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INDEPENDENT STATE AUDITOR'S REPORT ON CERTAIN ACTIVITIES OF THE DEPARTMENT OF PUBLIC HEALTH'S DRUG CONTROL PROGRAM

OFFICIAL AUDIT REPORT

OCTOBER 24, 2007

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Prescription drug abuse is a critical public health problem for Massachusetts and the nation. The 2004 National Survey on Drug Use and Health indicated that the category of drug use with the highest number of new initiates was non-medical use of pain relievers, totaling 2.4 million new users. In Massachusetts, emergency department visits for non-heroin related opioid (a narcotic drug generally prescribed to manage pain) use, which includes prescription drugs such as Oxycontin® and other oxycodone products, increased 134% between 1999 and 2002. Treatment data from the U.S. Substance Abuse and Mental Health Services Administration shows that treatment admissions in Massachusetts for the category "other opiates," which includes prescription opioid analgesics, increased 950% from 1992 (325 admissions) to 2005 (3,409 admissions). Over a similar period, from 1993 to 2006, the Department of Public Health (DPH) Drug Control Program (DCP) and Prescription Monitoring Program (PMP) showed that the number of prescriptions for all Schedule II (those pharmaceuticals with the highest potential for abuse, e.g., narcotics and stimulants) opioids, including oxycodone products, increased 261%, from 789,000 to 2.85 million. At the end of that period, in 2005, the U.S. Drug Enforcement Administration reported that Massachusetts ranked 13th among the states in the per capita rate of consumption of oxycodone products.

In addition to addiction, the increased diversion of prescription drugs for illegal purposes is a disturbing trend in the nation's battle against drug abuse. The Drug Enforcement Administration has stated that the diversion and abuse of legitimately produced controlled pharmaceuticals constitutes a multi-billion dollar illicit market nationwide.

The DPH established the PMP in 1992, pursuant to joint regulations of the Drug Control Program (105 CMR 700.006(J)) and the Board of Registration in Pharmacy (247 CMR 5.04), to help address the problem of drug diversion and abuse in the Commonwealth. The program utilizes a computer-based Electronic Data Transfer (EDT) system to collect prescribing and dispensing information on Schedule II drugs, which are among those most sought for illicit and inappropriate (non-medical) use.

According to the records maintained by the DPH, there are approximately 36,500 licensed healthcare professionals registered with DPH who can prescribe, dispense, and administer controlled substances. In addition, DPH registers an additional 4,200 hospitals, clinics, manufacturers/distributors, and community-based programs to dispense controlled substances. Furthermore, the Massachusetts Board of Registration in Pharmacy licenses over 1,000 community/chain pharmacies. During fiscal year 2005, approximately 1,200 community, clinic and hospital outpatient pharmacies in Massachusetts collectively reported over 2.6 million prescriptions for Schedule II drugs to the EDT system.

Data from the system is used to determine prescribing and dispensing trends; provide educational information to healthcare providers; and provide case information to regulatory and law enforcement agencies concerning drug distribution and diversion. Medical Review Groups (MRGs), comprised of practitioners (e.g., physicians, dentists) and pharmacists review a wide range of prescribing and dispensing practices in Massachusetts and assist the Department in the evaluation of prescription information for subsequent release to law enforcement and/or regulatory authorities. Since 1994, data related to over 1,800 cases have

been reviewed by the MRGs, largely in response to requests from such agencies (Massachusetts State Police, Office of the Attorney General, U.S. Drug Enforcement Administration, etc.) for information relating to ongoing investigations.

In accordance with Chapter 11, Section 12 of the General Laws, the Office of the State Auditor (OSA) conducted an audit of DPH's PMP. Our audit was conducted in accordance with applicable generally accepted government auditing standards for performance audits. The purpose of our review was to determine whether DPH was efficiently and effectively managing its Drug Control Program. More specifically, we attempted to determine whether DPH (1) was properly registering all doctors, hospitals, clinics, pharmacies, etc. who distribute Schedule II drugs; and (2) has established adequate monitoring and oversight systems to ensure adherence to standards and regulations for drug distribution.

Although the Massachusetts Prescription Monitoring Program (PMP) has contributed to public health and safety by providing case information to regulatory and law enforcement agencies concerning drug distribution and diversion, the full potential of the Program has not been realized and it has also become less effective in utilizing collected data to determine aberrant prescribing and dispensing trends. This reduced effectiveness comes during a time of significant increases in the number of pain reliever prescriptions and the increase in substance abuse and drug diversion. Three specific factors contribute to the PMP's reduced effectiveness: 1) the individual responsible for extracting and interpreting queries relating to possible drug diversion no longer works for the Program; 2) 105 CMR 700.00(4), Privacy and Confidentiality, which restricts the dissemination of PMP information, has not been amended to reflect MGL Chapter 94C, Section 24, that confers authority to release information to practitioners, specifically "if the commissioner determines that a research subject or patient is receiving a controlled substance from more than one source and in quantities which he determines to be harmful to the health of research subject or patient"; and 3) out-of-state pharmacies are not required to report prescription data to Massachusetts, thereby giving an incomplete picture of what a patient may be receiving or a healthcare professional may be prescribing.

Although a significant increase in the number of prescriptions for Schedule II controlled substances continues, referrals by the PMP to Medical Review Groups (MRGs) for possible drug diversion referral to law enforcement authorities and regulatory authorities is decreasing. As a result, the PMP has become more reactive--with most requests for possible drug diversion coming from outside entities, such as the Massachusetts State Police, U.S. Drug Enforcement Administration, or the Board of Registration in Medicine--rather than proactive, generating and analyzing possible drug diversion on its own. Information provided to us by DPH disclosed that in 1998, 25% of all cases referred to the MRG were from the PMP. During the three-year period included in our review, PMP referrals (13 of 254 referrals) represented only 5% of total referrals.

The DCP, in addressing shortfalls identified, has sought and received almost $1 million in federal funding to enhance the PMP by meeting the following goals:

1. Improving analysis of the PMP database to more efficiently and accurately identify cases needing investigation.

2. Improving access to and utilization of the PMP findings by law enforcement and regulatory agencies.

3. Engaging prescribers and the wider healthcare community (e.g., clinics, hospitals, manufacturers/distributors, etc.) in addressing prescription drug abuse, addiction, and diversion by means of increasing their awareness and use of PMP data.

4. Improving the quality and enhancing the value of the data being collected.

5. Assessing the efficiency and effectiveness of the program and facilitating the exchange of information and prescription data among the northeastern states (CT, MA, ME, NH, NJ, NY, PA, RI, and VT).

In order to meet these goals, four project activity categories were initially established: (1) technological enhancements, (2) an epidemiological tracking system, (3) a physician data pilot test, and (4) coordination and collaboration with key stakeholders (Massachusetts State Police Drug Enforcement Unit, Board of Registration in Medicine, Board of Registration in Pharmacy, U.S. Drug Enforcement Administration, pain management physicians, researchers, other states, etc.). Detailed objectives related to the additional grant funding received, is included in the body of this report.

