aug; 37(7):477-480.

Portenoy R, Dole V, Joseph H, et al. (1997). Pain management and chemical dependency: Evolving perspectives. *Journal of the American Medical Association 2*78:592-593.

Potter M, Schafer S, et al., (2001). Opioids for chronic nonmalignant pain: Attitudes and practices of primary care physicians in the UCSF/Stanford Collaborative Research Network. *Journal of Family Practice,* 50(2):145-51.

Remschmidt H (2005). Global consensus on ADHD/HKD. *European Child and Adolescent Psychiatry* 14(3):127-137.

Ross-Degnan, D., Simoni-Wastila, L., Brown, J. S., Gao, X., Mah, C., Cosler, L. E., et al. (2004). A controlled study of the effects of state surveillance on indicators of problematic and non-problematic benzodiazepine use in a Medicaid population. *International Journal of Psychiatry in Medicine, 34*(2), 103-123.

Schneider EC, Zaslavsky AM and Epstein AM (2002). Racial disparities in the quality of care for enrollees in Medicare managed care. *Journal of the American Medical Association,* 287, 1288-1294.

Scimeca MM, Savage SR, Portenoy R, et al. (2000). Treatment of pain in methadone-maintained patients. *Mount Sinai Journal of Medicine,* 67(5-6), 412-422.

Secnik K, Swensen A and Lage MJ (2004). Comorbidities and costs of adult patients diagnosed with attention deficit hyperactivity disorder. *Pharmacoeconomics,* 23(1), 93-102.

Sees KL (1999). Pain management in a patient with an addiction history. *Journal of the American Osteopathic Association,* 99(6: Suppl), 11-15.

Simeone R and Holland L (2006). An Evaluation of Prescription Monitoring Programs. U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Assistance.

Simoni-Wastila L and Tompkins C (2001). Balancing diversion control and medical necessity: The case of prescription drugs with abuse potential. *Substance Use and Misuse, 36(9-10), 1275-1296.*

Simoni-Wastila L (2000). The use of abusable prescription drugs: The role of gender. Journal of Women's Health and Gender-Based Medicine, 9(3), 289-297.

Simoni-Wastila, L., Ross-Degnan, D., Mah, C., Gao, X., Brown, J., Cosler, L. E., et al. (2004). A retrospective data analysis of the impact of the New York triplicate prescription program on benzodiazepine use in Medicaid patients with chronic psychiatric and neurologic disorders. *Clinical Therapeutics, 26*(2), 322-336.

Smith MY and Woody G (2005). Non-medical use and abuse of scheduled medications prescribed for pain, pain-related symptoms, and psychiatric disorders: patterns, user characteristics, and management options. *Current Psychiatry Reports,* 337-343.

Swartz M, Landerman R, George LK, et al. (1991). Benzodiazepine anti-anxiety agents: Prevalence and correlates of use in a southern community. *American Journal of Public Health,* 81, 592-596.

Swenson AR, Birnbaum HG, Secnik K, et al. (2003). Attention-deficit/hyperactivity disorder: Increased costs for patients and their families. *Journal of the American Academy of Child and Adolescent Psychiatry,* 42, 1415-1423.

Teno JM, Weitzen S, Wetle T, et al. (2001). Persistent pain in nursing home residents (research letter). *Journal of the American Medical Association,* 285(16), 2081.

Todd KH, Deaton C, D'Adamo AP, et al. (2000). Ethnicity and analgesic practice. *Annals of Emergency Medicine,* 35(1), 11-16.

Todd KH, Samaroo N and Hoffman JR (1993). Ethnicity as a risk factor for inadequate emergency department analgesia. *Journal of the American Medical Association,* 269(12), 1537-1539.

Trauth JM, Musa D, Siminoff L (2000). Public attitudes regarding willingness to participate in medical research studies. *Journal of Health and Social Policy,* 12(2), 23-43.

Turk DC and Okifuji A (1997). What factors affect physicians' decisions to prescribe opioids for chronic noncancer pain patients. *Clinical Journal of Pain,* 13, 330-336.

Twillman R (2006). Impact of prescription monitoring programs on prescription patterns and indicators of opioid abuse. *The Journal of Pain,* 7(4S), 7.

U.S. General Accounting Office. (2002). *Prescription drugs: State monitoring programs provide useful tool to reduce diversion* (GAO Pub. No. 02-634). Washington, DC: U.S. General Accounting Office.

Vocci F, Acri J and Elkashef A (2005). Medications development for addictive disorders: The state of the science. *American Journal of Psychiatry,* 162, 1432-1440.

Volkow ND, Wang GJ, Fowler JS, et al. (2005). Imaging the effects of methylphenidate on brain dopamine: New model on its therapeutic actions for attention-deficit/hyperactivity disorder. *Biological Psychiatry,* 57(11), 1410-1415.

Wagner AK, Soumerai SB, Zhang F, et al. (2003). Effects of state surveillance on new post-hospitalization benzodiazepine use. *International Journal for Quality in Health Care,* 15(5), 423-431.

Wastila LJ and Bishop C (1996). The influence of multiple copy prescription programs on analgesic utilization. *Journal of Pharmaceutical Care in Pain and Symptom Management,* 4(3), 3-19.

Weinstein SM, et al. (2000). Physicians' attitudes toward pain and the use of opioid analgesics: Results of a survey from the Texas Cancer Pain Initiative. *Southern Medical Journal,* 93, 479–487.

Wilford BB and Deatsch JH (2003). Prescribing Controlled Drugs: Helping Your Patients, Protecting Your Practice (course syllabus). Tampa, FL: University of South Florida College of Medicine.

Wilford BB, Smith DE and Bucher RD (2005). Internet pharmacy: A new source of abused drugs. *Psychiatric Annals,* 35(3), 241-252.

Wolfe J, Grier HE, Klar N, et al. (2000). Symptoms and suffering at the end of life in children with cancer. *New England Journal of Medicine,* 342, 326-333.

World Health Organization (1996). *Cancer Pain Relief, With a Guide to Opioid Availability*. Geneva, Switzerland: WHO.

Zacny J, Bigelow G, Compton P, Foley K, Iguchi M and Sannerud C (2003). College on Problems of Drug Dependence taskforce on prescription opioid non-medical use and abuse: Position statement. Drug and Alcohol Dependence, 69, 215-232.

APPENDIX A: METHODOLOGY

TIMELINE

The work plan for the assessment was approved by CSAT on April 26, 2006. The assessment research was conducted between April 30 and June 30, 2006. The results were compiled and the report drafted between July 1 and July 30, 2006. The report was submitted to CSAT and to a group of outside experts for review, beginning August 1, 2006. Comments and suggestions received from CSAT officials and the outside reviewers as of December 7, 2006, are reflected in this document.

ORGANIZATION

The assessment was conducted under the direction of senior staff of DB Consulting Group, Inc. and JBS International, Inc. The work was conducted by the staffs of those organizations, based on a study design and work plan approved by CSAT.

SOURCES OF INFORMATION

The assessment employed four approaches to information-gathering (i.e., literature review, data analysis, key informant questionnaires and publicly available information). The methods specific to each component of the assessment are described in the report.

THE LITERATURE REVIEW

Sources. The medical literature published since 1980 – that is, within the past 25 years – was the subject of a search through the National Library of Medicine's PubMed system. To ensure that no relevant literature was overlooked, a separate search was conducted through the library at England's Cambridge University.

In addition, a Library Information Specialist contacted the manager of each state CSMP to ask if the State had published a report, study or evaluation of the CSMP. If so, a copy of the document was requested.

Methods. The Library Information Specialist first searched for any reports or evaluations produced by or for the States that operate CSMPs. In each of those States, the manager of the CSMP was contacted by phone and asked if the State had published a report, study or evaluation of the controlled substance monitoring program. If so, a copy of the document was requested.

For the literature search, the principal search terms employed were:

- National All Schedules Prescription Electronic Reporting Act/NASPER
- Prescription monitoring program/PMP
- Triplicate prescription program/TPP/3Rx
- Multiple-copy prescription program/MCPP
- Prescription monitoring/prescription control
- Prescription drug diversion/prescription drug abuse
- Controlled substances/controlled drugs

- Barriers to medication use/hassle factor/chilling effect

Only articles published in peer-reviewed journals or reports sponsored by established organizations (e.g., government entities, health professions associations or academic institutions) were selected for review.

Limitations. The principal limitation encountered in conducting the literature review, which affects all research of this type, is related to the lag time between the occurrence of an event, completion of an article describing it, submission to and peer review/acceptance by a journal, and actual publication of the article. With the leading peer-reviewed journals, this process frequently requires 12 to 18 months. Thus, it is difficult to find published articles on very recent events.

Results. The literature search yielded more than 400 articles published in peer-reviewed journals, of which approximately 275 were found to be relevant to the assessment. In addition, reports were obtained from the CSMPs in 11 States: California, Hawaii, Illinois, Indiana, Kentucky, Maine, Massachusetts, Michigan, Oklahoma, Virginia, and Washington State (see Appendix D).

THE DATA ANALYSIS

Sources. The data analysis employed information from publicly accessible datasets, such as the Automation of Reports and Consolidated Orders System (ARCOS) data from the Drug Enforcement Administration. One of the indicators of the impact of a CSMP on access to pharmacotherapies is the volume of drugs distributed before and after enactment of laws establishing a CSMP, as well as comparative data on drug distribution within CSMP and non-CSMP States. ARCOS allows measurement of such distribution through its comprehensive drug reporting system that monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the retail level through hospitals, retail pharmacies, practitioners, and teaching institutions.

The study was enhanced by access to preliminary findings of research under way by the Center for Financing Access and Cost Trends of the Agency for Healthcare Research and Quality (AHRQ), using data from the Medical Expenditure Panel Survey (MEPS) to examine the association between State CSMPs and purchases of Schedule II drugs. MEPS is an ongoing survey that collects nationally representative data on health care utilization, expenditures, sources of payment, insurance coverage, and health status for the U.S. civilian, non-institutionalized population.

Methods. With the ARCOS data, DEA's reports of total drug distribution at the national and State levels were employed, as were the DEA rankings of States by per capita consumption.

Within MEPS, the Prescribed Medicines (PMED) files capture date on households' reported use of outpatient prescription drugs (drugs used in inpatient hospital, nursing home, or other institutional setting are not included). Household respondents are asked for permission to contact pharmacies and for every reported use of a prescribed medicine during the survey year, pharmacies are asked to provide computerized printouts containing information on the

medication name, national drug code (NDC), strength, quantity, total charge, and payments by source.

Data were drawn from the MEPS household component for the years 1996 through 2003. Investigators assigned each drug mentioned in MEPS to a therapeutic class, subclass, active ingredient, brand name and CSA Schedule, using the National Drug Code to link the PMED files to the Multum Lexicon database (a proprietary product of Cerner Multum, Inc.). Information on implementation of State CSMPs was taken from a table prepared by the national Alliance for Model State Drug Laws. They then compared drug use in States that had a CSMP with States that never had a CSMP for every year from 1996-2003 (States that first implemented a CSMP during the study period were excluded from the analysis).

Published Studies. To compensate for some of the limitations of the available datasets (such as the lack of statistical information on the benzodiazepines), the researchers also sought out epidemiologic and other data-based studies published in peer-reviewed journals. The data in such studies were incorporated into the report wherever they were found to shed additional light on the issues addressed in the assessment.

Limitations. Because of changes in Federal data collection methods, only ARCOS data for the years 1997 through 2004, plus the first six months of 2005, were suitable for the assessment. This limitation should be borne in mind when reviewing the findings presented here.

Results. With the ARCOS data, DEA's reports of total drug distribution at the national and State levels were employed, as were the DEA rankings of States by per capita consumption.

With the MEPS data, two different indicators of Schedule II drug use were used: 1) the percentage of persons who made any purchase of a Schedule II drug during the year; and 2) the average number of purchases per person. Both measures were examined for four classes of drugs: all Schedule II drugs, Schedule II and Schedule III combination analgesic products, Schedule II stimulants.

KEY INFORMANTS

Sources. Key informants were selected to represent the populations identified in the NASPER statute, as well as to be representative of States that have adopted CSMPs. A list of 24 national organizations, six types of State organizations, and 12 potential study States were identified as appropriate sources of information (Appendix C). From these lists, a narrower group of nine national organizations, four types of State organizations, and nine study States were selected. Once the organizations were identified, each was contacted to identify a specific key informant.

Methods. Information was collected through use of a series of structured questionnaires (Appendix C), which consisted of 14 questions, some with branching sub-questions. Questions invited multiple types of responses, including "Yes/No," Likert scale, and open-ended responses. Some questions asked about the policies or activities of an organization (e.g., "Does your organization have a formal position on NASPER?"), while other questions asked about opinions and/or experiences reported by the organizations' members (e.g., "If your organization has received reports that prescription monitoring programs are having a negative impact on access to pharmacotherapies, how would you characterize the intensity of that effect?)

Limitations. This component of the assessment encountered a number of process and content limitations specific to this assignment, as well as limitations routinely encountered in studies of this type. The principal process limitations were:

- Some national organizations had yet to develop formal position statements on the Federal NASPER statute or State CSMPs.
- The executives of some organizations, at both the national and State levels, were unwilling to participate without first consulting with or obtaining the approval of their Boards of Directors – a process that could not be completed within the timeframe of the study.
- Because of the short study period, there was not sufficient time for a large survey and the burden imposed by the questionnaires had to be kept within carefully defined limits.
- Many State organizations operated in jurisdictions that had enacted but not yet fully implemented their CSMPs (a process that typically requires about two years), so their actual experience with the programs was somewhat limited.

The principal content limitations are related to the small number of participants and the limited time available to administer the questionnaires. For example:

- Given the limit on the number of potential participants, the sample could not be fully representative of the geographically and demographically diverse populations of patients and providers identified in the NASPER Act.
- Also because of the small number of participants, a robust response from one community or type of organization had the potential to exert a larger effect on the overall results than would have been the case with a larger pool of responders.
- In States that had adopted but not yet fully implemented CSMPs, the only effect that could be measured was that of discussion and debate around adoption of the CSMP, rather than its actual operation. Some reports in the literature describe such "expectation effects" as potentially more intense than the effects arising from actual experience with a program.

Finally, several limitations are common to studies of this type and should be considered when interpreting the results:

- The self-report nature of the questionnaires means that results are limited by the potential inaccuracy of human recall.
- Despite the application of rigorous methods, some limitations to the study design could not be avoided. For example, the small sample size limits the generalizability of the findings.
- In an effort to maximize the opportunity to obtain useful information, the participants selected were those most likely to be knowledgeable about CSMPs. While this group was unusually productive in terms of collecting information, it was not representative of the universe of health care professionals or patient advocacy organizations.

Results. Of the nine national organizations invited to participate, five or 55.6 percent had key informants complete and return questionnaires. Of the 36 State-level organizations invited to participate, 18 or 50 percent had key informants complete and return questionnaires. In total, completed questionnaires were received from key informants representing 23 of the 45 organizations invited to participate, for a response rate of 51 percent. The distribution of key informants is depicted in Appendix C.