In its response to the audit report, DPH stated that the audit report's statement that the downward trend for PMP-referred cases continued despite the significant increase in the number of prescriptions for Schedule II controlled substances is inaccurate. DCP indicated that it generated 36 new cases, or 35% of the caseload of 104 cases for fiscal year 2006. However, the information provided by DPH for fiscal years 2003 through 2005 is accurately portrayed in this report. The increase in referrals during fiscal year 2006 began at a time when DPH was aware of our preliminary audit results. As we state in this report, there has been a significant downward trend for PMP-referred cases, and DPH should improve its efforts to identify aberrant prescribing and dispensing trends and subsequently notify regulatory and law enforcement agencies concerning drug distribution and diversion.

Finally, because of the serious concerns about the impact and effects on our youth concerning the abuse of prescription medications and illicit drugs, Chapter 189 of the Acts of 2004 was enacted, establishing a special commission to investigate this problem. Specifically, related to DPH's PMP, the Commission recommended, as have we, to enhance and expand the scope of the Commonwealth's program. As a result, the Committee on Public Health first called for DPH to report back to the Committee by March 31, 2007 "on their activities and progress in implementing the recommendations, and barriers encountered and proposed approaches to overcome these barriers" in adopting the Commission's recommendations. As of August 9, 2007 DPH has been unresponsive to this requirement.

In conclusion, because of the proliferation of prescription drugs, diversion, illicit use and the resultant societal problems, improvements are critical in preventing and defeating prescriptions drug fraud. Part of the solution is maintaining and strengthening the Commonwealth's prescription monitoring program.

INTRODUCTION

Background

Commercial dispersion of controlled substances has increased dramatically over the last five to ten years. Oxycontin® sales in particular rose significantly over the past five years. Thus, prescription drugs are increasingly accessible to abusers by virtue of their growing prevalence. According to the Department of Public Health, PMP data show that an estimated 3.5% of prescriptions for Schedule II opioids were involved with individuals who appear to be obtaining such prescriptions from multiple prescribers and pharmacies above a threshold (i.e., possible "doctor shopping").

Easy access to controlled substances is also enhanced by the relatively decentralized way in which drugs are acquired and used in the United States. While manufacturers, doctors, pharmacists, and other healthcare professionals[1] are regulated, patients have easier availability to acquire prescriptions from any doctor of their choosing, and then select any pharmacist they wish to fill it. They may use the same doctor and pharmacist repeatedly, or they may switch regularly. There is no single national database that keeps centralized records of medication acquisition. Consequently, prescription drug diversion--the channeling of licit pharmaceuticals for illegal purposes or abuse--has become a national epidemic and a disturbing trend in our nation's battle against drug abuse.

Methods of Drug Diversion

Diversion of prescription drugs can occur primarily in four ways: prescription fraud, "doctor shopping," theft, and the use of the Internet.

Prescription Fraud

Prescription fraud covers a wide range of schemes, from forging or altering prescriptions to creating counterfeit prescriptions. In addition, while constituting only a small percentage, some physicians and pharmacists create or dispense fraudulent prescriptions for personal use, or in exchange for a fee, sexual favors, or other benefits to individuals who do not need the medication.

[1] As used in this report, "healthcare professionals" includes physicians, physician assistants, advanced practice nurses, veterinarians, podiatrists, optometrists, etc.

"Doctor Shopping"

Drug diversion also occurs through "doctor shopping." "Doctor shopping" occurs when individuals visit a variety of different doctors to obtain multiple prescriptions for a drug. While the concept of "doctor shopping" is not new, the practice of "doctor shopping" has become more pronounced. Those who doctor shop for the purposes of abuse may have come to their abuse through many different means and doctor shoppers who abuse prescription drugs may or may not have had a legitimate use for those drugs in the past.

Theft

Millions of controlled substances are also diverted every year through theft from pharmacies, manufacturers, distributors, hospitals, nursing homes, and other institutions that legally handle controlled substances, as well as from people who have legitimate prescriptions. The size and methods of thefts vary widely, from sophisticated schemes involving multiple individuals and millions of dollars worth of stolen pharmaceuticals to robberies by individual addicts.

The Internet

The Internet is fast evolving into a significant means for drug diversion. As described in an October 2003 Washington Post article, "with little notice or meaningful oversight, the Internet has become a pipeline for narcotics and other deadly drugs. A customer can simply pick from a vast array of painkillers, antidepressants, stimulants and steroids with few controls and virtually no monitoring. The resulting abuse has been ravaging, stretching from Florida to California. The Internet pipeline has left a trail of deaths, overdoses, addictions and emotional[ly] devastated families."

Prescription drug abuse is a critical public health problem for Massachusetts and the nation. The 2004 National Survey on Drug Use and Health indicated that the category of drug use with the highest number of new initiates was non-medical use of pain relievers, totaling 2.4 million new users. In Massachusetts, hospital and other facility emergency department visits for non-heroin related opioid use, which includes prescription drugs such as OxyContin® and other oxycodone products, increased 134% between 1999 and 2002. Treatment data from the U.S. Substance Abuse and Mental Health Service Administration shows that treatment admissions in Massachusetts for the category "other opiates," which includes prescription opioid analgesics, increased 950% in the

decade from 1992 (325 admissions) to 2002 (3,409 admissions). From 1993 to 2006, the Massachusetts Prescription Monitoring Program (PMP) showed that the number of prescriptions for all Schedule II opioids, including oxycodone products, increased approximately 261%, from 789,000 to approximately 2.85 million. At the end of 2005, the U.S. Drug Enforcement Administration reported that Massachusetts ranked 13th among the nation in the per capita rate of consumption of oxycodone products.

Massachusetts' Drug Control Program (DCP) promotes access to safe and effective pharmaceutical care services and protects consumers against fraud, deception, and unsafe practices in the distribution, handling, and use of pharmaceuticals and medical devices. The Program has statutory responsibility to set standards for the control of prescribing, dispensing, and administration of pharmaceuticals by healthcare providers, as well as distribution of pharmaceuticals by healthcare facilities (e.g., hospitals, clinics, long-term care) and other entities (e.g., manufacturers, distributors, community-based programs). The DCP undertakes initiatives to promote effective security and accountability measures and to prevent theft, tampering, misuse, and abuse of drugs.

In order to accomplish the goals of consumer protection, drug control, and improved healthcare management, the DCP develops legislation, regulations, policies, guidelines, and interpretations; issues controlled substances registrations and hypodermic syringe licenses (as of September 2006, the DCP no longer issues hypodermic syringe licenses); conducts routine inspections and special investigations; collects evidence for analysis; participates in and develops cooperative programs with other state, federal, and local agencies and non-governmental organizations; issues consumer advisories and disseminates information to the public; offers in-service and education programs; and undertakes enforcement actions (such as embargoes, administrative sanctions, and registration suspensions or revocations) that may result in civil or criminal penalties. Also, the Program is responsible for overseeing the destruction of illicit drugs confiscated by law enforcement agencies.