Several national and State organizations declined the invitation to participate or did not return a completed questionnaire. Reasons cited for non-participation included insufficient time to prepare a response, as well as concern about the political ramifications of expressing an opinion on this politically sensitive topic (despite assurances of confidentiality). A number of organizations accepted the invitation to submit related documents (position papers, testimony, etc.), which were analyzed for this report.

LIMITATIONS

Because of the relative recency with which most of the electronic monitoring systems have been implemented, it was not possible to gather enough data on the performance of electronic CSMPs to support a conclusion as to whether they have a substantial negative impact on access to treatment.

For example, a large-scale survey of stakeholder groups or physician and patient populations, while desirable, would have required approval of the Office of Management and Budget and thus could not be undertaken. Similarly, time and resource limitations precluded the use of data from private vendors such as health insurers, pharmaceutical benefit managers, or firms such as the IMS National Prescription Audit Plus. (Such datasets are ideally suited to studies of this type because they capture information on drugs actually dispensed by brand name, formulation and strength; and track the distribution to very small geographic areas.)

Therefore, the assessment compiled available information on *all* prescription monitoring systems – paper-based or electronic – and analyzed it for relevance to the current assignment. The results are presented in this report.

APPENDIX B: FEDERAL SCHEDULES OF CONTROLLED DRUGS

Certain drugs, called “controlled substances,” are subject to additional requirements of the Controlled Substances Act (CSA). The CSA is designed to ensure both the availability and control of regulated substances. Its requirements parallel the provisions of international treaties to which the United States is signatory. Under the CSA, availability of regulated drugs is accomplished through a system that establishes quotas for drug production and a distribution system that closely monitor the importation, manufacture, distribution, prescribing, dispensing, administering, and possession of controlled drugs. To effectively regulate the availability of and commerce in controlled substances, and to comply with international treaty obligations, the CSA established an elaborate system of administrative reporting requirements to track regulated drugs and chemicals from their point of origin to the end-user at the retail pharmacy or health care facility. Civil and criminal sanctions for serious violations of the statute are part of the government's control apparatus. The Drug Enforcement Administration (DEA) implements the CSA through guidelines set out in Title 21, Chapter II, of the Code of Federal Regulations.

The CSA provides that responsibility for scheduling controlled substances is shared between the FDA and the DEA. In granting regulatory authority to these agencies, the Congress noted that both public health and public safety needs are important and that neither takes primacy over the other, but that both are necessary to ensure the public welfare. To accomplish this, the Congress provided guidance in the form of factors that must be considered by the FDA and DEA when assessing public health and safety issues related to a new drug or one that is being considered for rescheduling or removal from control. The factors that must be considered in deciding whether a drug ought to be controlled and, if so, in what schedule include:

- The drug's actual or relative potential for abuse.
- Scientific evidence of the drug's pharmacologic effects, if known.
- The state of current scientific knowledge regarding the drug.
- The drug's history and current pattern of abuse.
- The scope, duration and significance of abuse.
- The degree of risk (if any) the drug poses to the public health.
- The drug's "psychic or physiological dependence liability."
- Whether the drug is an immediate precursor of a substance already controlled.

The CSA designates the Attorney General, after consultation with the Secretary of Health and Human Services, as the official who determines the appropriate schedule for any drug or other substance proposed to be controlled in, or removed from, the Schedules. (The Attorney General and the Secretary of Health and Human Services have delegated the authority for making these determinations to the DEA and FDA, respectively.) The factors cited earlier must be used in establishing findings that justify the level of scheduling, according to the following standards and definitions:

Schedule I drugs and other substances have a high potential for abuse and no currently accepted medical use, and there is a lack of accepted safety for use of the drug or other substance under medical supervision. Thus, these drugs are not available for medical practice. Schedule I includes certain opium derivatives (heroin), some synthetic opioids (alpha-methylfentanyl), and the hallucinogens (LSD).

Schedule II drugs and other substances have a high potential for abuse and a currently accepted medical use in treatment in the U.S. with severe restrictions; abuse of the drug or other substance may lead to severe psychological or physical dependence. Opioid analgesics, stimulants such as the amphetamines and methylphenidate, and the short-acting barbiturates are in this schedule.

Schedule III drugs and other substances have less potential for abuse than drugs in Schedules I and II and a currently accepted medical use in treatment in the U.S.; abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence. Some stimulant and depressant drugs (such as barbiturates not included in other schedules), as well as preparations containing limited quantities of codeine, are in this schedule.

Schedule IV drugs and other substances have a low potential for abuse relative to the drugs or other substances in Schedule III and a currently accepted medical use in treatment in the U.S., as well as a limited potential to produce physical or psychological dependence relative to the drugs in Schedule III. Drugs included in this schedule include certain sedative-hypnotics and anti-anxiety agents not in another schedule (e.g., phenobarbital and the benzodiazepines), analgesics such as pentazocine and propoxyphene, and the stimulant drug phentermine.

Schedule V drugs and other substances (including a few over-the-counter preparations) have a low potential for abuse relative to the drugs or other substances in Schedule IV and a currently accepted medical use in treatment in the U.S.; they have limited potential to produce physical or psychological dependence relative to the drugs in Schedule IV. Antitussive, antidiarrheal, and other mixtures containing limited quantities of opioids with nonopioid drugs are included in this schedule (CSA, 1970).

Note that some drugs are classified in more than one schedule. For example, codeine alone is classified in Schedule II, but combination products containing codeine (such as Tylenol #3, Tussionex, and Vicodin) are classified in Schedule III.

NOTE: The following table is based on Federal law. State law may result in different classifications.

	Schedule I	Schedule II	Schedule III	Schedule IV	Schedule V
OPIOID AGONISTS	Benzylmorphine Dihydromorphinone Heroin Ketobemidone Levomoramide Morphine-methylsulfanote Nicocodeine Nicomorphine Racemoramide	Codeine various Fentanyl Sublimaze® Hydrocodone Hydromorphone Dilaudid® Meperidine Demerol® Methadone Morphine Oxycodone Endocet® OxyContin® Percocet® Oxymorphone Numorphan®	Buprenorphine Buprenex® Subutex® Codeine compounds Tylenol #3® Hydrocodone compounds Lorcet® Lortabs® Tussionex® Vicodin®	Propoxyphene Darvon® Darvocet®	Opium preparations Donnagel PG® Kaopectalin®
MIXED AGONIST-ANTAGONISTS			Buprenorphine + naloxone Suboxone®	Pentazocine + naloxone Talwin-Nx®	
STIMULANTS	N-methyl-amphetamine 3,4-methylenedioxy amphetamine MDMA, Ecstasy	Amphetamine Adderall® Cocaine Dextro-amphetamine Dexedrine® Methamphetamine Desoxyn® Methylphenidate Concerta® Metadate® Ritalin® Phenmetrazine Fastin® Preludin®	Benzphetamine Didrex® Pemoline Cylert® Phendimetrazine Plegine®	Diethylpropion Tenuate® Fenfluramine Phentermine Fastin®	1-deoxy-ephedrine Vicks Inhaler®
HALLUCINOGENS, OTHER	Lysergic acid diamine LSD Marijuana Mescaline Peyote Phencyclidine PCP Psilocybin Tetrahydrocannabinols		Dronabinol Marinol®		

SEDATIVE-HYPNOTICS	Methaqualone Quaalude® Gamma-hydroxy butyrate GHB	Amobarbital Amytal® Glutethimide Doriden® Pentobarbital Nembutal® Secobarbital Seconal®	Butabarbital Butisol® Butalbital Fiorecet® Fiorinal® Methyprylon Noludar®	Alprazolam Xanax® Chlordiaze-poxide Librium® Chloral betaine Chloral hydrate Noctec® Clonazepam Klonopin® Clorazepate Tranxene® Diazepam Valium® Estazolam Prosom® Ethchlorvynol Placidyl® Ethinamate Flurazepam Dalmane® Halazepam Paxipam® Lorazepam Ativan® Mazindol® Sanorex® Mephobarbital Mebaral® Meprobamate Equanil® Methohexital Brevital Sodium® Methyl-phenobarbital Midazolam Versed® Oxazepam Serax® Paraldehyde Paral® Phenobarbital Luminal® Prazepam Centrax® Temazepam Restoril® Triazolam Halcion® Zaleplon Sonata® Zolpidem Ambien®	Diphenoxylate preparations Lomotil®
OPIOID AGONISTS	Benzylmorphine Dihydromorphin one Heroin Ketobemidone Levomoramide Morphine-	Codeine various Fentanyl Sublimaze® Hydrocodone Hydromor-phone	Buprenorphine Buprenex® Subutex® Codeine compounds Tylenol #3® Hydrocodone	Propoxyphene Darvon® Darvocet®	Opium preparations Donnagel PG® Kaopectalin®

	methylsulfanote Nicocodeine Nicomorphine Racemoramide	Dilaudid® Meperidine Demerol® Methadone Morphine Oxycodone Endocet® OxyContin® Percocet® Oxymorphone Numorphan®	compounds Lorcet® Lortabs® Tussionex® Vicodin®		
MIXED AGONIST-ANTAGONISTS			Buprenorphine + naloxone Suboxone®	Pentazocine + naloxone Talwin-Nx®	
STIMULANTS	N-methyl-amphetamine 3,4-methylenedioxy amphetamine MDMA, Ecstasy	Amphetamine Adderall® Cocaine Dextro-amphetamine Dexedrine® Methamphet-amine Desoxyn® Methylphenidate Concerta® Metadate® Ritalin® Phenmetrazine Fastin® Preludin®	Benzphetamine Didrex® Pemoline Cylert® Phendi-metrazine Plegine®	Diethylpropion Tenuate® Fenfluramine Phentermine Fastin®	1-deoxy-ephedrine Vicks Inhaler®
HALLU-CINOGENS, OTHER	Lysergic acid diamine LSD Marijuana Mescaline Peyote Phencyclidine PCP Psilocybin Tetrahydro-cannabinols		Dronabinol Marinol®		
SEDATIVE-HYPNOTICS	Methaqualone Quaalude® Gamma-hydroxy butyrate GHB	Amobarbital Amytal® Glutethimide Doriden® Pentobarbital Nembutal® Secobarbital Seconal®	Butabarbital Butisol® Butalbital Fiorecet® Fiorinal® Methyprylon Noludar®	Alprazolam Xanax® Chlordiaze-poxide Librium® Chloral betaine Chloral hydrate Noctec® Clonazepam Klonopin® Clorazepate Tranxene® Diazepam Valium® Estazolam Prosom® Ethchlorvynol	Diphenoxylate preparations Lomotil®

				Placidyl® Ethinamate Flurazepam Dalmane® Halazepam Paxipam® Lorazepam Ativan® Mazindol® Sanorex® Mephobarbital Mebaral® Meprobamate Equanil® Methohexital Brevital Sodium® Methyl- phenobarbital Midazolam Versed® Oxazepam Serax® Paraldehyde Paral® Phenobarbital Luminal® Prazepam Centrax® Temazepam Restoril® Triazolam Halcion® Zaleplon Sonata® Zolpidem Ambien®	

APPENDIX C: KEY INFORMANTS AND QUESTIONS

National Organizations

American Academy of Pain Medicine
American Academy of Pediatrics
American Alliance of Cancer Pain Initiatives
American Association for the Treatment of Opioid Dependence
American Medical Association
American Osteopathic Academy of Addiction Medicine
American Society of Anesthesiologists
CHADD (Children and Adults with Attention Deficit Disorder)
Clinical Trials Network

State Medical Associations

Alabama
California
Hawaii
Kentucky
Maine
Michigan
New York
Tennessee
Texas

State Pain Initiatives

Alabama
California
Hawaii
Maine
Massachusetts
Michigan
New York
Tennessee
Wisconsin

State Addiction Treatment Organizations

Alabama
California
Hawaii
Maine
Maryland
Michigan
New York
Tennessee
Texas

State Chapters of the American Academy of Pediatrics

Alabama
California
Hawaii
Indiana
Maine
Michigan
New York
Tennessee
Texas

QUESTIONS ASKED OF THE KEY INFORMANTS

YOUR SOCIETY'S POLICIES AND ACTIVITIES

1. **Does your State Medical Society have a formal position on prescription monitoring programs?**
   ☐ Yes ☐ No **(If no, Skip to Question 2)**

   1a. If it is in a written form, may we have a copy? ☐ Yes (please mail to address below) ☐ No

2. **Did your State Medical Society testify at the time your State's prescription monitoring program was being considered?**
   ☐ Yes ☐ No **(If no, Skip to Question 3)**

   2a. In what form/capacity did they testify? (Please check all that apply)
   ☐At Hearings
   ☐In Writing
   ☐Other (Please specify)

   2b. What was the nature of the testimony?

   2c. If it is in written form, may we have a copy?
   ☐ Yes (please mail to address below) ☐ No

3. **Did your State Medical Society have any input into the design of your State's prescription monitoring program?**
   ☐ Yes ☐ No **(If no, Skip to Question 4)**

   3a. If so, what was your organization's role?

4. **Is anyone in your State Medical Society assigned to follow the implementation of your State's prescription monitoring program?**
   ☐ Yes ☐ No **(If no, Skip to Question 5)**

   4a. Who is that person?

   4b. What is his/her title?

FEEDBACK FROM MEMBERS OF YOUR STATE MEDICAL SOCIETY

5. **Has your State Medical Society created a process to receive physicians' feedback about your State's prescription monitoring program?**

   ☐ Yes ☐ No **(If no, Skip to Question 6)**

5a. Has your State Medical Society compiled any reports based on members' feedback as to the effects of your State's prescription monitoring program?

☐ Yes ☐ No

5b. What kinds of information are collected? (Please check all that apply)

☐Statistical information
☐Anecdotal reports
☐Other (Please specify)

5c. If the information is in written form, may we have a copy?

☐ Yes (please mail to address below) ☐ No

6. How would you characterize the feedback you have received regarding the impact of your State's prescription monitoring programs on patients' access to care?

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Negative Impact		No impact		Positive impact

7. If your State Medical Society has received feedback that your State's prescription monitoring program is having a negative impact on access to care, how would you characterize the intensity of that effect?

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Minimal		Moderate		Significant

8. If your State Medical Society has received feedback that your State's prescription monitoring program is having a negative impact on enrollment in clinical trials, how would you characterize the intensity of that effect?

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Minimal		Moderate		Significant

9. If your State Medical Society has received feedback that your State's prescription monitoring program is having a negative impact on physicians' willingness to treat and/or refer patients with pain or substance use disorders, how would you characterize the intensity of that effect?

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Minimal		Moderate		Significant

10. Based on the feedback you have received, do you believe that your State's prescription monitoring program is having an effect on physicians' willingness to:

10a. Prescribe opioids for pain in children?

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
No effect		Moderate effect		Significant effect

10b. Prescribe opioids for pain in adults?

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
No effect		Moderate effect		Significant effect

10c. Prescribe sedative-hypnotic drugs for anxiety or sleep disorders?

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

No effect Moderate effect Significant effect

10d. Prescribe stimulant drugs for ADHD in children or adults?