The DCP is organized into five major areas of activity: Drug Diversion Control (including field operations), the Drug Registration and Monitoring Program (including PMP), the Medication Administration Program, the Drug Formulary Commission, and Drug Control Policy.

Drug Diversion Control

The DCP was extensively involved in efforts, including field operations, to curtail the diversion of prescription drugs in the Commonwealth. Diversion is the deflection of pharmaceuticals from licit medical use to illicit channels. The goal is to reduce the opportunities for theft, tampering, misuse, and abuse of pharmaceuticals by improving the standards for control in healthcare facilities and community-based programs, raising the level of compliance among controlled substances registrants, and providing education to healthcare providers and the general public. The Commissioner's briefing for fiscal year 2005 showed that 275 out of 719 diversion reports involved "diversion investigations", now called "field investigations", with 135 referrals to professional boards (Medicare, Pharmacy, etc.). The 444 reports that were not subject to an on-site field investigation did undergo a desk audit with follow-up as appropriate. Additionally, the unit performed some 360 inspections of both new and existing facilities (nursing homes, etc.).

Drug Registration and Monitoring Program

The DCP is responsible for the issuance and oversight of individual Massachusetts Controlled Substances Registrations (MCSRs), and for the monitoring of trends and activities in prescribing and dispensing through the Drug Registration and Monitoring Program (DRMP). The DRMP maintains a current database of all practitioners, physicians' assistants, and advanced practice nurses registered to possess, dispense, administer, or prescribe controlled substances in Massachusetts. In addition, the DRMP electronically tracks all community, clinic and hospital outpatient prescriptions for Schedule II medications in the state. The controlled substances in Schedule II are among the most highly addictive pharmaceuticals, and are consequently among those most sought for illicit use. The state legislature established funding for the DRMP in fiscal year 1994.

Medication Administration Program

The Medication Administration Program (MAP) was implemented in fiscal year 1994 to increase the safety and security of medication administration for individuals with mental illness or mental retardation living in licensed or certified community-based residences. DPH serves as the lead agency for MAP, which is administered jointly with the Department of Mental Health (DMH) and Department of Mental Retardation (DMR). As the lead agency, DPH issues MCSRs to community residential and day programs, provides oversight and monitoring of medication administration in

registered programs, provides technical assistance to service providers and their staff, and works in conjunction with DMH and DMR to assure uniformity in policies and procedures for MAP.

Drug Formulary Commission

Massachusetts law requires interchange of the less expensive, therapeutically equivalent drug products listed in the Massachusetts List of Interchangeable Drugs. The Drug Formulary Commission reviews petitions to include or remove pharmaceutical products on the state formulary and issues policies on drug interchangeability and midstream interchange in order to provide pharmacists, prescribers, and patients with sufficient opportunity to communicate whenever a product is deemed changeable during the course of ongoing drug therapy.

Drug Control Policy

The DCP reviews and provides testimony on legislation before the Joint Committee on Public Health and the Joint Committees on Criminal Justice, State Administration, and Local Affairs. DCP continues to review all of its regulations in accordance with Executive Order 384, Reducing Unnecessary Regulatory Burden. This review will result in other regulations being redrafted or modified. The DCP, in conjunction with the Office of General Counsel, provided policy guidelines and interpretations to ensure public understanding of and compliance with the requirements. Other components within the Drug Control Policy concern Publications and Electronic Media, Interagency Efforts, Emergency Response, Dietary Supplements, Community Health Networks, Drug Recalls, and the Pharmacy Internship Program.

The Department established the Prescription Monitoring Program (PMP) in 1992, pursuant to joint regulations of the Drug Control Program (105 CMR 700.006(J)) and the Board of Registration in Pharmacy (247 CMR 5.04), to help address the problem of drug diversion and abuse in the Commonwealth. The Program utilizes a computer-based Electronic Data Transfer (EDT) system to collect prescribing and dispensing information on Schedule II drugs, which are those pharmaceuticals with the highest potential for abuse (e.g., narcotics stimulants), and are consequently among those most sought for illicit and inappropriate (non-medical) use. During fiscal year 2005, approximately 1,200 community clinic and hospital outpatient pharmacies in Massachusetts collectively reported over 2.6 million prescriptions for Schedule II drugs to the EDT system.

Data from the system is used to determine prescribing and dispensing trends, provide educational information to healthcare providers, and provide case information to regulatory and law enforcement agencies concerning drug distribution and diversion. Medical Review Groups (MRGs), comprised of practitioners (e.g., physicians, dentists) and pharmacists, will review a wide range of prescribing and dispensing practices in Massachusetts and shall assist the Department in the evaluation of prescription information for subsequent release to law enforcement and regulatory authorities. Since 1994, data related to over 1,800 cases have been reviewed by the MRGs, largely in response to requests from such authorities for information related to ongoing investigations.

The Department also has the authority to release PMP data to practitioners. Chapter 94C, Section 24 of the Massachusetts General Laws (MGL) (enacted by Chapter 104, Section 7 of the Acts of 1998) authorizes the Department to notify practitioners when a patient receives a controlled substance from more than one source and in quantities harmful to the health of the patient. Section 24 also authorizes the Department to adopt regulations to prevent the dispensing of a controlled substance to the same individual from multiple sources or the unlawful diversion of controlled substances. To date, the Department has not promulgated regulations to carry out this section of the law.

Regulatory Framework

There is no question that there is a legitimate federal and state interest for duly licensed and registered physicians, pharmacists, and other professionals to prescribe, dispense, and administer controlled substances for legitimate medical purposes and in the normal and customary course of their respective practices. State and federal governments not only respond to diversion and abuses of controlled substances, but also monitor the treatment needs and quality of care that healthcare professionals provide to their respective patients.

Regulatory agencies, such as the Massachusetts Division of Professional Licensure and others, endeavor to ensure by examination, licensing, monitoring, and inspection that professionals and healthcare facilities are qualified to care for ill and injured individuals. The federal government, through the Drug Enforcement Administration (DEA), and several states, including the Commonwealth of Massachusetts, also issue controlled substances registration to state practitioners for prescribing, dispensing, and administering controlled substances. In the Commonwealth of

Massachusetts, the Department of Public Health (DPH) regulates healthcare professionals to enable them to legally prescribe, dispense, and administer controlled substances.

According to the records maintained by the DPH, there are approximately 36,500 licensed healthcare professionals registered with DPH who can prescribe, dispense, and administer controlled substances. In addition, DPH registers 4,200 hospitals, clinics, manufacturers/distributors, and community-based programs to dispense controlled substances. Furthermore, the Massachusetts Board of Registration in Pharmacy licenses over 1,000 community/chain pharmacies.

MGL Chapter 94C, Section 7 requires that every person who manufactures, distributes, prescribes, dispenses, or possesses controlled substances must obtain a Controlled Substances Registration (CSR) from the Commissioner of Public Health's Drug Control Program (DCP). The onus for obtaining a CSR license is on the registrant. The only exceptions to this requirement are long-term care facilities, which are licensed by the Department of Public Health/Division of Healthcare Quality, and pharmacists, retail pharmacies, and wholesale druggists that are licensed by the Board of Registration in Pharmacy. 105 CMR 700.004(2) set forth the types of businesses and activities that require a separate CSR. Except for licenses issued to physicians, dentists, podiatrists, and veterinarians, all other CSR licenses are valid for a one-year registration period.