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

No effect Moderate effect Significant effect

10e. Other (please specify)

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

No effect Moderate effect Significant effect

11. Based on the feedback you have received, which classes of drugs do you think are most likely to be affected by prescription monitoring programs? [check all that apply]

11a. ___ Opioids/pain relievers (e.g., OxyContin, Duragesic, Dilaudid, Percodan, morphine)
11b. ___ Sedative-hypnotics (e.g., Valium, Xanax, other tranquilizers or sleep aids)
11c. ___ Stimulants/ADHD drugs (e.g., Ritalin, Adderall, methylphenidate)
11d. ___ Psychiatric medications
11e. ___ Other (please specify)
11f. ___ Unknown

12. Based on the feedback you have received, if physicians are less willing to prescribe certain drugs because of your State's prescription monitoring program, why do you think that is the case? [check all that apply]

12a. ___ Protect patient privacy/concerns about confidentiality
12b. ___ Avoid intrusion into the doctor-patient relationship
12c. ___ Fear of regulatory oversight
12d. ___ Negative publicity about prescription monitoring programs
12e. ___ Lack of information about your State's prescription monitoring program
12f. ___ The "hassle factor" involved in the requirement to use a special prescription form
12g. ___ Press reports of sanctions against physicians
12h. ___ Other (please specify)
12i. ___ Unknown

13. Are you aware of any other indicators of or reports on the impact of your State's prescription monitoring program on patients' access to care?

☐ Yes ☐ No

13a. If yes, please describe those indicators or reports:

14. Based on the feedback you have received, does your State Medical Society have any suggestions or comments regarding ways in which prescription monitoring programs could be improved in their design or implementation?

Appendix D: Reports Obtained from CSMP States

COPIES OF THE FOLLOWING REPORTS WERE OBTAINED AND ANALYZED FOR THE ASSESSMENT:

CALIFORNIA

California Bureau of Narcotic Enforcement (2002). CURES (Controlled Substance Utilization Review and Evaluation System) Report to the Legislature. Sacramento, CA: California Department of Justice.

ILLINOIS

State of Illinois (n.d.). Comparison of Illinois' Triplicate Prescription Program/Electronic Monitoring Program. Springfield, IL: Illinois Department of Law Enforcement.

INDIANA

Anonymous (n.d.). Indiana Scheduled Prescription Electronic Collection and Tracking (INSPECT Program). Indianapolis, IN: Controlled Substances Advisory Committee.

KENTUCKY

Kentucky Cabinet for Health and Family Services (2004). 2004 KASPER Satisfaction Survey Executive Summary Reducing the Diversion of Scheduled Prescription Medications in the Commonwealth of Kentucky. Frankfurt, KY: Office of the Inspector General.

MAINE

Lambert, D (2006). Evaluation of the Implementation of Maine's Prescription Drug Monitoring Program. Portland, ME: Muskie School of Public Service, University of Southern Maine.

MASSACHUSETTS

Carrow G (2006). Informational Briefing on Amendments to 105 CMR 700.000; Implementation of M.G.L. c.94C. Boston, MA: January 24th.

MICHIGAN

Anonymous (2003). Overview of the Michigan Automated Prescription System (MAPS) – First Year of Operation 2003. Ann Arbor, MI: Bureau of Narcotics and Dangerous Drugs.

OKLAHOMA

Oklahoma State Bureau of Narcotics and Dangerous Drugs Control (1994). OSTAR Update. Oklahoma City, OK: The Bureau.

VIRGINIA

Department of Health Professions and Virginia State Police (2004). Prescription Monitoring Program. Richmond, VA: Department of Health Professions and Virginia State Police.

WASHINGTON

Williams DH (1993). Triplicate Prescriptions in Washington State (Research Monograph 131:194-199). Rockville, MD: National Institute on Drug Abuse (NIH Pub. No. 93-3507).

APPENDIX E: STATUS OF STATE CSMPS

As of December 1, 2006, 33 States have signed laws authorizing the creation of a CSMP, 25 States have active CSMPs, and 8 States have begun implementation of legislatively authorized programs.

Operational CSMPs (25)

Alabama	New York
California	Ohio
Hawaii	Oklahoma
Idaho	Pennsylvania
Illinois	Rhode Island
Indiana	Tennessee
Kentucky	Texas
Maine	Utah
Massachusetts	Virginia
Michigan	Washington
Mississippi	West Virginia
Nevada	Wyoming
New Mexico	

Non-Operational CSMPs with Enacted Laws (8)

Colorado	North Carolina
Connecticut	North Dakota
Iowa	South Carolina
Louisiana	Vermont

Other States are in the process of proposing, preparing, or considering legislation.

This section provides a lists the program name, year of implementation, links to the authorizing legislation, manager of the program, the controlled drugs monitored by each State's program, average number of prescriptions collected per year, advisory/oversight, operating budget, the frequency of data collection, funding source, the group requesting summary reports, average requests received per month, the number of DEA registered pharmacies.

The majority States (20) monitor schedules II-IV. Of the 21 States for which we obtained information on pertaining to the average number of prescriptions collected annually, California reported the highest number with approximately 21 million and the lowest was Virginia with 400,000. Twenty-one States used public health departments or professional boards. New York had the largest with $17,000,000 and Utah the smallest with $47,000. More States (14) collected data monthly than on any other schedule. California and Michigan had the highest average number of information requests per month (5,000) and Illinois the lowest (2).

The cost of implementing and operating a monitoring program differs from State to State. The average cost to start a program is approximately $350,000, and annual operating

costs for CSMPs range from $47,000 to $17 million. Cost variations occur due to the frequency of data collection (bi-weekly vs. monthly, for example), the use of a third party vendor, the number of prescriptions written/filled in a State, the number of schedules (II-V) collected, and the use of official forms.

Pharmacies are registered by the Drug Enforcement Agency, and each registered pharmacy is required to submit information to the States' CSMP. California had the greatest number of pharmacies (5,982) and Wyoming had the least (121).

State Controlled Substance Monitoring Reports

Alabama's Prescription Drug Monitoring Program (CSMP)

Program Name	Controlled Substance Prescription Database
Year of Implementation	2006
Authorizing Legislation	www.pdmp.alabama.gov/pdm_laws.html
Contact	Charles Thomas
Controlled Drugs Monitored	Schedules: II-V
Average Number of Prescriptions Collected per year	9-10 Million
Advisory and Oversight	Department of Justice, Bureau of Narcotic Enforcement
Operating Budget	Start-Up $1,150,000
Frequency of Data Collection	4 x month
Funding Source	Grants, Portion of controlled substance registration Fee
Group Requesting Summary Reports	Licensing Boards (100 %)
Average Requests Received Per Month	80
Number of DEA Registered Pharmacies *(September 2006)*	1,315

California's Prescription Drug Monitoring Program (CSMP)

Program Name	Controlled Substance Utilization Review and Evaluation Systems (CURES)
Year of Implementation	1939
Authorizing Legislation	www.caag.state.ca.us/bne/trips.htm
Contact	Katherine Ellis
Controlled Drugs Monitored	Schedules: II
Average Number of Prescriptions Collected per year	21 Million
Advisory and Oversight	Pharmacy and Law Enforcement
Operating Budget	$296,000 (Personnel Costs not included; start-up: $1,000,000)
Frequency of Data Collection	1 x month
Funding Source	State General Fund/Regulatory board reimbursement
Group Requesting Summary Reports	Physicians (70 %), Law Enforcement and Licensing Boards (15 %) Pharmacies (15 %)
Average Requests Received Per Month	5,000
Number of DEA Registered Pharmacies *(September 2006)*	5,982

Colorado's Prescription Drug Monitoring Program (CSMP)

Program Name	Not Yet Operational
Year of Implementation	Not Yet Operational
Authorizing Legislation	Laws are drafted but not ratified.
Contact	Jody Gingery
Controlled Drugs Monitored	Schedules: II-V
Average Number of Prescriptions Collected per year	Not Yet Operational
Advisory and Oversight	Department of Regulatory Agencies
Operating Budget	$400,000
Frequency of Data Collection	Not Yet Operational
Funding Source	Grants
Group Requesting Summary Reports	Not Yet Operational
Average Requests Received Per Month	Not Yet Operational
Number of DEA Registered Pharmacies *(September 2006)*	806

Connecticut's Prescription Drug Monitoring Program (CSMP)

Program Name	Not Yet Operational
Year of Implementation	Enacted Not Operational
Authorizing Legislation	www.search.cga.state.ct.us/dtSearch_lpa.html
Contact	John Gadea
Controlled Drugs Monitored	Schedules: II-V
Average Number of Prescriptions Collected per year	Not Yet Operational
Advisory and Oversight	Commissioner of Consumer Protection
Operating Budget	$400,000
Frequency of Data Collection	Not Yet Operational
Funding Source	Grants
Group Requesting Summary Reports	Not Yet Operational
Average Requests Received Per Month	Not Yet Operational
Number of DEA Registered Pharmacies *(September 2006)*	664

Hawaii's Prescription Drug Monitoring Program (CSMP)

Program Name	Electronic Prescription Accountability System
Year of Implementation	1943
Authorizing Legislation	www.capitol.hawaii.gov/hrscurrent/Vol06_Ch0321-0344/HRS0329/HRS_0329-0014.htm
Contact	Glen Kimura
Controlled Drugs Monitored	Schedules: II-IV
Average Number of Prescriptions Collected per year	1.4 Million
Advisory and Oversight	Law Enforcement
Operating Budget	$250,220
Frequency of Data Collection	1 x Month
Funding Source	Grants
Group Requesting Summary Reports	Law Enforcement (70 %) Pharmacies (15 %) Physicians (15 %)
Average Requests Received Per Month	270
Number of DEA Registered Pharmacies *(September 2006)*	194

Idaho's Prescription Drug Monitoring Program (CSMP)

Program Name	Prescription Tracking Program
Year of Implementation	1967
Authorizing Legislation	www.state.id.us/idstat/TOC/3702702KTOC.html
Contact	Richard Markuson
Controlled Drugs Monitored	Schedules: II-IV
Average Number of Prescriptions Collected per year	1.5 Million
Advisory and Oversight	Pharmacy Board
Operating Budget	$143,000
Frequency of Data Collection	1 x Month
Funding Source	Licensing Fees and Grants
Group Requesting Summary Reports	Physicians (90 %), Pharmacies (5 %), Law Enforcement (3 %), Licensing Boards (2 %)
Average Requests Received Per Month	1,100
Number of DEA Registered Pharmacies *(September 2006)*	311

Illinois's Prescription Drug Monitoring Program (CSMP)

Program Name	Illinois Prescription Drug Monitoring Program
Year of Implementation	1961
Authorizing Legislation	www.natlalliance.org/pdfs/illinois.pdf
Contact	Stanley Tylman
Controlled Drugs Monitored	Schedules: II
Average Number of Prescriptions Collected per year	1.6 Million
Advisory and Oversight	Public Health
Operating Budget	$169,000 (Start-up $200,000)
Frequency of Data Collection	2 x Month
Funding Source	Annual Appropriations
Group Requesting Summary Reports	Law Enforcement (50 %) Licensing Board (50 %)
Average Requests Received Per Month	2
Number of DEA Registered Pharmacies *(September 2006)*	2,383

Indiana's Prescription Drug Monitoring Program (CSMP)

Program Name	Indiana's Scheduled Prescription Electronic Collection and Tracking (INSPECT)
Year of Implementation	1997
Authorizing Legislation	www.in.gov/pla/bandc/isbp/inspectmanual-2.pdf
Contact	Marty Allain
Controlled Drugs Monitored	Schedules: II-V
Average Number of Prescriptions Collected per year	5 Million
Advisory and Oversight	Professional Licensing Agency
Operating Budget	$250,000
Frequency of Data Collection	2 x Month
Funding Source	Percentage of Licensing Fee
Group Requesting Summary Reports	Law Enforcement (100 %)
Average Requests Received Per Month	80
Number of DEA Registered Pharmacies *(September 2006)*	1,208

Iowa's Prescription Drug Monitoring Program (CSMP)

Program Name	Not Yet Operational
Year of Implementation	Enacted Not Operational
Authorizing Legislation	www.natlalliance.org/pdfs/PMP %20Bill %20Status %20August %202006.pdf
Contact	Terry Witowski
Controlled Drugs Monitored	Schedules: II-IV
Average Number of Prescriptions Collected per year	Not Yet Operational
Advisory and Oversight	State Board of Pharmacy Examiners
Operating Budget	Not Yet Operational
Frequency of Data Collection	Not Yet Operational
Funding Source	Not Yet Operational
Group Requesting Summary Reports	Not Yet Operational
Average Requests Received Per Month	Not Yet Operational
Number of DEA Registered Pharmacies *(September 2006)*	801

Kentucky's Prescription Drug Monitoring Program (CSMP)

Program Name	Kentucky All Schedule Prescription Electronic Reporting (KASPER)
Year of Implementation	1999
Authorizing Legislation	www.lrc.ky.gov/kar/902/055/110.htm
Contact	Zach Ramsey
Controlled Drugs Monitored	Schedules: II-V
Average Number of Prescriptions Collected per year	8.2 Million
Advisory and Oversight	Public Health
Operating Budget	$350,000 (start-up $1,400,000)
Frequency of Data Collection	4 x Month
Funding Source	General State Funds/State Legislature
Group Requesting Summary Reports	Prescribers (92 %), Pharmacies (3 %), Law Enforcement (3 %), Licensing Boards (1 %), Other (1 %)
Average Requests Received Per Month	2,200
Number of DEA Registered Pharmacies *(September 2006)*	1,115

Louisiana's Prescription Drug Monitoring Program (CSMP)

Program Name	Not Yet Operational
Year of Implementation	Enacted (6/29/06) Not Operational
Authorizing Legislation	www.natlalliance.org/pdfs/PMP %20Bill %20Status %20August %202006.pdf
Contact	Malcolm Broussard
Controlled Drugs Monitored	Not Yet Operational
Average Number of Prescriptions Collected per year	Not Yet Operational
Advisory and Oversight	Board of Pharmacy
Operating Budget	$400,000
Frequency of Data Collection	Not Yet Operational
Funding Source	Grants
Group Requesting Summary Reports	Not Yet Operational
Average Requests Received Per Month	Not Yet Operational

Number of DEA Registered Pharmacies *(September 2006)*	1,234

Maine's Prescription Drug Monitoring Program (CSMP)

Program Name	Maine's Prescription Monitoring Program
Year of Implementation	2004
Authorizing Legislation	www.natlalliance.org/pdfs/maine.pdf
Contact	Chris Baumgartner
Controlled Drugs Monitored	Schedules: II-IV
Average Number of Prescriptions Collected per year	1.8 Million
Advisory and Oversight	HHS, Office of Substance Abuse
Operating Budget	$300,000, (Start-up: $190,000)
Frequency of Data Collection	2 x month
Funding Source	Grants
Group Requesting Summary Reports	Physicians (83 %) Pharmacies (17 %)
Average Requests Received Per Month	1,100
Number of DEA Registered Pharmacies *(September 2006)*	297

Massachusetts' Prescription Drug Monitoring Program (CSMP)

Program Name	Massachusetts Prescription Monitoring Program
Year of Implementation	1992
Authorizing Legislation	www.natlalliance.org/pdfs/massachusetts.pdf
Contact	Grant Carrow
Controlled Drugs Monitored	Schedules: II
Average Number of Prescriptions Collected per year	2.6 Million
Advisory and Oversight	Public Health
Operating Budget	Not calculated independently part of retained revenue account
Frequency of Data Collection	1 x month
Funding Source	Returned Revenue Account/Licensing Fees

Group Requesting Summary Reports	Law Enforcement (61 %) Licensing Boards (30 %) other (9 %)
Average Requests Received Per Month	10
Number of DEA Registered Pharmacies *(September 2006)*	1,150

Michigan's Prescription Drug Monitoring Program (CSMP)

Program Name	Michigan Automated Prescription System (MAPS)
Year of Implementation	1988
Authorizing Legislation	www.natlalliance.org/pdfs/michigan.pdf
Contact	Michael Wissel
Controlled Drugs Monitored	Schedules: II-V
Average Number of Prescriptions Collected per year	15 Million
Advisory and Oversight	Board of Health Professions
Operating Budget	$60,000, (Start-up: $400,000)
Frequency of Data Collection	1 x month
Funding Source	Licensing Fees
Group Requesting Summary Reports	Physicians (80 %), Pharmacies (15 %), Law Enforcement (5 %)
Average Requests Received Per Month	5,000
Number of DEA Registered Pharmacies *(September 2006)*	2,335

Mississippi's Prescription Drug Monitoring Program (CSMP)

Program Name	Mississippi Prescription Monitoring Program
Year of Implementation	2005
Authorizing Legislation	www.pmp.ms.gov/
Contact	Mac McDivitt
Controlled Drugs Monitored	Schedules: II-V
Average Number of Prescriptions Collected per year	6 Million
Advisory and Oversight	Board of Pharmacy, MS Controlled Substance Authority (MCSA)
Operating Budget	$150,000, (Start-up: $50,000)

Frequency of Data Collection	1 x month
Funding Source	State Pharmacy Board/Grants
Group Requesting Summary Reports	Licensing Board (50 %), Law Enforcement (50 %)
Average Requests Received Per Month	100
Number of DEA Registered Pharmacies *(September 2006)*	818

Nevada's Prescription Drug Monitoring Program (CSMP)

Program Name	Prescription Controlled Substance Abuse Prevention Program
Year of Implementation	1995
Authorizing Legislation	www.natlalliance.org/pdfs/nevada.pdf
Contact	Joanee Quirk
Controlled Drugs Monitored	Schedules: II-IV
Average Number of Prescriptions Collected per year	3 Million
Advisory and Oversight	Pharmacy Board, Law Enforcement
Operating Budget	$300,000, (Start-up: $131,000)
Frequency of Data Collection	2 x month
Funding Source	Board of Pharmacy/Grants
Group Requesting Summary Reports	Physicians (85 %), Pharmacies (5 %), Licensing Boards (5 %), Law Enforcement (5 %)
Average Requests Received Per Month	1,100
Number of DEA Registered Pharmacies *(September 2006)*	483

New Mexico's Prescription Drug Monitoring Program (CSMP)

Program Name	New Mexico Prescription Monitoring Program
Year of Implementation	2005
Authorizing Legislation	www.state.nm.us/pharmacy/statutes.html
Contact	Bill Harvey
Controlled Drugs Monitored	Schedules: II-IV
Average Number of Prescriptions Collected per year	N/A
Advisory and Oversight	Board of Pharmacy

Operating Budget	N/A
Frequency of Data Collection	1 x month
Funding Source	N/A
Group Requesting Summary Reports	N/A
Average Requests Received Per Month	N/A
Number of DEA Registered Pharmacies *(September 2006)*	294

New York's Prescription Drug Monitoring Program (CSMP)

Program Name	Prescription Monitoring Program
Year of Implementation	1972
Authorizing Legislation	www.public.leginfo.state.ny.us/menugetf.cgi?COMMONQUERY=LAWS
Contact	James Giglio
Controlled Drugs Monitored	Schedules: II-V
Average Number of Prescriptions Collected per year	12 Million
Advisory and Oversight	Public Health
Operating Budget	$17,000,000
Frequency of Data Collection	1 x month
Funding Source	Sub allocation from the state insurance fund
Group Requesting Summary Reports	N/A
Average Requests Received Per Month	N/A
Number of DEA Registered Pharmacies *(September 2006)*	4,521

North Carolina's Prescription Drug Monitoring Program (CSMP)

Program Name	Not Yet Operational
Year of Implementation	Enacted Not Operational
Authorizing Legislation	Laws are drafted but not ratified
Contact	John Womble
Controlled Drugs Monitored	Schedules: II-V
Average Number of Prescriptions Collected per year	$400,000
Advisory and Oversight	Department of Health and Human Services
Operating Budget	Not Yet Operational
Frequency of Data Collection	Not Yet Operational
Funding Source	Not Yet Operational
Group Requesting Summary Reports	Not Yet Operational
Average Requests Received Per Month	Not Yet Operational
Number of DEA Registered Pharmacies *(September 2006)*	1,927

North Dakota's Prescription Drug Monitoring Program (CSMP)

Program Name	Not Yet Operational
Year of Implementation	Enacted Not Operational
Authorizing Legislation	Laws are drafted but not ratified
Contact	Not Yet Operational
Controlled Drugs Monitored	Not Yet Operational
Average Number of Prescriptions Collected per year	Not Yet Operational
Advisory and Oversight	Department of Health and Human Services
Operating Budget	Not Yet Operational
Frequency of Data Collection	Not Yet Operational
Funding Source	Grants
Group Requesting Summary Reports	Not Yet Operational
Average Requests Received Per Month	Not Yet Operational
Number of DEA Registered Pharmacies *(September 2006)*	178

Ohio's Prescription Drug Monitoring Program (CSMP)

Program Name	Prescription Monitoring Program
Year of Implementation	2006
Authorizing Legislation	www.ohioshp.org/index.php?option=com_contentandtask=viewandid=80andItemid=2
Contact	Tim Benedict
Controlled Drugs Monitored	Schedules: II-V
Average Number of Prescriptions Collected per year	N/A
Advisory and Oversight	Bureau of Pharmacy
Operating Budget	$400,000 (Start-up: $350,000)
Frequency of Data Collection	2 x month
Funding Source	N/A
Group Requesting Summary Reports	N/A
Average Requests Received Per Month	N/A
Number of DEA Registered Pharmacies *(September*	2,442

2006)

Oklahoma's Prescription Drug Monitoring Program (CSMP)

Program Name	Oklahoma Prescription Monitoring Program
Year of Implementation	1990
Authorizing Legislation	www.obn.state.ok.us/index.html
Contact	John Duncan
Controlled Drugs Monitored	Schedules: II-V
Average Number of Prescriptions Collected per year	$600,000
Advisory and Oversight	Law Enforcement
Operating Budget	$350,000, (Start-up: $350,000)
Frequency of Data Collection	1 x month
Funding Source	N/A
Group Requesting Summary Reports	Law Enforcement (60 %) Licensing Boards (40 %)
Average Requests Received Per Month	200
Number of DEA Registered Pharmacies *(September 2006)*	886

Pennsylvania's Prescription Drug Monitoring Program (CSMP)

Program Name	Prescription Monitoring Program
Year of Implementation	2002
Authorizing Legislation	www.natlalliance.org/pdfs/pennsylvania.pdf
Contact	Lawrence Cherba
Controlled Drugs Monitored	Schedules: II
Average Number of Prescriptions Collected per year	4.1 Million
Advisory and Oversight	Office of the Attorney General
Operating Budget	$257,216, (Start-up: $260,000)
Frequency of Data Collection	1 x month
Funding Source	Office of the Attorney General
Group Requesting Summary Reports	Law Enforcement (100 %)
Average Requests Received Per Month	80
Number of DEA Registered Pharmacies *(September 2006)*	3,014

Rhode Island Prescription Drug Monitoring Program (CSMP)

Program Name	Prescription Monitoring Program
Year of Implementation	1978
Authorizing Legislation	www.health.ri.gov/hsr/professions/csr_reporting.php
Contact	Catherine Cordy
Controlled Drugs Monitored	Schedules: II-III
Average Number of Prescriptions Collected per year	N/A
Advisory and Oversight	Public Health
Operating Budget	N/A
Frequency of Data Collection	1 x month
Funding Source	N/A
Group Requesting Summary Reports	N/A
Average Requests Received Per Month	N/A
Number of DEA Registered Pharmacies *(September 2006)*	191

South Carolina's Prescription Drug Monitoring Program (CSMP)

Program Name	Not Yet Operational
Year of Implementation	Enacted Not Operational
Authorizing Legislation	Laws are drafted but not ratified
Contact	Wilbur Harling
Controlled Drugs Monitored	Not Yet Operational
Average Number of Prescriptions Collected per year	Not Yet Operational
Advisory and Oversight	Department of Health and Environmental Control
Operating Budget	$350,000
Frequency of Data Collection	Not Yet Operational
Funding Source	Grants
Group Requesting Summary Reports	Not Yet Operational
Average Requests Received Per Month	Not Yet Operational

Number of DEA Registered Pharmacies *(September 2006)*	1,031

Tennessee's Prescription Drug Monitoring Program (CSMP)

Program Name	Tennessee Controlled Substance Database
Year of Implementation	2006
Authorizing Legislation	www.state.tn.us/commerce/boards/pharmacy/controlled_substance/pdf/TNRxReportingManual.pdf
Contact	Terry W. Grinder
Controlled Drugs Monitored	Schedules: II-V
Average Number of Prescriptions Collected per year	N/A
Advisory and Oversight	The Tennessee Board of Pharmacy
Operating Budget	N/A
Frequency of Data Collection	2 x Month
Funding Source	N/A
Group Requesting Summary Reports	N/A
Average Requests Received Per Month	N/A
Number of DEA Registered Pharmacies *(September 2006)*	1,584

Texas's Prescription Drug Monitoring Program (CSMP)

Program Name	Texas Prescription Program
Year of Implementation	1981
Authorizing Legislation	www.txdps.state.tx.us/criminal_law_enforcement/narcotics/pages/prescription.htm
Contact	Kelli Cox
Controlled Drugs Monitored	Schedules: II
Average Number of Prescriptions Collected per year	3.3 Million
Advisory and Oversight	Department of Public Safety
Operating Budget	$1,400,000
Frequency of Data Collection	1 x Month
Funding Source	N/A
Group Requesting Summary Reports	Physicians (40 %), Licensing Board (40 %), Law Enforcement (20 %)

Average Requests Received Per Month	100
Number of DEA Registered Pharmacies *(September 2006)*	4,384

Utah's Prescription Drug Monitoring Program (CSMP)

Program Name	Utah Controlled Substance Database Program
Year of Implementation	1995
Authorizing Legislation	www.natlalliance.org/pdfs/utah.pdf
Contact	Marvin Sims
Controlled Drugs Monitored	Schedules: II-V
Average Number of Prescriptions Collected per year	3.9 Million
Advisory and Oversight	Commerce's Licensing Division
Operating Budget	$47,000, (Start-up: $50,000)
Frequency of Data Collection	1 x Month
Funding Source	Portion of Controlled Licensing Fee
Group Requesting Summary Reports	Physicians (40 %), Licensing Board (40 %), Law Enforcement (20 %)
Average Requests Received Per Month	4,200
Number of DEA Registered Pharmacies *(September 2006)*	476

Vermont's Prescription Drug Monitoring Program (CSMP)

Program Name	Vermont Prescription Monitoring System (VPMS)
Year of Implementation	Enacted (5/31/06) not operational
Authorizing Legislation	Laws are drafted but not ratified.
Contact	Mark Ames
Controlled Drugs Monitored	Schedules: II-IV
Average Number of Prescriptions Collected per year	N/A
Advisory and Oversight	Department of Health
Operating Budget	$350,000
Frequency of Data Collection	Not Yet Operated
Funding Source	Grants

Group Requesting Summary Reports	N/A
Average Requests Received Per Month	N/A
Number of DEA Registered Pharmacies *(September 2006)*	140

Virginia's Prescription Drug Monitoring Program (CSMP)

Program Name	Virginia Prescription Monitoring Program
Year of Implementation	2003 (pilot) 2006 (statewide)
Authorizing Legislation	www.dhp.state.va.us/dhp_programs/pmp/pmp_laws.asp
Contact	Ralph Orr
Controlled Drugs Monitored	Schedules: II-IV
Average Number of Prescriptions Collected per year	400,000 PILOT
Advisory and Oversight	Department of Health Professions
Operating Budget	$230,553 (FY 2006) (Start-up: $128,000)
Frequency of Data Collection	2 x month
Funding Source	Grants
Group Requesting Summary Reports	Physicians (78 %), Law Enforcement (19 %), Licensing Board (3 %)
Average Requests Received Per Month	600
Number of DEA Registered Pharmacies *(September 2006)*	1,468

Washington's Prescription Drug Monitoring Program (CSMP)

Program Name	Prescription Monitoring Program
Year of Implementation	1984
Authorizing Legislation	www.natlalliance.org/pdfs/washington.pdf
Contact	Steven Saxe
Controlled Drugs Monitored	N/A
Average Number of Prescriptions Collected per year	N/A
Advisory and Oversight	Department of Health
Operating Budget	N/A
Frequency of Data Collection	N/A

Funding Source	N/A
Group Requesting Summary Reports	N/A
Average Requests Received Per Month	N/A
Number of DEA Registered Pharmacies *(September 2006)*	1,261

West Virginia's Prescription Drug Monitoring Program (CSMP)

Program Name	Prescription Monitoring Program
Year of Implementation	1995
Authorizing Legislation	www.wvbop.com/main.htm
Contact	William Douglass
Controlled Drugs Monitored	Schedules: II-IV
Average Number of Prescriptions Collected per year	3.3 Million
Advisory and Oversight	Board of Pharmacy
Operating Budget	$152,173
Frequency of Data Collection	4 x month
Funding Source	N/A
Group Requesting Summary Reports	Physicians (65 %), Pharmacies (25 %), Law Enforcement (8 %), Licensing Board (2 %)
Average Requests Received Per Month	1,000
Number of DEA Registered Pharmacies *(September 2006)*	516

Wyoming's Prescription Drug Monitoring Program (CSMP)

Program Name	Prescription Drug Monitoring Program
Year of Implementation	2004
Authorizing Legislation	www.natlalliance.org/pdfs/wyoming.pdf
Contact	James Carder
Controlled Drugs Monitored	Schedules: II-IV
Average Number of Prescriptions Collected per year	540,000
Advisory and Oversight	Wyoming Board of Pharmacy

Operating Budget	$85,000, (Start-up: $215,000)
Frequency of Data Collection	1 x month
Funding Source	Controlled Substance Licensing Fee
Group Requesting Summary Reports	Physicians (85 %), Pharmacies (10 %), Licensing Board (3 %), Law Enforcement (2 %)
Average Requests Received Per Month	200
Number of DEA Registered Pharmacies *(September 2006)*	121

Appendix F: KEY FEATURES OF A NASPER CSMP

Consistent with NASPER, all States that wish to establish a statewide program must adhere to the provisions discussed in the statute. NASPER has an array of provisions that must accompany a functioning CSMP.