There are a number of checks and balances that are part of an overall system that assist the DPH in monitoring individuals who are writing prescriptions for Schedule II drugs. First, all practitioners writing prescriptions on controlled substances must have a license issued by the DEA. The license issued by the DEA is valid for three years from the date of issuance and the DEA will not issue a DEA license (DEA number) unless it receives confirmation from the DPH that the individual is currently registered with DCP. The DEA and DCP have established a data link whereby the DCP transmits to the DEA electronically the names of individuals that have current CSRs. In order to coordinate with the DEA licensing procedure, DCP has instituted a recall program under MGL Chapter 94C, Section 7, which essentially requires each physician, dentist, podiatrist, and veterinarian to renew his or her CSR license every three years. The recall program is generated by DCP by mailing out notices to the appropriate individuals on a monthly schedule.

Secondly, practitioners who are permitted to practice medicine at a licensed hospital or other healthcare facility also undergo an annual review at each facility to assure those facilities that the individuals who practice medicine at such facilities are properly licensed and/or registered.

Massachusetts Oxycontin® and Other Drug Abuse Commission

Chapter 189 of the Acts of 2004 established the Massachusetts Oxycontin® and Other Drug Abuse Commission. The Commission's primary responsibility was to investigate the effects of the abuse of prescription medications and illicit drugs on people of all ages in the Commonwealth. Additionally, the Commission expanded its scope to also consider public policy options for all age groups for the prevention, control, and treatment of drug abuse in general, not just prescription drugs. The membership of the Commission, outlined in Section 1 of Chapter 189 of the Acts of 2004, comprised eleven members from various governmental and non-governmental posts. These eleven included four members of the Massachusetts General Court, a representative from the state's Department of Mental Health, and the state's Department of Public Health Bureau of Substance Abuse Services. In addition to these governmental representatives, there were five members of the public who have expertise in the drug abuse field, two of whom were appointed by the Senate President and three by the Governor.

Based upon its review, the Commission made four general recommendations for policy actions and legislation. Those recommendations include the following areas: (1) prevention and education; (2) distribution, dispensing, and handling; (3) prescribing and monitoring; and (4) expansion of access to treatment services. For purposes of this review, we will focus on the Commission's general recommendation on prescribing and monitoring. The Commission recommended that the Commonwealth expand the scope, timeliness, and availability of reports and data on prescribing of Schedule II and other high-risk drugs, including irregular patterns of use. The Commission also recommended that the Commonwealth explore legislation, similar to mandatory reporting laws, that provides a process for reporting prescription drug abuse to proper authorities within the Commonwealth. Additionally, the Commission stipulates that the expanded prescription monitoring capabilities shall include the following:

1. Increased analytic capacity of the current Prescription Drug Monitoring Program so that prescriptions can be analyzed by the patient and the prescriber, and irregular patterns can be detected.

2. Development of a confidential and fair reporting system for prescribing physicians in order to identify atypical patterns of prescription refills among patients.

3. Expanded list of drugs monitored by the Prescription Drug Monitoring Program. The list shall include other abused drugs beyond the Schedule II drugs currently being reported.

4. Modify current regulations as permitted under existing privacy laws to allow the transfer of necessary prescription data for more timely and comprehensive access to data for pharmacies, prescribing physicians, the Board of Registration, law enforcement, and others as necessary. Provide education and training to clarify the limits and scope of privacy regulations.

5. Improved Prescription Drug Monitoring Program software and applications to take advantage of current technologies that include a secure, Internet-based application. This application should increase the timeliness of data and improve the speed with which prescribers, pharmacies, and others can identify individuals with multiple prescriptions and patterns of abuse.

6. The Commonwealth shall prepare a report to the Legislature on the costs and benefits of developing a tamper-proof prescription pad system, similar to the one employed in the state of New York.

7. Consistent with existing privacy and other legislation, the Commonwealth shall also improve the overdose and Emergency Room monitoring system so that patterns of abuse can be detected and actions are taken to mitigate additional health risks. Specifically, the Commonwealth shall revise any necessary regulations to increase hospitals' and other healthcare providers' compliance and reporting of any drug overdoses, including alcohol and all Schedule II drugs.

Finally, the Commission stipulated that the Committee on Public Health have the Department of Public Health report back to the Committee no later than March 31, 2007 and annually thereafter on their activities and progress in implementing the recommendations, any barriers encountered, and proposed approaches to overcome those barriers. Specifically, the reports should address:

> *(3) Prescribing and Monitoring: The Department of Public Health shall prepare a report and provide testimony to the Committee on Public Health on the progress DPH has made in redesigning and expanding the scope of its Prescription Monitoring Program and reporting procedures to accomplish the recommendations.*

As of August 9, 2007, DPH has not submitted the report to the Committee on Public Health.

Audit Scope, Objectives, and Methodology

In accordance with Chapter 11, Section 12 of the General Laws, the Office of the State Auditor conducted an audit of the Department of Public Health's Drug Control Program. Our audit was

conducted in accordance with applicable generally accepted government auditing standards for performance audits. The purpose of our review was to determine whether the DPH (1) was efficiently and effectively managing its Drug Control Program, (2) was properly registering all doctors, hospitals, clinics, pharmacies, etc. who distribute Schedule II drugs, and (3) has established adequate monitoring and oversight systems to ensure that standards and regulations for drug distribution are being complied with.

Our audit procedures consisted of the following:

- Reviewing applicable laws, regulations, organization charts, policies, and procedures to determine whether the DPH's DCP is efficiently and effectively managing its funds and activities.

- Interviewing DCP management personnel and key employees to analyze the level of compliance with stated policies, procedures, and stated goals.

- Obtaining and reviewing data pertaining to the Prescription Monitoring Program to determine the effectiveness of the analysis of the data and its use in detecting drug diversion.

- Reviewing the relationship of DCP with the licensing boards within the DPH to determine the relationship between the licensing of medical professionals and the registering of those professionals to prescribe and distribute Schedule II drugs.

- Obtaining and reviewing information pertaining to the diversion of Schedule II drugs.

- Reviewing budgetary and funding data relative to the operation of the DCP.

Based upon our audit, except for the issue disclosed in the Audit Results section of this report, the Commonwealth's Drug Control Program was in compliance with applicable laws, regulations, policies and procedures for the areas tested.

AUDIT RESULTS

PRESCRIPTION MONITORING PROGRAM NEEDS TO BE STRENGTHENED

Although the Massachusetts Prescription Monitoring Program (PMP) has contributed to public health and safety by providing case information to regulatory and law enforcement agencies concerning drug distribution and diversion, the full potential of the Program has not been realized and has become less effective in meeting a secondary goal of utilizing collected data to determine aberrant prescribing and dispensing trends. This reduced effectiveness comes during a time of significant increases in the number of pain reliever prescriptions and the increase in substance abuse and drug diversion.