Limitations	The effective establishment of a CSMP must not adversely affect a person's access to treatment if he/she is prescribed controlled substances.
Controlled Substances	All CSMPs are required to monitor drugs in Schedules II, III, and IV.
Database Creation	There must be the creation of an electronic database that will be used for storing all the information necessary to running an effective CSMP.
Disclosure of Information	Only a select group of professionals, under restricted circumstances, may obtain access to database information (i.e., Physician, Dentist, Veterinarian, Scientific Investigator, Pharmacy, Hospital, or person licensed or certified by the State). Local, State and Federal law enforcement authorities have only limited access to summary statistics of CSMP information, unless otherwise authorized by law.
Interoperability*	CSMPs electronically share database information with other CSMP States.
Notification	A mechanism must be designed that alerts practitioners and pharmacies of information that might assist them in identifying possible prescription drug abuse and notifying the appropriate law enforcement officials like the DEA when necessary.
Advisory and Oversight	A State's CSMP may have an advisory council which oversees the activities of the program. The advisory council can consist of either State pharmacy councils, law enforcement agencies, or both.
Funding	Much of the CSMP funding comes from Federal grants monies. After money is allocated from the Federal Government, States begin to fund their own programs either through the State legislature, States fees or grants.
Confidentiality	Confidentiality of individually identifiable patient information must be maintained.
Review Process	After a designated period of no later than 3 years, the review process must start. The process must examine the effectiveness of State CSMPs. All information is then submitted to the United States Congress for further consideration and review.

***INTEROPERABILITY OR SHARING INFORMATION ACROSS STATE BORDERS**

To share health data, agencies need to adopt the same clinical vocabularies and the same ways of transmitting that information." The Consolidated Health Informatics (CHI)

establishes a portfolio of existing clinical vocabularies and a "grammar" of messaging standards that enable Federal agencies to build interoperable Federal health data systems. These systems "speak the same language," allowing agencies to share information without the high cost of translation or data re-entry. Interoperability is "the ability of the program to electronically share reported information, including each of the required report components described in subsection (d) with another State if the information concerns either the dispensing of a controlled substance to an ultimate user who resides in such other State, or the dispensing of a controlled substance prescribed by a practitioner whose principal place of business is located in such other State." CHI initiative standards are compatible with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) transactions and code sets, security and privacy standards. About 20 department/agencies including HHS, Veterans Affairs (VA), Department of Defense (DOD), Social Security Administration (SSA), General Services Administration (GSA), and National Institute of Standards and Technology (NIST) are active in the CHI governance process. Since November, 2003, the Department of Justice has been a CHI Federal partner.

On March 21, 2003, HHS, DOD and VA announced the National Council on Prescription Drug Programs (NCPDP) standards for ordering drugs from retail pharmacies to standardize information between health care providers and the pharmacies. The NCPDP SCRIPT standard, v. 5.0, has been adopted under the Medicare Modernization Act for entities prescribing covered part D drugs for part D eligible individuals.

Beginning in fiscal year 2002, Congress has appropriated funds to the U.S. Department of Justice (DOJ) for support of CSMPs. The problem DOJ addressed was the ineffective communication between CSMPs.

The Alliance of State with Prescription Monitoring Programs participates with the Integrated Justice Information Systems Institute (IJIS) committee for setting standards for transfer of prescription data between State programs. The project provides a systematic way for States to communicate prescription data across State lines, and has created a model standard for the exchange of information between States.

Types of reports that can be shared between States using the system include patient activity reports, a history of patients' prescriptions; a history of prescriptions issued by practitioners; an activity report; a history of prescriptions dispensed by pharmacies; bulk data reports; a method for transmitting to an adjoining State all prescriptions filled in the transmitting State for residents of the adjoining State or for practitioners who issued the prescription in the adjoining State; and alert notifications.

The IJIS CSMP committee is currently working on a pilot project to share CSMP data between the States of California and Nevada. The next phase will include a data sharing project involving Kentucky, Indiana, Ohio, West Virginia and Michigan. The IJIS committee effort is focused on developing a technical architecture for CSMP data exchange and establishing technical guidelines, formats, processes and agreements for sharing the data that will be consistent with the laws and regulations for each State.

APPENDIX G: GLOSSARY

Accurate use of terminology is essential to understanding and formulating a balanced approach that fosters appropriate use while discouraging the non-medical use of prescription medications. Yet scientists, clinicians, regulators, and the lay public use disparate definitions of terms related to addiction.

Many of the terms used in this report have definitions that differ somewhat from one group to another. Where possible, the authors employ standardized terminology from established organizations and experts. The following list contains the definitions used herein.

Abuse. The definition of "abuse" varies widely, depending on the context in which it is used and who is supplying the definition. For example, the Drug Enforcement Administration defines drug abuse as involving the use of prescription medications outside "the scope of sound medical practice" (DEA, 2002). In contrast, the American Psychiatric Association in its *Diagnostic and Statistical Manual of Mental Disorders* (1994) defines drug abuse as "a maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by one or more behaviors." More recently, the American Society of Addiction Medicine (ASAM) described abuse of a medication as use in a manner that "deviates from approved medical, legal, and social standards, generally to achieve a euphoric state ('high') or sustain an established dependence." This report employs the ASAM definition, which reflects a consensus among addiction experts.

Abuse Potential. The *abuse potential* of a drug – licit or illicit – has been described as "the relative ease with which a prescribed medication can be extracted or modified to yield the desired psychic effect" (Ling, Wesson et al., 2003). Pharmacologically, the abuse potential of a drug usually is assessed according to (1) the drug's reward-reinforcing effects, as measured by various indicators of liking or "high" in humans and their propensity to vigorous self-administration in non-human animals, and (2) the characteristic induction of sensitization when given to laboratory animals on a daily basis (DuPont and DuPont, 2003; DuPont and Gold, 1995). Abuse potential also is related to drug formulation, in that formulations that impede ingestion by the intranasal and intravenous routes of administration – through which the active agents circulate more rapidly to the brain – are less likely to be abused (Compton and Volkow, 2006; CPDD, 2006; Woody, Cottler et al., 1993).

Addiction. Addiction to a prescription medication, like every other form of addiction, involves a complex interplay of biological and environmental factors (Vaillant, 2003). Alan Leshner, Ph.D., former director of the National Institute on Drug Abuse, has described addiction as a "disease of the brain," explaining that in vulnerable individuals, repeated self-administration of a drug produces a qualitative change in the way the brain functions. As a result, "the affected individual has an intense need for, and focus on, repeating the drug experience. But there comes a point**…** at which the drug user becomes an addict. At that

point, it appears that a figurative 'switch' has been thrown and the individual suffers a significant loss of his or her ability to make free choices about continued use of the drug" (Leshner, 2001). Reflecting this understanding of addiction, the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine have agreed on the following definition: "Addiction is a primary, chronic, neurobiological disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving" (AAPM, APS, and ASAM, 2001).

Analgesic. Most potent analgesic agents are derived from opium or are synthetic adaptations of opium. They depress the central nervous system and relieve pain. They also can be used by persons who are addicted to opioids to avoid or suppress withdrawal (Brushwood, 2003).

Appropriate Use (also termed "therapeutic use"): Appropriate use involves avoidance of undermedication (underprescribing), overmedication (overprescribing), and drug misuse or abuse.

ARCOS Data. Data from the *Automation of Reports and Consolidated Orders System* (ARCOS) measure the amounts of controlled substances distributed to the retail level from manufacturers and importers. The data are collected by the U.S. Drug Enforcement Administration (DEA) and reported in total grams and in grams per 100,000 population. Changes made in the data collection methodology in 1997 resulted in significantly increased quantities reported to ARCOS. Consequently, it is not valid to compare ARCOS data for periods after 1997 with those before that date. The DEA Office of Diversion Control has recently made ARCOS reports available on its Web site; they can be accessed at www.deadiversion.usdoj.gov/arcos/index.html.

Chilling Effect. Used to describe a (hypothesized) action in which prescription monitoring systems discourage the prescribing of covered drugs, particularly opioid analgesics. Multiple mechanisms (such as the inconvenience associated with a requirement to use a special prescription form, fear of regulatory oversight, and concern for patient privacy), have been offered to explain the presence of such an effect.

Controlled Substance. A *controlled substance* or *controlled drug* is one that has been classified by the Drug Enforcement Administration under one of the schedules of the Federal Controlled Substances Act of 1970 (Code of Federal Regulations, Title 21, Chapter 2). The CSA designates the Attorney General, in consultation with the Secretary of Health and Human Services, as the official who determines the appropriate schedule for any drug or other substance proposed for control under the CSA. The Attorney General and the Secretary of Health and Human Services have delegated the authority to make such determinations to the DEA and FDA, respectively. See Appendix B for examples of federally controlled drugs.

Dependence. In various editions of the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders*, the term "addiction" has been replaced with the term "dependence," which has caused confusion among caregivers and policymakers alike. Such confusion loses the important distinction between physical dependence arising from abuse of a drug, and the *physical dependence without addiction* that can and does occur within the context of good medical care (as when a patient prescribed an opioid analgesic for pain becomes physically dependent on the medication) (DuPont and DuPont, 2003). According to the World Health Organization, "The development of tolerance and physical dependence denote normal physiologic adaptations of the body to the presence of an opioid" (WHO, 1996, p. 41). The American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine have agreed on the following definition: "Physical dependence is a state of adaptation that is manifested by a drug class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist" (AAPM, APS, and ASAM, 2001). This distinction is reflected in the two primary diagnostic classification systems used by health care professionals: the *International Classification of Mental and Behavioural Disorders, 10th Edition* (*ICD-10*; WHO, 1996) of the World Health Organization (WHO), and the *Diagnostic and Statistical Manual* of the American Psychiatric Association (*DSM;* APA, 1994). The distinction is observed in this report.

Diversion. The Federal Controlled Substances Act (21 U.S.C. §§ 801 et seq.) establishes a closed system of distribution for drugs classified as controlled substances. Records must be kept from the time a drug is manufactured to the time it is dispensed. Health care professionals who are authorized to prescribe, dispense, and otherwise control access to these drugs are required to register with the Drug Enforcement Administration (DEA). Drugs that make their way outside this closed system are said to have been "diverted" from the system, and those individuals who are responsible for the diversion are in violation of the law.

Although not identical, *abuse* and *diversion* are closely related, in that the degree to which a prescribed medication is abused depends in large part on how easily it is redirected (diverted) from the legitimate distribution system (Ling, Wesson and Smith, 2003).

Doctor-Shopping. Used to describe a practice in which an individual visits multiple physicians in roughly the same period of time to seek prescriptions for the same or similar drugs. A defining characteristic is the failure to disclose to any physician the fact that the "patient" is obtaining prescriptions for similar drugs from other practitioners. It generally is assumed that such drugs are sought for non-medical purposes, although some experts suggest that certain "doctor shoppers" actually are individuals who seek help for undertreated or untreated medical disorders such as pain.

Hassle Factor. Like "doctor-shopping," the term "hassle factor" has found wide use in medical circles to describe conditions created by what physicians perceive to be excessive paperwork. With regard to CSMPs, it is a term of art used to describe physicians' reactions to requirements that they use a special type of form (e.g., State-

issued, multiple-part, et al.) to order certain drugs. It is used in the report to convey that specific set of physician attitudes.

Inappropriate Prescribing. This term is used to describe the behavior of a *physician* who prescribes a medication for the wrong indication, to a patient who will not benefit, at too high a dose, or for too long.

Misuse. The term *misuse* often is used to describe incorrect use of a medication by a patient who uses a drug for other than the prescribed purpose, takes too little or too much, takes it too often, or takes it for too long.

Narcotic. The terms "opioid" and "narcotic" are virtually synonymous, but the former term is used consistently in the health care community, while the latter term is used consistently in the regulatory and law enforcement communities. Both terms refer to drugs that are derived from opium or are synthetic adaptations of opium (Brushwood, 2003).

Non-Medical Use. "Non-medical use" of a prescription medication is defined in the NSDUH as use of a psychotherapeutic agent "even once, that was not prescribed for you, or that you took only for the experience or feeling it caused" (OAS, 2003a). The term encompasses all uses of prescription medications other than those that are directed by a physician and used by a patient within the law and the requirements of good medical practice.

Opioid. The term *opioid* refers to natural and semi-synthetic derivatives of the opium poppy, as well as to similar synthetic compounds that have analgesic (or pain-relieving) properties because of their effects on the central nervous system. These agents include codeine, morphine, hydromorphone, hydrococone, oxycodone and fentanyl. Opioids sometimes are inappropriately referred to as *narcotics*, a legal term that is no longer used in medicine because it incorrectly suggests that opioids relieve pain by inducing sedation (Joranson, Gilson et al., 2003).

Overmedication. Overmedication involves the medically unjustified use of a drug. The prescription of a drug is deemed unjustified when a drug is used for an indication that is no longer accepted medical practice (obsolete) as determined by drug utilization criteria and standards; when there is no proper indication or sound scientific basis for its use; when administration continues despite proven ineffectiveness in curing the disease, disorder, or condition or ameliorating its symptoms; when more effective or less hazardous drugs are available; when the dose is excessive; when a mixture is used but only one of its components is indicated; or when more drugs are prescribed than are required (polypharmacy).

Prescription Monitoring Program. Prescription monitoring programs (PMPs) facilitate the collection, analysis, and reporting of information on the prescribing, dispensing, and use of controlled substances (GAO, 2003). Most such programs employ electronic data transfer systems, under which prescription information is transmitted from the dispensing pharmacy

to a State agency, which collates and analyzes the information. The older, paper-based monitoring programs (so-called "triplicate prescription programs" or "multiple-copy prescription programs") are being phased out (Alliance for Model State Drug Laws, 2002).

Problematic Use. Although more frequently associated with alcohol use (NIAAA, 2005), the concept of "problematic use" has relevance for prescription drug use as well. It is used to describe a range of behaviors – which may fall short of the criteria for abuse or addiction – that serve to elevate the risk for drug-related problems or complicate the management of other health problems. Thus, it encompasses *risk* for adverse results, as well as the actual *presence* of such consequences.

Pseudo-addiction. Addiction and pseudo-addiction are easily confused, but they are very different. Addiction is a neurobehavioral syndrome that results in psychological dependence and "is characterized by compulsive use despite harm." Pseudoaddiction is a "pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction" (FSMB, 1998).

Undermedication. Undermedication occurs when the patient fails to receive adequate drug therapy. For example, the negative impact of excessive concern about psychological and/or physical dependence is revealed by reports that acute and chronic pain often is inadequately treated. Relief of suffering is a legitimate goal of medical practice. Failure to provide such relief may result from timidity ("pharmacophobia"), incorrect or assessment of severity, or lack of knowledge or faith in the value of a controversial drug, even when its administration is indicated. Finally, patients may fail to comply or to convey the severity of their symptoms to the physician. Thus, the factors contributing to undermedication are diverse and disparate and span the fields of medicine, psychology, economics, and sociology.

Appendix H: Model Prescription Monitoring Act

Alliance of States with Prescription Monitoring Programs
and
National Association of State Controlled Substances Authorities

PRESCRIPTION MONITORING PROGRAM MODEL ACT

October 2002

Section 1. Short Title

This Act shall be known and may be cited as the "Prescription Monitoring Program Model Act."

Section 2. Legislative Findings

[insert State findings]

Section 3. Purpose

This act is intended to improve the State's ability to identify and stop diversion of prescription drugs in an efficient and cost effective manner that will not impede the appropriate medical utilization of licit controlled substances or other licit drugs of abuse.

Section 4. Definitions

(a) "Controlled substance" has the meaning given such term in [section of the State controlled substances act].
(b) [Designated State agency] means the State agency responsible for the functions listed in Section 5.
(c) "Patient" means the person or animal who is the ultimate user of a drug for whom a prescription is issued and/or for whom a drug is dispensed.
(d) "Dispenser" means a person who delivers a Schedule II–V controlled substance as defined in subsection (e) to the ultimate user, but does not include:
    (I) a licensed hospital pharmacy that distributes such substances for the purpose of inpatient hospital care [or the dispensing of prescriptions for controlled substances at the time of discharge from such a facility];
    (II) a practitioner, or other authorized person who administers such a substance; or
    (III) a wholesale distributor of a Schedule II–V controlled substance.
(e) "Schedule II, III, IV and/or V controlled substances" mean controlled substances that are listed in Schedules II, III, IV, and V of the Schedules provided under [insert section of the State controlled substances act] or the Federal Controlled Substances Act (21 U.S.C. 812).

Section 5. Requirements for Prescription Monitoring Program

(a) The [designated State agency] shall establish and maintain a program for the monitoring of prescribing and dispensing of all Schedule II, III and IV controlled substances [and, if selected by the State, Schedule V controlled

substances and/or additional drugs identified by the designated State agency as demonstrating a potential for abuse] by all professionals licensed to prescribe or dispense such substances in this State.

(b) Each dispenser shall submit to the [designated State agency] by electronic means information regarding each prescription dispensed for a drug included under paragraph (a) of this section. The information submitted for each prescription shall include, but not be limited to:

(I) Dispenser identification number.
(II) Date prescription filled.
(III) Prescription number.
(IV) Prescription is new or is a refill.
(V) NDC code for drug dispensed.
(VI) Quantity dispensed.
(VII) Number of days supply of the drug
(VIII) Patient identification number.
(IX) Patient name.
(X) Patient address.
(XI) Patient date of birth.
(XII) Prescriber identification number.
(XIII) Date prescription issued by prescriber.
(XIV) Person who receives the prescription from the dispenser, if other than the patient.
(XV) Source of payment for prescription.
(XVI) State issued serial number [if State chooses to establish a serialized prescription system].

(c) Each dispenser shall submit the information in accordance with transmission methods and frequency established by the [designated State agency]; but shall report at least every thirty days, between the 1st and the 15th of the month following the month the prescription was dispensed.

(d) The [designated State agency] may issue a waiver to a dispenser that is unable to submit prescription information by electronic means. Such waiver may permit the dispenser to submit prescription information by paper form or other means, provided all information required in paragraph (b) of this section is submitted in this alternative format.

Note: the following paragraphs, (e) - (h), are intended for those States that choose to establish a serialized prescription system as part of the prescription monitoring program.

(e) A serialized [single copy or multiple copy] prescription form, shall be issued by the [designated State agency] to individual [insert “and institutional” if practitioners in health care institutions issue prescriptions that can be filled in pharmacies outside the institutions] prescribers and shall be used for all prescriptions for drugs in [Schedule II, III, IV and/or V] controlled substances. Each series of prescriptions shall be issued to a specific prescriber and shall only be used by that prescriber.

(f) Each prescriber shall only prescribe drugs in [Schedule II, III, IV and/or V] controlled substances on official serialized prescription forms issued by the [designated State agency].
(g) Each dispenser shall only dispense drugs in [Schedule II, III, IV and/or V] controlled substances on such official serialized prescription forms.
(h) The [designated State agency] shall charge each prescriber an amount sufficient to cover the costs of processing requests for forms, printing the prescription forms, and operating the prescription monitoring program.

Note: States may chose to use alternative method than paragraph (h) to pay the cost of their serialized prescription forms and monitoring system, for example, through controlled substances registration fees. In such instances, paragraph (h) can be deleted.

Section 6. Access to Prescription Information

(a) Prescription information submitted to the [designated State agency] shall be confidential and not subject to public or open records laws, except as provided in paragraphs (c), (d), and (e) of this section.

Note: States may choose to also amend their open record statutes to specifically exclude from disclosure prescription information collected by their prescription monitoring program.

(b) The [designated State agency] shall maintain procedures to ensure that the privacy and confidentiality of patients and patient information collected, recorded, transmitted, and maintained is not disclosed to persons except as in paragraphs (c), (d), and (e) of this section.

(c) The [designated State agency or entity] shall review the prescription information. If there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, the [designated State agency] shall notify the appropriate law enforcement or professional licensing, certification or regulatory agency or entity, and provide prescription information required for an investigation.
(d) The [designated State agency] shall be authorized to provide data in the prescription monitoring program to the following persons.
(I) Persons authorized to prescribe or dispense controlled substances, for the purpose of providing medical or pharmaceutical care for their patients.
(II) An individual who requests the individual's own prescription monitoring information in accordance with procedures established under [insert State statute granting individuals access to State held data concerning themselves].
(III) [insert name or type of State boards and regulatory agencies that supervise or regulate a profession that is authorized for controlled substances activity].
(IV) Local, State and Federal law enforcement or prosecutorial officials engaged in the administration, investigation or enforcement of the laws governing licit drugs.
(V) [insert State Medicaid agency] regarding Medicaid program recipients.

(VI) [insert judicial authorities] under grand jury subpoena or court order [or equivalent judicial process in each State].

(VII) Personnel of the [designated State agency] for purposes of administration and enforcement of this Act, or [insert State controlled substances act], [if any other State statute is applicable, insert "or" and reference the other statutes].

(e) The [designated State agency] may provide data to public or private entities for statistical, research, or educational purposes after removing information that could be used to identity individual patients and/or persons who received prescriptions from dispensers.

Section 7. Authority to Contract

The [designated State agency] is authorized to contract with another agency of this State or with a private vendor, as necessary, to ensure the effective operation of the prescription monitoring program. Any contractor shall be bound to comply with the provisions regarding confidentiality of prescription information in Section 6 of this Act and shall be subject to the penalties specified in Section 8 of this Act for unlawful acts.

Section 8. Rules and Regulations

The [designated State agency] shall promulgate rules and regulations setting forth the procedures and methods for implementing this Act.

Section 9. Unlawful Acts and Penalties

(a) A dispenser who knowingly fails to submit prescription monitoring information to the [designated State agency or entity] as required by this Act or knowingly submits incorrect prescription information shall be subject to [insert appropriate administrative, civil or criminal penalty].

(b) A person authorized to have prescription monitoring information pursuant to this Act who knowingly discloses such information in violation of this Act shall be subject to [insert appropriate administrative, civil or criminal penalty.]

(c) A person authorized to have prescription monitoring information pursuant to this Act who uses such information in a manner or for a purpose in violation of this Act shall be subject to [insert appropriate administrative, civil or criminal penalty.]

Section 10. Severability

If any provision of this Act or application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the Act which can be given effect without the invalid provisions or applications, and to this end the provisions of this Act are severable.

Section 11. Effective Date

This Act shall be effective on [insert specific date or reference to normal State method of determination of the effective date].

Adopted by *Alliance of States with Prescription Monitoring Programs*, October 22, 2002 and *National Association of State Controlled Substances Authorities*, October 25, 2002

APPENDIX I: CASE STUDIES

SOURCES OF INFORMATION

Information was collected from government organizations such as the United States' Government Accountability Office, Texas Department of Public Safety (www.txdps.state.tx.us/criminal_law_enforcement/narcotics/pages/goals.htm), and nonprofit organizations such as the National Alliance for Model State Drug Laws (www.natlalliance.org/prescriptiondrug.asp). Kentucky's CSMP Web site was useful (www.techlines.ky.gov/2004/dec/drugmonitor.htm). Basic information on CSMPs was retrieved from the University of Wisconsin's Pain and Policy Studies Group (www.medsch.wisc.edu/painpolicy/domestic/diversion.htm). James Giglio, President of the Alliance of States with Prescription Monitoring Programs, provided information about interoperability between programs.

Alabama. In April 2006, the State Department of Public Health instituted a monitoring program that requires reporting of all prescriptions for Schedule II –V drugs. The program includes an educational and outreach effort to inform practitioners and the general public about the nature and extent of prescription misuse or abuse. The program is capturing data at a rate that would average 8-10 million prescriptions per year.

California. In 1996, the State implemented a program through the State Department of Justice to monitor prescriptions for Schedule II drugs. In 2005 the program was expanded to include Schedule III drugs. Data on approximately 21 million prescriptions per year is available to licensing and professional boards, law enforcement agencies, and individual practitioners and pharmacies. Physicians make most (70 percent) requests for information; law enforcement and pharmacies each make 15 percent of all requests, which average 5,000 per month.

Kentucky. The Kentucky All Schedule Prescription Electronic Reporting (KASPER) program began in 1999. It captures data on more than 8 million prescriptions (Schedule II-V drugs) annually and responds to an average 2,200 requests per month (92 percent from practitioners, 3 percent from pharmacies, 3 percent from law enforcement, and 1 percent each from licensing boards and "other"). In a 2004 survey, users (practitioners, pharmacies, law enforcement) reported a generally high level of satisfaction with the system as a tool to assist treatment. A web-based version of the system was implemented in 2005.

Maine. The Maine program began operation in 2004 under the jurisdiction of the Office of Substance Abuse (OSA). It captures data for all prescriptions issued to State residents for Schedule II, III, and IV drugs. The program mandates disclosure by pharmacies and requires that law enforcement agencies obtain a specific court order to gain access to any information in the program. The State reports that 83 percent of information requests come from physicians, 17 percent from pharmacies. An OSA survey found that stakeholders feel the program respects confidentiality, is properly focused on public health rather than law enforcement considerations, has not had a negative impact on patient care, and includes an extensive education and outreach component. The most commonly expressed criticism was slow response to information requests.

Nevada. In 1995, the State implemented a monitoring program consistent with the intent of the NASPER Act. The program collects data twice a month from pharmacies and dispensing

practitioners regarding controlled substance prescriptions (schedules II through IV). The State established a task force to oversee the implementation of the monitoring program. Nevada's program produces three reports: patient drug utilization report, threshold report, and a monthly pharmacy report. In 2005, 431 out of approximately 483 (89 percent) pharmacies in the State reported to the CSMP. The number of reports requested has increased considerably since the year 2000. In 2005, 26,264 reports were requested, while in the year 2000, 4,530 reports were requested. The majority of the reports (85 percent) were requested by physicians. In addition to the in-State reporting, CSMP has taken initial steps in developing interoperability between States.

New York. The State implemented a monitoring program in 1972 for prescriptions written for Schedule II drugs. In 1989, the program was expanded to include Schedule III and IV drugs in an effort to monitor benzodiazepine use and possible abuse. The program was amended in 1998 to require electronic transmission of prescription information and eliminate triplicate prescription forms. Evaluations of the program suggest that it has reduced illicit prescription drug activity without having a negative influence on patient care.

Virginia. A pilot program, limited to the southwest region of Virginia, was implemented in September 2003. The program gathered information twice each month on prescriptions (averaging 400,000 per year) for Schedule II-IV drugs. The program received an average of 600 requests for information each month—78 percent from physicians, 19 percent from law enforcement, 3 percent from licensing boards. An evaluation of the pilot program indicated that illicit prescription drug activity shifted away from the region, with no effect on legitimate prescription activity. A statewide program took effect in May 2006.

CASE STUDIES: PROGRAM EVALUATION RESULTS

The program evaluation (Maine and Kentucky) results reviewed in this section show evidence of effective program components. The program descriptions (Virginia, New York, Alabama, and California) in this section demonstrate organizational structures across different States.

Maine's Controlled Substance Monitoring Program. State statute creating the program was enacted in 2003 and regulations put in place in June, 2004. Under Maine's CSMP, all transactions from pharmacies dispensing prescriptions to Maine residents for Schedules II, III, and IV drugs are submitted electronically to a database maintained by the Maine Office of Substance Abuse (OSA).

An alarming increase in the abuse of prescription drugs in Maine prompted State policymakers to develop Maine's CSMP. Treatment admissions for prescription drug abuse had increased from 83 in 1995 to 1,148 in 2003. The number of overdose deaths increased steadily – as did the proportion of these deaths caused by prescription drug abuse. In 2001, there were 90 drug deaths in the State; 70 (78 percent) were caused by a pharmaceutical. One year later, in 2002, the number of overdose deaths had nearly doubled to 166; 148 of these deaths (89 percent) were caused by a pharmaceutical. Arrests for prescription drug diversion increased steadily, accounting for 16 percent of arrests made by Maine Drug Enforcement Agency in 2003. In 2002, more than 20 percent of Maine high school seniors reported that they have used prescription drugs to get high.

A consensus emerged that a monitoring program should be used as a public health and clinical intervention tool to reduce the illicit use of prescription drugs. Under the leadership of Maine's Office of Substance Abuse and with the participation and support of Maine's medical community, pharmacies, attorney general's office, department of licensure and regulation, and other stakeholders a working consensus was formed for how Maine's monitoring program should work to support this goal. This group evolved into the CSMP Advisory Committee. The passage of the Bill in 2003 gave the Office of Substance Abuse the authority to develop the program, but did not authorize a State expenditure. The program secured funding in October 2003**.**

The Muskie School of Public Service, University of Southern Maine, conducted a process evaluation of Maine's CSMP in late summer and fall 2005. The purpose was to assess the implementation of the program from the perspective of stakeholders participating in the development of the CSMP and the experience of participating practitioners and pharmacies. The evaluation consisted of three components:

1. Key stakeholder interviews with OSA staff, members of the CSMP Advisory Committee, and the contractor (GHS Data Management).
2. Survey of pharmacies who submit data to the program.
3. Survey of practitioners who have registered in the CSMP system.

Stakeholder Interviews. Interviews were conducted with OSA staff, members of the CSMP Advisory Committee, and the data contractor. Although questions varied somewhat for each stakeholder group, stakeholders were asked about their participation in the CSMP program, what the major goals of the CSMP were, whether the program would be likely to meet these goals in the long-run, how the program was working so far (including the generation and use of data reports), whether they had any issues or concerns, and how program outcomes should be evaluated. Respondents were also asked what two things they would recommend to OSA. Findings from these interviews are synthesized below.