Three specific factors can be cited as determining causes for the PMP's not reaching its full potential: 1) the individual responsible for extracting and interpreting queries relating to possible drug diversion no longer works for the Program; 2) 105 CMR 700.00(4), Privacy and Confidentiality, which restricts the dissemination of PMP information, has not been amended to reflect MGL Chapter 94C, Section 24, that confers authority to release information to practitioners, specifically "if the commissioner determines that a research subject or patient is receiving a controlled substance from more than one source and in quantities which he determines to be harmful to the health of research subject or patient", and; 3) out-of-state pharmacies are not required to report prescription data to Massachusetts, thereby giving an incomplete picture of what a patient may be receiving or a healthcare professional may be prescribing.

According to a 1998 annual report issued by the Department of Public Health (DPH), the PMP collected data on approximately 1.2 million prescriptions in 1998 and generated 25% of the cases referred to the DPH's Medical Review Group (MRG), with the remaining 75% of cases coming from law enforcement agencies or other licensing boards. By way of contrast, for calendar year 2005, PMP collected data on 2.6 million prescriptions; however, PMP generated approximately 4% of the cases referred to MRG. The 1998 report stated that, since the first cases were reviewed by the PMP and brought before the MRG in March 1994, the Program has reviewed some 795 cases. However, more recent statistics provided by the DCP indicate that for fiscal year 2003 through fiscal year 2005, only 254 cases were reviewed by DCP, of which only 5%

were generated by the PMP. For fiscal year 2005, 92 cases were reviewed, with only four originating from the PMP. See Table I for the breakdown of PMP cases for fiscal year 2005.

Table I
PMP Cases for Fiscal Year 2005
By Requesting Entity

Requesting Entity	Number	Percentage
Board of Registration in Medicine	16	17.4%
Diversion Investigative Unit, Massachusetts State Police	39	42.4%
Drug Control Program, DPH	4	4.3%
Office of the Attorney General	18	19.6%
U.S. Drug Enforcement Administration	12	13.0%
Other	3	3.3%
	92	100.0%

Table II
PMP Cases for Fiscal Years 2003 to 2005
By Requesting Entity

Requesting Entity	Number	Percentage
Board of Registration in Medicine	56	22.1%
Diversion Investigative Unit, Massachusetts State Police	135	53.2%
Drug Control Program, DPH	13	5.1%
Office of the Attorney General	13	5.1%
U.S. Drug Enforcement Administration	33	12.9%
Other	4	1.6%
	254	100.0%

The downward trend for PMP-referred cases continued from fiscal year 2003 through fiscal year 2005 despite the significant increase in the number of prescriptions for Schedule II controlled substances.

According to DCP management, the reason for the decrease in referred cases is due to the fact that the primary individual in the unit whose job it was to extract and interpret queries relating to possible drug diversion no longer works for the Commonwealth. Since the departure of this individual, the PMP has not run queries for review on its behalf on a regular basis. As a result, the PMP has basically become reactive, with most PMP data requests coming from outside entities, rather than proactive, generating and analyzing data on its own.

Information is available and queries could be established, because in accordance with CMR 700.006 (J)(1)(a), every pharmacy registered with the DPH that dispenses controlled substances in Schedule II pursuant to a prescription is required to transmit to the DPH or its agent the

following information for each such prescription: (1) prescription number, (2) pharmacy number, (3) patient identifier, where feasible, (4) date the controlled substance was dispensed, (5) metric quantity of controlled substance dispensed, (6) national drug code (NDC) of controlled substance dispensed, (7) estimated days' supply of controlled substance dispensed, and (8) prescriber's U.S. Drug Enforcement Administration (DEA) registration number.

DPH has contracted with Atlantic Associates, Inc. (AAI) to manage the Electronic Data Transmission System for Pharmacy data. Under the terms of the contract, AAI will provide a cost-effective means to capture information on all Schedule II prescriptions filled within the Commonwealth and transmit the data to the DCP on a monthly basis.

Additionally, we identified another problem with the PMP being able to effectively run its Program. MGL Chapter 94C, Section 24, *Dispensing by practitioner for narcotic drug research or treatment of drug dependent persons*, authorizes the Department to notify practitioners when a patient receives a controlled substance from more than one source and in quantities harmful to the health of the patient. Section 24 also authorizes the Department to adopt regulations to prevent the dispensing of a controlled substance to the same individual from multiple sources or the unlawful diversion of controlled substances. To date, the Department has not promulgated regulations to carry out this section of the law. Currently, 105 CMR 700.006(4), *Privacy and Confidentiality,* states that information collected pursuant to 105 CMR 700.000 shall not be disseminated to anyone other than:

- a duly authorized representative of the board or agency responsible for the registration, regulation, or discipline of practitioners authorized to prescribe or dispense Schedule II controlled substances;
- law enforcement agencies conducting a bona-fide criminal investigation or prosecution of criminal violations; and
- an individual who is the data subject; however, access is limited by certain statutory and regulatory conditions and restrictions.

The existing PMP regulations, in permitting disclosure of PMP data to law enforcement and regulatory agencies, created an exemption to the Fair Information Practices Act (FIPA), that is both consistent with the intent of FIPA and a way to further implement provisions of MGL Chapter 94C, Section 24. With respect to the authority in MGL Chapter 94C, Section 24 to

provide PMP data to practitioners concerning their patients, because the PMP is not authorized to collect patient-identifying information, there is no patient-specific PMP information to provide to practitioners. That is, the PMP cannot meet the condition in the provision of MGL Chapter 94C, Section 24 that confers authority to release information to practitioners, specifically "*if* the commissioner determines that a research subject or patient is receiving a controlled substance from more than one source and in quantities which he determines to be harmful to the health of such research subject or patient" (emphasis added). At the time that the Department established the PMP, PMPs were established as law enforcement tools, and there were no states that permitted the disclosure of patient information to practitioners or pharmacies. When the regulations were proposed, numerous parties expressed concern to the Department about carving out an exemption to FIPA, particularly if it involved disclosure of patient information. The focus on law enforcement therefore represented an application of the best practices at the time and an attempt to reconcile concerns about privacy with the desire to improve our efforts to reduce diversion. More recently, as several other states' PMPs have begun to collect patient data and provide it to practitioners, and as concerns about prescription drug diversion have grown, there appears to be increased acceptance of the Department collecting patient information and disclosing it to practitioners as a clinical tool. As a result, the Department decided that it would be justifiable, and consistent with the intent of FIPA, to expand the disclosure exemption. Hence, in January 2006, the Department proposed regulations to authorize the collection of patient-identifying information and the disclosure of patient-related PMP data to practitioners.

Currently, the PMP does not release information to practitioners dispensing Schedule II drugs, thus preventing the possible earlier intervention of unlawful diversion.

Finally, PMP is limited geographically, since it only applies to pharmacies located within the Commonwealth. Out-of-state pharmacies are not required to report prescriptions sent into Massachusetts to the PMP. The lack of this data can give an incomplete picture of what a patient may be receiving or what healthcare professionals may be writing. For example, individuals who engage in "doctor shopping" for the purpose of obtaining controlled substances for illicit use can obtain multiple prescriptions from several healthcare professionals and visit numerous pharmacies outside the jurisdiction of the PMP and can have their prescriptions filled without the information being furnished to the PMP, thereby preventing potential detection by

the PMP. The detection aspects of the PMP are further exacerbated by the use of "out-of-state" Internet or "mail order" pharmacies, which are not required to report prescription activity to the PMP. The inherent weakness in the system makes it even more difficult to detect drug diversion, since there is no reciprocity or sharing of information among states that have prescription monitoring programs, and it becomes even more difficult when you consider that almost half the states do not have a prescription-monitoring program. Other states have enacted legislation that require out-of-state pharmacies that send prescription-filled drugs into their respective state to be licensed in that state; therefore, such out-of-state pharmacies would be required to report such data to that state prescription monitoring program. The US Department of Justice is working on this issue from a national perspective and has funded the Integrated Justice Information System (IJIS) to develop strategies for more efficient and cost effective means of obtaining interstate data through data sharing.

Program Initiatives

The DCP, in addressing shortfalls identified, has sought and received almost $1 million in federal funding to enhance the PMP by meeting the following overall goals:

1. Improving analysis of the PMP database to more efficiently and accurately identify cases needing investigation.
2. Improving access to and utilization of the PMP findings by law enforcement and regulatory agencies.
3. Engaging prescribers and the wider healthcare community in addressing prescription drug addiction and diversion by means of increasing their awareness and use of PMP data.
4. Improving the quality and enhancing the value of the data being collected.
5. Assessing the efficiency and effectiveness of the program and facilitating the exchange of information and prescription data among northeastern states.

In order to meet these goals, four initial project activity categories were established: (1) technological enhancements, (2) an epidemiological tracking system, (3) a physician data pilot test, and (4) coordination and collaboration with key stakeholders. With the additional grant funding received, additional objectives augmenting the previous enhancements include:

- Convening a work group of northeastern states to develop strategies for exchange of PMP data.
- Developing baseline measures of current prescription dispensing activities that may indicate diversion across state lines.
- Initiating data sharing appropriate to the identified problem.
- Monitoring changes in drug marketing and diversion control efforts to assess effectiveness of data sharing.
- Helping neighboring states seeking to establish PMPs by giving them information about the benefits of utilizing such data.
- Engaging physicians and other health care professionals and their organizations in designing intervention strategies, and developing and testing educational and other processes that use PMP information to improve medical care and reduce diversion.
- Including physicians and medical experts in neighboring states in the process so the interventions can be applied to multiple states in the northeast.
- Designing systematic diversion intervention strategies that practitioners can use when they receive PMP data identifying potential doctor shoppers and other forms of diversion.

(1) Technological Enhancements

An enhancement effort to the PMP involved the development of an interface system, using a SQL Server system containing the automated algorithms developed for doctor shopping and forgery. The interface system allows for more efficient searches of requested reports. Some new features include the ability to: (1) use "wild cards" while searching the Customer ID field, (2) create an "ignore" list containing invalid Customer ID data, (3) look up multiple Customer ID numbers during a single search; and (4) look up additional information from different data sources, such as the Pharmacy NABP (National Association of Boards of Pharmacy) number and Practitioners' DEA number databases, by simple selecting data fields from the results screen.

During the course of this project, it was recognized that a tracking database of past cases needed to be developed as a prerequisite to identifying new cases for investigation. This is necessary to avoid duplication of effort and unintended interference with ongoing investigations. Therefore, a Case Information Database was created to electronically store information regarding requested and released PMP case reports. The database will also help maintain an account of the use of the PMP as it becomes more accessible to current and potential end-users. This database is used

in an ongoing effort to systematically document requested reports from law enforcement and regulatory agencies as well as identify potential doctor shopping individuals who are identified using the interface system containing automated algorithms.

(2) Epidemiological Tracking System

The epidemiological analysis plan consisted of four subcategories: (1) examine trends in Schedule II opioid prescriptions over several years; (2) derive estimates of the number of individuals who obtained opioid prescriptions in a given year; (3) determine which products were being most frequently prescribed; and (4) derive estimates of the number of individuals engaged in questionable activities using different threshold criteria of multiple prescribers and pharmacies and the associated products. The PMP data has a number of limitations in the identification of unique individuals that result in underestimates of individuals, the number of prescriptions per individual, and the number of individuals engaged in questionable activities. Nevertheless, because these limitations are fairly constant, the general trends on opioid use and misuse in Massachusetts may be determined. In summary, the analysis showed that from 1996 to 2005, Massachusetts experienced steady increases in the quantity and dosage units of Schedule II opioid prescriptions dispensed, the number of identifiable individuals to whom opioid prescriptions were dispensed, the ratio of prescriptions per individual, and the number of individuals engaged in questionable activity. For example, the number of Schedule II opioid prescriptions dispensed from fiscal year 1996 to 2005 increased by about 120% (from 820,659 to 1,820,044 prescriptions), while the number of dosage units dispensed increased by about 185% (from 25,204,765 to 95,250,085 dosage units) over the same period. In addition, the number of individuals engaged in questionable activity, defined as a Customer ID number linked with multiple pharmacies beyond a certain threshold during one year, increased 180%, from 1,210 to 3,389 individuals. While 80% of the identified individuals had only one or two prescriptions in fiscal year 2005, over 3% had more than 12, and over 1% had more than 20.

(3) Practitioner Data Dissemination Pilot Test (PDDPT)

The PDDPT was developed collaboratively between the PMP review team and a member of DPH's Medical Review Group by analyzing and comparing data within the PMP and a selected sample of patient medical records from the member of the MRG. The member was asked to make a professional judgment of how likely it was that a patient was engaging in doctor

shopping, drug diversion, or other inappropriate behavior with regard to their opioid prescription drugs before and after his review of a corresponding PMP data report. The DPH generated a report of the member's patients who received a controlled substance from more than one source and in quantities that may be harmful to the health of a patient. For each patient in the sample, the MRG member received a report on Schedule II drugs prescribed by the MRG member and his colleagues. Based on the member's assessment of the PMP data reports, the member felt that some 22% of the 83 patients reviewed might be engaging in inappropriate use of their prescription drugs. Therefore, the general finding of the pilot test indicates that the PMP system is a valuable and useful clinical tool in providing appropriate care for patients undergoing pain treatment.

Prescription records were also reviewed to test the accuracy of the data collected in the PMP system by comparing records in the PMP data reports with patient medical files. The review process found that all prescription records documented in the PMP data reports were verified in the files. However, approximately 30% of prescription records in the medical files were missing in the PMP data reports. Reasons for the missing records may include issues involving patient noncompliance with their medical treatment or missing Customer ID numbers (since patients are not required to present ID, not all prescription records in the database are associated with an ID number, and thus some records are missing Customer ID numbers) in the PMP system, which were used to produce PMP reports for the Physician Data Pilot Test. Findings from this test pilot will aid DPH in its efforts to amend the regulations to collect additional data fields from pharmacies and provide PMP reports to practitioners in the future. As a result of this project, it is clear that the ability to identify unique individuals in the database through the collection of additional prescription information is a prerequisite to the sharing of data with practitioners.