Stakeholders agreed that the major goal of the Maine CSMP was to reduce the illicit use of prescription drugs in Maine by giving practitioners a tool for improved patient care and giving both practitioners and pharmacies information that helps identify patients who might be abusing prescription drugs. Nearly all stakeholders were clear to draw the distinction between the public health focus of these goals and the law enforcement goals found in other States. A number of stakeholders noted that early and timely clinical intervention was important, before a patient's prescription abuse became more severe or had greater consequences. Several stakeholders indicated that there was also a more global and long term public health goal for the program, in which the CSMP database could be used to show the extent and distribution of prescription drug abuse geographically and by age group across Maine.

The major concern in developing the program was patient confidentiality. At a political and policy level, this issue was resolved relatively early. Confidentiality is an ongoing consideration that needs to be addressed while balancing access to and speed of data retrieval with the accuracy and confidentiality of the data.

Stakeholders uniformly praised the CSMP Advisory Committee, saying it provided an important and productive forum for identifying and resolving potential problems. Stakeholders reported that the OSA Director listened and responded to stakeholder concerns, trying to find a satisfactory solution to problems and issues (often around confidentiality). Advisory Committee members interviewed were appreciative of the clear and useful information presented at the meetings.

Stakeholders reported that the CSMP had been successfully implemented. Early use of Threshold Reports and Patient History Reports appear to have gone well. Both State medical associations reported that their members participating in the CSMP seem pleased with the program. Early concerns over patient confidentiality or the potential use of CSMP data by law enforcement—a potential barrier to care—have not materialized. Reporting of data from pharmacies to the data contractor has improved steadily over time, both with respect to the timeliness and the accuracy of the data. Similarly, the generation of threshold reports has improved with respect to how low or high to set the threshold and for regularity and timeliness of the reports. Participants look forward to implementation of an on-line portal.

There were relatively few and minor concerns expressed about the program. Concerns included calibrating the level on threshold reports; more timely access to the database; more timely and consistent submission of data to the data contractor, particularly by smaller and non-computerized pharmacies. Several stakeholders noted the need to secure and maintain external funding and that any effort to shift some of the costs of the program onto participants could jeopardize the program.

The trade-off between accuracy and confidentiality of information and the speed and usefulness of this information remains. There is enthusiasm about the CSMP web portal which will offer enhanced access to practitioners and pharmacies. Yet creating this access (almost universally desired by practitioners and pharmacies) increases the potential for security violations. Under the present system there is an opportunity for someone to review manually requests for reports. This will not be true under the new web portal. However, consensus exists that the benefits of quick access for providers, particularly emergency room doctors, outweigh the reduced oversight.

Practitioner Survey. A survey was mailed to the 350 practitioners who had registered under the Program. One-hundred and thirty-six practitioners completed the survey for a response rate of 38.9 percent.

Nearly three out of four practitioners (71.3 percent) reported receiving a threshold report on one or more of their patients. The majority of these respondents found the threshold report easy to understand (94.5 percent) and helpful (80.4 percent). Two–thirds of the respondents indicating that they had received a threshold report gave an answer to the question “What happened as a

result of the report?" Their responses (which allow for multiple answers) indicate that the threshold report was being used much as the program hoped it would be—as a potential flag for possible abuse and to result in follow-up action.

Just under half of the respondents had requested a patient history report; 75 percent of those requesting the patient history file found it useful. Over half (61 percent) of those who had not requested a patient history report expected to request one over the next six months. Sixty-three percent indicated that they had requested a patient history report gave an answer to the question "What happened as a result of the report?" Their responses (which allow for multiple answers) indicate that the patient history report was being used much as the program hoped it would be—to serve as a potential flag for possible abuse and to result in follow-up action. Five respondents reported that they had requested a report and never received one.

Twenty-one percent of the respondents had a concern about the program. The major concern was that there was too long of a delay between requesting and receiving information. Practitioners wanted real-time, internet-based access that would help them when their patients were in their office or emergency room.

The most common recommendation for improving the CSMP is to reduce the time lag between requesting and receiving data; other common recommendations were to improve the process for registering and using the program and to provide better information about the program.

Pharmacy Survey. A survey was mailed to 66 registered pharmacies; 21 returned completed surveys (31.8 percent response rate). The most common questions pharmacies had about the program were about software and implementation issues and general data reporting requirements. The majority of pharmacies thought the reporting requirements under the monitoring program were easy or very easy. Twenty-five percent of respondents thought that the reporting requirements were somewhat difficult or very difficult.

Respondents were evenly divided about whether or not the monitoring program was useful (somewhat or very) or not useful (not very/not at all) to their pharmacy. Less than half of the pharmacies had requested a patient history report and only six of those eight found the report helpful. One third of those not requesting a patient history reported that they expected to request a report over the next six months. Pharmacies requesting a patient history report were asked what happened as a result of that report. The most common result was that it was confirmed that the patient was misusing medications.

Half the respondents reported concerns about the CSMP. The most common concern was that it was too long of a lag between requesting and receiving information; a related concern was that there should be proactive reporting to pharmacies. Not surprisingly the most common recommendation for improving the program was to reduce the time lag between requesting and receiving information.

Discussion and Recommendations. The CSMP has been implemented successfully and is meeting its current goals. By all accounts, the Office of Substance Abuse has done an excellent job in developing and implementing the program. Stakeholders commended the Office of

Substance Abuse for (1) establishing and maintaining a prevention and treatment goal for the CSMP (and not a law enforcement goal); (2) listening to the medical and other stakeholders in establishing and implementing the program, and (3) its extensive outreach and educational efforts. Chris Baumgartner, the data manager and currently the acting Director was praised for his technical expertise, clarity, and availability to answer any questions or concerns.

Practitioner registration for the program is increasing and, in general, practitioners have requested and used Patient History Reports as intended.

To meet its longer term goals, the CSMP must continue to increase the number of registered prescribers actively using the program and its database. This requires that the number of prescribers registered and actively using the program continue to increase. There is every reason to believe this will happen. Prescribers currently using the program find it very useful and an important source of information (and encouragement) for other prescribers registering and using the program. Nevertheless prescribers are very busy and face increasing administrative and clinical demands from many sources in their day-to-day clinical practice.

Generally, pharmacies have participated in and realized the benefits of the CSMP as it was designed. Compared to the practitioners, there may be a bit more "wait and see" attitude among pharmacies as to the utility of the Program, relative to their reporting requirements. Continued technical refinements in the database system (primarily involving reducing the time between requesting and receiving information) should continue to bolster the support and use of the program by pharmacies.

A central consideration in establishing the monitoring program was the assurance of data security and confidentiality. This concern represents an on-going challenge for the CSMP to balance the needs of data users to have "real-time" access to the data with the need to maintain data security and confidentiality.

The CSMP has established credibility and support within Maine's medical community. For the most part, practitioners who are engaged in this program are using it and realizing the benefits intended by the developers of the program. The CSMP should continue to expand this support and extend the number of actively participating practitioners by:

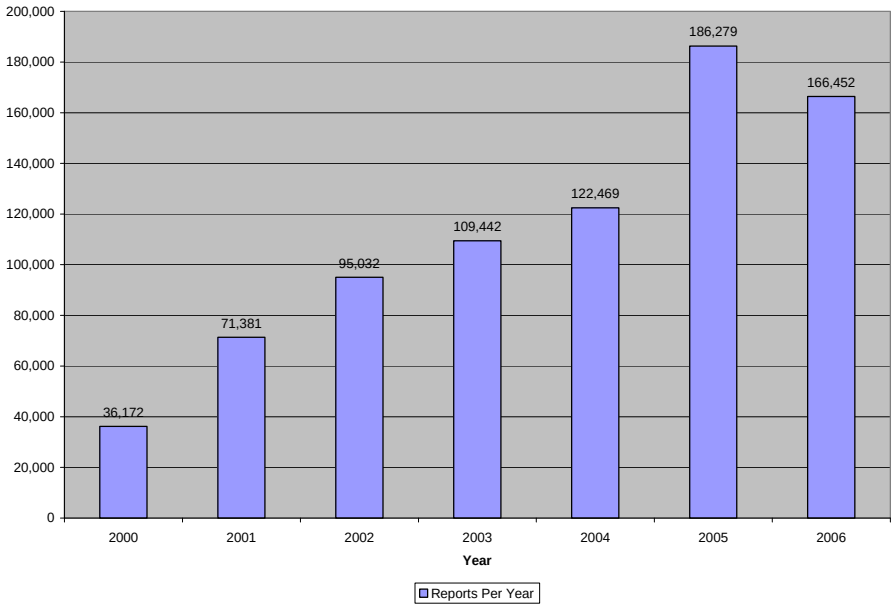
- Providing ongoing outreach and information sessions.
- Providing accessible technical assistance to remind practitioners how to register and use the system (including finding the password they may have forgotten).
- Reducing the time between requesting and receiving information.

Given its successful implementation, the program should begin to consider longer-term issues of sustainability and how the program may be used to booster the public health substance abuse prevention goals of the State. Under a separate, but potentially related initiative—SAMHSA's Strategic Prevention Framework, State Incentive Grant (SPF-SIG)—Maine is currently undertaking a major transformation of its public health and substance abuse prevention infrastructure and has identified reducing abuse of prescription medication as a major objective

for local communities to address. Areas of strategic convergence between the CSMP and SPF-SIG programs should be identified and explored.

Kentucky's Controlled Substance Monitoring Program. The Kentucky All Schedule Prescription Electronic Reporting (KASPER) system was implemented in 1999. It was designed to be both a source of health care information for practitioners and pharmacies and as an investigative tool for law enforcement. Requests for reports have continued to grow from 3,105 requests processed in the first six months of operation to 166,452 requests in 2006 (see Exhibit 9). In October 2004, a survey was launched to gather the opinions of the user community to assess user satisfaction, and to evaluate the effectiveness of the program as a tool for practitioners, pharmacies, and law enforcement.

Exhibit 9: Kentucky Controlled Substance Monitoring Program Report Requests per Year: 2000-2006



In 2004, Kentucky surveyed manager, program staff, law enforcement personnel, and members of the licensure boards. The satisfaction survey was designed to address objectives identified for the FY 2004 Prescription Drug Monitoring Program grant.

The survey indicated a high level of CSMP use by respondents. The results suggest that once a health care practitioner becomes aware of the capabilities of Kentucky's CSMP, they realize the usefulness of the system and begin to request reports for their patients when appropriate. The results further indicate that users tend to believe the system is an effective tool to assist in treatment, however there appear to be concerns about the quality (and possibly the timeliness) of the data. Initial analyses indicate that the system and reports are relatively easy to use and require minimal training. In March 2005, Kentucky implemented a web-based version of the system called Enhanced KASPER (eKASPER), intended to increase the number of practitioners using the web-based system and improve the overall efficiency of the system.

A 2006 KASPER Satisfaction Survey is planned for users of the eKASPER system. The 2006 Satisfaction Survey will apply to the eKASPER system and allow a comparison of satisfaction with the original system versus the web-based system.

CASE STUDIES: PROGRAM DESCRIPTIONS

Nevada's Controlled Substance Monitoring Program (CSMP). In 1995, the Nevada State Legislature passed into law Nevada Revised Statute (NRS) 453.1545 mandating that the Nevada State Board of Pharmacy, the Nevada Division of Investigation and the State Bureau of Alcohol and Drug Abuse develop a computerized program to track controlled substance prescriptions. The statute also directed the establishment of a group, named the Controlled Substance Abuse Prevention Task Force, to oversee the implementation of the CSMP. The Task Force consists of 22 representatives from three State agencies, health care boards, practitioner associations, pain management specialists, and the district attorney's association.

Nevada's CSMP was developed to help prevent the inappropriate distribution and use of prescription controlled substances. Day-to-day operation and administration of the CSMP are carried out by one staff person with management and analytical skills, a full-time database analyst, and the data collection contractor. The first year costs for the program have been offset by grants from the Nevada State Board of Medical Examiners and two private corporations. A portion of the biannual controlled substance registration fee of $50 (paid for by practitioners) covers subsequent year costs.

The CSMP collects data twice a month from pharmacies and dispensing practitioners regarding controlled substance prescriptions (schedules II through IV). This data collection allows for the identification of consumers who use multiple pharmacies and practitioners and are suspected of drug seeking behavior. With the funding from a 2004 enhancement grant, the CSMP hired a case manager. Once the case manager becomes involved, the doctors' care is coordinated, and the patient is referred to specialists as needed.

The CSMP produces three reports: patient drug utilization report, threshold report, and a monthly pharmacy report.

Patient Drug Utilization Report. The patient drug utilization report is produced when a patient is identified as potentially abusing controlled substance prescription medication. The report contains information regarding the patient, the practitioners who prescribed the controlled substances, the pharmacies that dispensed the prescriptions, and the prescriptions filled for the patient. The report is sent to each practitioner and pharmacy that has prescribed or dispensed controlled substances to the patient. This report provides information regarding the total prescriptions obtained by their patient so they can better treat the patient and, when appropriate in their professional judgment, modify prescribing.

Threshold Report. The Threshold Report is an internal report listing patients who have exceeded exception thresholds. It contains 12-month's summary information on each patient who exceeds the thresholds, including patient name, the number of controlled substances prescriptions filled and dosage units received, number of practitioners who issued prescriptions to patient, and number of pharmacies that dispensed prescriptions to patient. It can be sorted by number of

practitioners who issued controlled substances prescriptions to the patient so the program can readily identify the patients going to the highest volume of practitioners. It helps the CSMP categorize patients' access to controlled substances.

Monthly Pharmacy Report. The Monthly Pharmacy Report is used to verify that all pharmacies are transmitting data. It contains 12 months of information regarding each pharmacy, with the total number of controlled substances dispensed during each month.

A summary of Nevada's CSMP reporting follows. In 2005, 431 out of approximately 483 (89 percent) pharmacies in the State reported to the CSMP. The number of reports requested has increased considerably since the year 2000. In 2005, 26,264 reports were requested, while in the year 2000, 4,530 reports were requested. The majority of the reports (85 percent) were requested by physicians. In addition to the in-State reporting, the CSMP has taken initial steps in developing interoperability between States. Nevada and California have volunteered to participate in a pilot project to demonstrate the feasibility of an automated information exchange between the State programs.

Virginia's Controlled Substance Monitoring Program. The 2002 Acts of Assembly amended the *Code of Virginia* to create a CSMP as a pilot program limited to State Health Planning Region III in Southwest Virginia. The Department of Health Professions was awarded a Federal grant through the Prescription Drug Monitoring Program to implement and support initial operations of the program in April 2003. An additional grant was awarded in 2004 to sponsor a conference on prescription drug abuse and prescription monitoring programs and to conduct a survey of practitioners regarding the prescribing of controlled substances and their impressions of the program.