The potential value of PMP data in helping physicians and other medical practitioners minimize prescription opioid abuse is vast. One example of the system's value in targeting specific prescribing issues was demonstrated during the mid-1990's, when DPH directed educational information to prescribers of the sedative hypnotic glutethimide, resulting in the elimination of the prescribing of this drug in Massachusetts. Information from the PMP can also provide assurance to practitioners and help eliminate doubt about particular patients as well as provide a legitimate cause to confront patients regarding opioid misuse or treatment compliance. Optimal

use of the PMP data by practitioners will require education and outreach. Since most practitioners have not had the opportunity to view a PMP data report, proposed project activities will have to include educational strategies for practitioners' use of PMP data reports. Also, patients who truly are doctor shopping or misusing their prescriptions should have treatment readily available, which will require further collaboration and coordination of resources and services among key stakeholders.

(4) Collaboration and Coordination of PMP Enhancement Efforts

To increase stakeholder satisfaction in the Prescription Monitoring Program and increase the efficiency of investigational efforts, the project staff should continue to work closely with other key stakeholders of PMP system. PMP end-user surveys have been disseminated, collected, and analyzed. The survey was developed based on baseline qualitative interviews with current and potential end-users of the PMP data system, with the aim of documenting changes over time in the objectives and improvements in the functionality and responsiveness of the PMP system for its end-users. The purpose of the survey was to quantify three broad areas: (1) actual and potential end users' level of experience with and priorities for the PMP system, (2) users' overall level of satisfaction with the current system, including the system's usefulness and responsiveness, and (3) users' perception of trends in their environments with which, ideally, an improved PMP system would be compatible. A total of 13 surveys were collected, representing the Massachusetts State Police Drug Investigative Unit, DPH's Drug Control Program, U.S. Drug Enforcement Administration, Board of Registration in Medicine, Board of Registration in Pharmacy, pain management physicians, researchers, and the MRG. In summary, the surveys generally indicated that the PMP data system was useful for reducing investigation time, and that the data reports were usually accurate but incomplete. Most participants agreed that there was great potential for the PMP data system to prevent diversion, to identify and treat individuals abusing prescriptions opioids, and to assist in criminal investigations. In addition, almost all of the participants agreed that collecting Schedule III, IV and V prescription records in the PMP data system would be extremely valuable.

The enhancement of the PMP continues to be a work-in-progress, with many project activities still to be undertaken to meet the terms of the federal grant.

Finally, in its January 24, 2006 Informational Briefing on Amendments to 105 CMR 700.000; *Implementation of MGL 94C to the DPH Commissioner*, the DCP proposed to amend its regulations to further enhance the Massachusetts PMP. The purpose of the enhancements are to improve data quality, increase data utility and utilization, reduce the opportunities for drug diversion, and increase prevention of and facilitate interventions in drug addiction and abuse. Specifically, the amendments would:

1. Require that positive identification be obtained by pharmacies from the person picking up a Schedule II prescription. This requirement would help deter diversion of Schedule II drugs by ensuring that pharmacists consistently obtain information about customers obtaining such controlled substances on behalf of patients. Moreover, the requirement would ensure that the reports received by the PMP from pharmacies about the filling of Schedule II prescriptions contain more reliable information. The amendments would provide for exceptions to the requirement for positive identification to ensure that patients will not be unreasonably denied access to needed medications.

2. Require reporting by pharmacies of additional prescription information, including patient identification information, such as name and address. The fields proposed to be reported will improve the Department's ability to identify unique individuals in the database. The fields are those recommended by the Alliance of States with Prescription Monitoring Programs and the National Association of State Controlled Substances Authorities and are required to be reported to PMPs in many other states. Adding these fields would facilitate sharing of data with practitioners about prescriptions for Schedule II drugs and would enable statistically valid epidemiological analysis of prescription drug use and abuse. The patient information would be entirely confidential and could be disclosed only as provided in the regulations.

3. Authorize the sharing of PMP data with practitioners and pharmacies when patients seek prescriptions from more than one practitioner. By making data available to medical practitioners, the PMP could assist in identifying those at risk for or involved in prescription drug abuse and diversion, who can then be referred for appropriate treatment and/or interdiction. This initiative would assist practitioners concerned about drug diversion and provide a tool for improving care for their patients, including identification and prevention of drug abuse.

While the amendments proposed here are not intended to address every possible area of regulatory enhancement of the PMP, they are a first and necessary step toward enabling the Program to reach its full potential to protect the public health and safety.

These amendments would enable implementation of a number of the recommendations in the Commonwealth's Substance Abuse Strategic Plan and are one of a number of steps the Drug Control Program is taking to enhance the PMP as part of the enhancement initiatives funded in part by the U.S. Department of Justice. Additionally, these proposed amendments are critical to the ultimate goal of providing better data on the use and misuse of Schedule II opiods and other drugs.

Furthermore, these amendments would better enable DPH to assist law enforcement and regulatory agencies in intervention with prescription fraud and other forms of drug diversion, and to assist healthcare providers in the detection and identification of individuals at risk for, or involved in, non-medical use of Schedule II pharmaceuticals. Finally, these proposed amendments would set forth the requirements for clinic and hospital outpatient pharmacies. The Board of Registration in Pharmacy would need to promulgate companion amendments to set forth the same requirements for community pharmacies.

Recommendations

The DCP must continue in its efforts to improve the effectiveness of the PMP by utilizing and finalizing the project activities of the federal grants to enhance the quality of system data and use thereof. The DCP must also continue the process of amending 105 CMR 700.000 to bring regulations into compliance with MGL, Chapter 94C Section 24. In this manner, the ability and availability of PMP data to be utilized by physicians and pharmacies to better combat abuse and diversion of Schedule II drugs will be enhanced. Additionally, the DCP should continue to coordinate activities between states and the Integrated Justice Information System (IJIS) to develop strategies for more efficient and cost effective means of obtaining interstate data through data sharing. Furthermore, DPH should prepare and file its report with the Committee on Public Health on the progress it has made in redesigning and expanding the scope of its Prescription Monitoring Program and reporting procedures to accomplish the recommendations. Finally, and most importantly, the DCP, along with the DPH, must work with administration officials to seek out and determine ways to staff the DCP adequately in order to allow it to operate as intended. Automated system design enhancements provide better quality information for analysis, investigation, and referral to law enforcement. To successfully

utilize this data and have a Prescription Monitoring Program that is effective, it is necessary to dedicate adequate personnel to this increasingly important function.