Although not required by the statute, the Director of Health Professions formed an advisory committee in June 2003. The committee includes representatives of organizations with an interest in the monitoring program. The organizations include the American Cancer Society, the Hospice organization, the State Police, Boards of Pharmacy and Medicine, and the Medicaid Fraud unit of the Attorney General's Office. The committee advises the Department on the extent to which the statute had been successfully implemented, any changes that should be made in policies and practices of the program, what aspects of the program should be evaluated and any other issues related to the illegal diversion of controlled substances or access to appropriate drug therapy. The committee has met quarterly beginning in September, 2003 and has been instrumental in developing an evaluation work plan for the program, determining policy issues and making recommendations resulting from the review of these issues.

The program began operation in September 2003. Approximately 300 pharmacies and other pharmacies submitted twice-monthly reports of prescriptions dispensed for Schedule II controlled substances. Instituting the pilot program in only the Southwest portion of the Commonwealth appears to have caused some illegal prescription drug diversion to move outside the program area. State Police Drug Diversion Unit data comparing 2003 to 2004 show complaints received by the unit increased 26 percent statewide while decreasing in the program area by 47 percent. Arrests increased by 35 percent statewide versus 31 percent in the program area. It also appears that using the program may save substantial man-hours in performing

investigations. Data from the program showed a 53 percent decrease in man-hours spent doing pharmacy profiles between 2003 and 2004.

It appears that implementation of the CSMP has not significantly reduced the use of Schedule II medications; the amount of oxycodone and hydrocodone distributed in wholesale channels increased throughout Virginia at rates of 9 percent and 8 percent respectively from 2002 to 2003. Moreover, data compiled by the Department of Medical Assistance Services show that claims related to prescriptions for these drugs were 21 percent higher in the first quarter of 2004 than in the first quarter of 2001.

Accidental deaths due to prescription drug abuse or misuse continue to be a significant public health concern in Virginia, especially the southwest region of the Commonwealth. Since 2000, there has been a 100 percent increase in drug deaths in the Western District of the Office of the Chief Medical Examiner.

Data from SAMHSA shows substance abuse treatment admissions in Virginia for non-heroin opiates have increased significantly from 2000 to 2004. A staff member from the Department of Mental Health, Mental Retardation and Substance Abuse Services explained this does not reflect an increase in treatment capacity but rather a dramatic shift to persons seeking admission and treatment for abuse of opiates.

Under its original structure, the Virginia CSMP severely restricted access to data. For example, a pharmacy (pharmacist) could not query the system at all. The Advisory Committee evaluated the Virginia CSMP and recommended these changes:

1. Continue the program indefinitely;
2. Expand the program to include Schedule II through IV controlled substances;
3. Expand the program to the entire Commonwealth;
4. Allow pharmacies to access the program;
5. Allow a prescriber licensed in another State to request information from the CSMP;
6. Allow access to the CSMP for Department of Health Professions investigative personnel and designated Health Practitioners' Intervention Program personnel on a specific licensee, registrant, or certificate holder where there is an open investigation;
7. Allow Medical Examiners access to the CSMP for the purpose of performing their duties in accordance with the appropriate statues of the Code of Virginia;
8. Allow access to the Department of Medical Assistance Services for the purpose of investigating fraud when there is an open investigation on a recipient;
9. Allow access to the Drug Enforcement Agency when there is an open investigation on a practitioner or pharmacy;
10. Allow access to the program for research purposes to public and private entities where all personal identifying information is removed;

11. Allow access to the program for health/education purposes, providing information to practitioners and pharmacies on their patients who may be abusing, misusing, or fraudulently obtaining controlled substances; and

12. Require non-resident pharmacies to report to the program.

The revised program began May 1, 2006, for those pharmacies already reporting under the Southwest Virginia pilot program and incorporated all data already collected during the pilot program. The new program covers the entire State and requires all pharmacies to report, at least twice a month, prescriptions dispensed in Schedules II, III, and IV. The program also requires non-resident pharmacies to report dispensing of covered substances to Virginia residents.

All transactions must be submitted electronically at least twice monthly. Pharmacies who so choose may report more frequently than twice a month. Pharmacies with multiple facilities can submit one data transmission on behalf of all their facilities.

At present, there are 2,384 pharmacies licensed or permitted to dispense by the Board of Pharmacy. A pharmacy my request a waiver or exemption from reporting if they do not dispense any Schedule II, III, or IV controlled substances or meet the requirements for an exemption; 442 pharmacies now hold a waiver or exemption. Federal entities such as Veteran's Administration or Department of Defense pharmacies do not report to the CSMP.

To request information from the database, a practitioner must have a patient's specific written consent. A pharmacy must either post a sign notifying patients that the program may be used to verify the validity of a prescription, provide written notice, or obtain the patient's explicit consent.

There are two ways by which an authorized user may request information from the program. The first is to use a secure Web site through which, after registering as a user; the user may request information, and the report will be sent back on the Web site. The second method is to print out a request form from the program main web page and fax the request. The report will be faxed back to the requestor. Telephone or e-mail requests are not accepted. In most cases, requests will be processed within 30 minutes of being received during normal business hours. Online access will make most program information available 24/7 access to program information in most cases.

More than 4 million prescription records have been added to the data base since June 1, 2006. Requests for information from the program have increased from roughly 200 requests in May 2006 to more than 700 in September 2006. More requests were processed from June to September 2006 (2,198) than in all of 2005 (1,791). Practitioners made 70 percent of the requests, pharmacies made 15 percent, and other authorized users made 15 percent of requests. The program has also seen a substantial increase in the number of registered users.

New York's Controlled Substance Monitoring Program. New York's CSMP was established by the 1972 enactment of Article 33 of the Public Health Law, known as the New York State Controlled Substances Act (CSA). The purpose of the program is to curtail the diversion of prescription controlled substances prone to addiction and abuse by requiring them to be

prescribed only on an official New York State prescription form. The program originally applied to Schedule II controlled drugs. In 1989, in response to increasing abuse of benzodiazepines, a class of drugs used to treat anxiety, monitoring was extended to the schedule IV controlled substances.

New York's Department of Health distributes official prescription forms to practitioners and healthcare facilities. After dispensing prescribed medications, pharmacies submit official prescription information to the Department where it is stored in a secure database. The data is accessed for analysis by the Bureau of Narcotic Enforcement. Official prescription information is confidential and may be provided to other agencies only as specified by law.

The official prescriptions contain security features to deter alterations, counterfeiting, and forgeries. The prescriptions are serialized and can be tracked from vendor to practitioner to pharmacy. Lost or stolen serial numbers are posted on the Department's Web site for access by pharmacies prior to dispensing.

From 1972 to 2001, the official New York State prescription form consisted of three copies, often referred to as a "triplicate." A prescribing practitioner retained one copy for record keeping and gave the remaining two copies to the patient to take to a pharmacy. After dispensing the prescription, the pharmacy retained the second copy for its records and mailed the third copy to the Department of Health, where information from the prescription was manually entered into a secure database. In 2001, the "triplicate" prescription was converted to a single-part form to facilitate electronic transmission.

At the outset of the Official Prescription Program, the Department issued approximately 750,000 prescriptions annually, of which approximately 500,000 were reported dispensed. When benzodiazepines were added to the program, the Department's issuance increased to 3.8 million per year. By 2004, the Department was issuing some 8 million prescriptions annually, 4 million of which were reported as being dispensed.

The Department's experience with monitoring benzodiazepines demonstrates the effectiveness of the Official Prescription Program in curtailing drug abuse and diversion. A 1989 Office of Public Health study reported a decrease of, respectively, 55 percent, 27 percent, and 41 percent in the number of benzodiazepine prescriptions for Medicaid, the Empire Plan, and the EPIC program after monitoring began. This decrease was not offset by an increase in prescribing of substitute drugs indicates that the reduction in prescribing curtailed only illegal activities with benzodiazepines and not their legitimate use.

The effectiveness of the program is further demonstrated by Federal Drug Enforcement Administration (DEA) reports on the State-by-State consumption of OxyContin. For the years 1999 through 2002, New York ranked either 49th or 50th countrywide in consumption of the drug, leading DEA and New York's Bureau of Narcotics Enforcement to jointly conclude that monitoring by the Official Prescription Program curtails the diversion of OxyContin in New York.

In 1998, at the request of the Commissioner of Health, the New York State Public Health Council established the Ad Hoc Committee on Pain Management to identify barriers to effective pain management in the CSA and recommend ways to overcome those impediments. All of the Committee's recommendations were incorporated into Public Health Law that ensured and enhanced access to controlled substances for legitimate use in healthcare, including palliative care, while combating their illegal use and trade.

The centerpiece of the amendments to the CSA was the conversion of the "triplicate" prescription to a single-part form and pharmacy submission of official prescription information to the Department by electronic transmission for more efficient monitoring. The statute also allowed prescribing of an increased quantity of a controlled substance to treat approved chronic medical conditions and the partial filling of prescriptions by pharmacists to better provide for a patient's changing needs.

In 2004, a new Public Health Law expanded the Official Prescription Program to require that all prescriptions written in New York be issued on an official prescription form. By extending the program's monitoring success to all drugs, the new law will curtail prescription fraud. In January 2005, the Department began providing newly designed official prescriptions to practitioners and healthcare facilities free of charge. The Department anticipates that the number of prescriptions issued will increase to an estimated 220 million annually.

The 2004 law encourages electronic prescribing, an efficient method whereby a practitioner transmits a prescription to a pharmacy by electronic means. The Department plans to use $1 million in Federal grant funds to promote electronic prescribing, which minimizes medication errors due to misinterpretation of handwriting. Because electronic prescribing also does not require a paper prescription, the prescription can not be fraudulently altered to obtain drugs. The law also permits the Department to notify practitioners when an analysis of prescription data reveals individuals to be obtaining drugs from multiple sources.

Alabama's Controlled Substance Monitoring Program. A law inacted in 2004 placed responsibility for Alabama's CSMP within the Alabama Department of Public Health. The objectives of the program are:

- Promote appropriate use of controlled prescription drugs;
- Reduce the number of illegal prescriptions for Schedule II, III, IV, and V drugs,;
- Reduce the time and effort required by law enforcement and regulatory investigators to explore leads and assess the merits of possible drug diversion cases; and
- Educate practitioners, pharmacies, policy makers and the public about the existence and extent of diversion, and the drugs most likely to be diverted by individuals.

Mandatory reporting of controlled substance prescriptions to the database began April 1, 2006. In the first six months, more than 5 million controlled substance prescriptions were reported. Educational outreach is in the planning phase and has not yet been implemented. Plans include educating practitioners, pharmacies, policy makers and the public about the existence of the drug diversion problem in Alabama with brochures and Public Service Announcements. These

announcements will include facts about the extent of the problem in Alabama and will provide information to help recognize when a friend or loved one is suffering from abuse or addiction.

California's Controlled Substance Monitoring Program. In 1996, the Legislature passed Assembly Bill (AB) 3042 requiring that the California Department of Justice (DOJ) establish the Controlled Substance Utilization Review and Evaluation System (CURES), which automates the collection and analysis of all Schedule II controlled substance prescriptions issued in California.

On January 1, 2005, the program began collecting all prescribed Schedule III substances. In addition, prescriptions for Schedule II-V Controlled Substances are now written on new, tamper-resistant prescription forms. The data is available to the Medical, Pharmacy, Dental, Osteopathic, Veterinary and Registered Nursing Boards via the internet. DOJ provides the maintenance and technical support of the system, with annual financial assistance from the boards. Information is available to authorized employees as well as law enforcement and outside agencies who conduct investigations with or through California's Department of Justice.

California's program has developed a system of working with medical practitioners and pharmacy to assist them when they suspect a patient may be misusing prescription medication. The medical practitioner or pharmacy may request a prescribing history for a patient. DOJ can obtain copies of the data, which is considered medical information subject to the provisions of confidentiality. It is also the policy of DOJ to provide program information to law enforcement agencies and regulatory boards as a tool for investigations. The information maintained in California's CSMP includes:

- Prescription series numbers used until December 31, 2004;
- Prescription date;
- Patient's name and address;
- Practitioner's Drug Enforcement Administration registration number, address, and degree of license;
- Name, form, strength and quantity of the drug prescribed;
- Date filled; and
- Pharmacist's State number.

Appendix J: Field Reviewers

Nancy D. Berkman, Ph.D.
Project Director, Co-Occurring Disorders Study
Research Triangle Institute
Research Triangle Park, North Carolina

Daniel S. Connolly
Vice Chair, Rx Action Alliance, and
Managing Partner, Giuliani Partners LLC, and
Former Counsel to the Criminal Justice Coordinator, City of New York
New York, New York

June L. Dahl, Ph.D.
President, American Alliance of Cancer Pain Initiatives, and Professor of Medicine
University of Wisconsin School of Medicine and Public Health
Madison, Wisconsin

Robert L. DuPont, M.D.
Chair, Advisory Committee on Non-Medical Use of Stimulant Drugs, and
President, Institute for Behavior and Health, Inc., and
Former Director, National Institute on Drug Abuse, and Former Director, White House Drug Policy Office
Rockville, Maryland

John L. Eadie
Eadie Consulting
Former Director, Division of Public Health Protection, New York State Department of Health
Former President, National Association of State Controlled Substances Authorities
Rensselaer, New York

Scott Fishman, M.D.
Professor of Anesthesiology and Pain Medicine
and Chief, Division of Pain Medicine
University of California at Davis, and
Past President, American Academy of Pain Medicine, and Member of the Board, American Pain Foundation
Davis, California

Mark S. Gold, M.D.
Distinguished Professor, Department of Psychiatry, and Chief, Division of Addiction Medicine
University of Florida Brain Institute
Gainesville, Florida

Larry L. Greenhill, M.D.
Professor of Clinical Psychiatry, and Director, Research Unit on Pediatric Psychopharmacology
New York State Psychiatric Institute
New York, New York

Howard A. Heit, M.D., FACP, FASAM
Assistant Clinical Professor
Georgetown University School of Medicine, and
Private Practice of Pain and Addiction Medicine
Fairfax, Virginia

J. Harry Isaacson, M.D.
Associate Professor of Medicine, and
Director of Clinical Education
Department of General Internal Medicine
Cleveland Clinic Foundation
Cleveland, Ohio

Jennifer Kasten, M.S.W.
Senior Analyst
NSDUH, N-SSATS, TEDS, and DASIS Information Systems
Research Triangle Institute
Research Triangle Park, North Carolina

Jane C. Maxwell, Ph.D.
Director, Center for Excellence in Epidemiology,
Gulf Coast Addiction Technology Transfer Center, and Research Professor, School of Social Work
University of Texas
Austin, Texas

Francis B. Palumbo, Ph.D., Esq.
Professor of Pharmacy and Executive Director Center on Drugs and Public Policy
University of Maryland College of Pharmacy
Baltimore, Maryland

Martha J. Wunsch, M.D., FAAP, FASAM
Associate Professor and Chair of Addiction Medicine
Edward Via Virginia College of Osteopathic Medicine, and Board Member, American Society of Addiction Medicine
Blacksburg, Virginia

Richard A. Yoast, Ph.D.
Director, Office of Alcohol, Tobacco and Other Drug Abuse Prevention
Robert Wood Johnson Foundation Coordinating Center
American Medical Association
Chicago, Illinois