Auditee's Response

In its response, DPH stated that the audit report's statement that the downward trend for PMP-referred cases continued despite the significant increase in the number of prescriptions for Schedule II controlled substances was not accurate. Specifically, DPH stated:

> *As shown Appendix IX of the Report, in 2006 DCP generated 36 new cases, or 35% of the caseload of 104 cases for the year. This represents a level of this particular activity similar to that during the period from 1994 to 1999 in which the DCP generated an average of 42 new cases per year, or 25% of the caseload.*

Auditor's Reply

As our audit covered fiscal year 2005, and our fieldwork ended on May 26, 2006, the data and comments included in our report for fiscal year 2005 are accurate. The data included in Appendix IX in our report was provided by the DPH after our fieldwork had been completed. In analyzing Appendix IX, of the 36 new cases identified by the DPH, 12 have release (disposition) dates of May 31, 2006, and 18, or 50%, have a release (disposition) date of December 28, 2006. These 30 cases were released after our fieldwork had been completed and DPH was aware of our preliminary audit results. DPH should continue its vigilance and subsequent investigation of cases. The DPH must further continue in its efforts to identify aberrant prescribing and dispensing trends and to subsequently notify regulatory and law enforcement agencies concerning drug distribution and diversion.

APPENDIX I

Controlled Substances in Schedule II

Controlled Substance	Narcotic	Synonym
1-Phenylcyclohexylamine	No	PCP precursor
1-Piperidinocyclohexanecarbonitrile	No	PCC, PCP precursor
Alfentanil	Yes	Alfenta
Alphaprodine	Yes	Nisentil
Amobarbital	No	Amytal, Tuinal
Amphetamine	No	Dexedrine, Adderall, Obetrol
Anileridine	Yes	Leritine
Benzoylecgonine	Yes	Cocaine metabolite
Bezitramide	Yes	Burgodin
Carfentanil	Yes	Wildnil
Coca Leaves	Yes	-
Cocaine	Yes	Methyl benzoylecgonine, Crack
Codeine	Yes	Morphine methyl ester, Methyl morphine
Dextropropoxyphene, bulk (non-dosage forms)	Yes	Propoxyphene
Dihydrocodeine	Yes	Didrate, Parzone
Dihydroetorphine	Yes	DHE
Diphenoxylate	Yes	-
Diprenorphine	Yes	M50-50
Ecgonine	Yes	Cocaine precursor, in Coca leaves
Ethylmorphine	Yes	Dionin
Etorphine HCI	Yes	M 99
Fentanyl	Yes	Duragesic, Oralet, Actiq, Sublimaze,Innovar
Glutethimide	No	Doriden, Dorimide
Hydrocodone	Yes	Dihydrocodeinone
Hydromorphone	Yes	Dilaudid, Dihydromorphinone
Isomethadone	Yes	Isoamidone
Levo-alphacetylmethadol	Yes	LAAM, Long Acting Methadone, Levomethadyl acetate
Levomethorphan	Yes	-
Levorphanol	Yes	Levo-Dromoran
Meperidine	Yes	Demerol, Mepergan, Pethidine
Meperidine intermediate-A	Yes	Meperidine precursor
Meperidine intermediate-B	Yes	Meperidine precursor
Meperidine intermediate-C	Yes	Meperidine precursor
Metazocine	Yes	-
Methadone	Yes	Dolophine, Methadose, Amidone
Methadone intermediate	Yes	Methadone precursor
Methamphetamine	No	Desoxyn, D-desoxyephedrine, ICE, Crank, Speed
Methylphenidate	No	Concerta, Ritalin, Methylin
Metopon	Yes	-
Moramide intermediate	Yes	-
Morphine	Yes	MS Contin, Roxanol, Oramorph, RMS, MSIR
Nabilone	No	Cesamet
Opium, granulated	Yes	Granulated opium
Opium, powered	Yes	Powered opium
Opium, raw	Yes	Raw opium, Gum opium
Opium extracts	Yes	-
Opium fluid extract	Yes	-
Opium poppy	Yes	Papaver somniferum

APPENDIX I (CONTINUED)

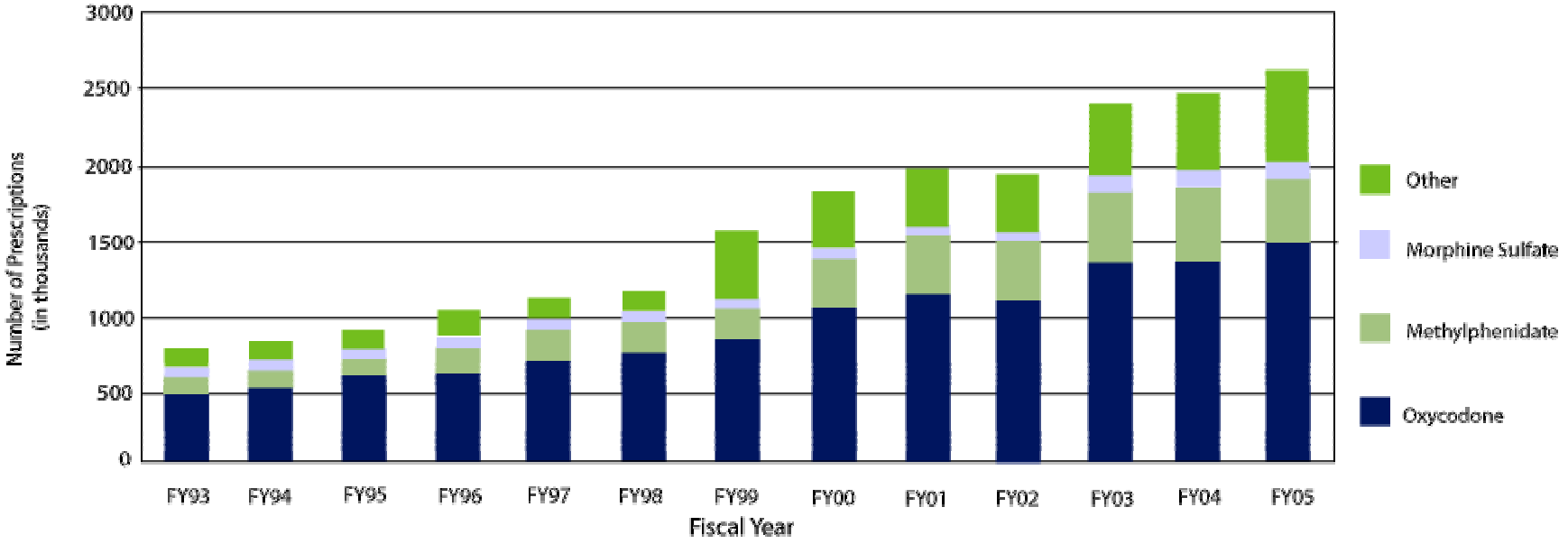
Controlled Substances in Schedule II

Controlled Substance	Narcotic	Synonym
Opium tincture	Yes	Laudanum
Oxycodone	Yes	Oxycontin, Percocet, Endocet, Roxicodone, Roxicet
Oxymorphone	Yes	Numorphan
Pentobarbital	No	Nembutal
Phenazocine	Yes	Narphen, Prinadol
Phencyclidine	No	PCP, Sernylan
Phenmetrazine	No	Preludin
Phenylacetone	No	P2P, Phenyl-2-propanone, Benzyl methyl ketone
Piminodine	Yes	-
Poppy Straw	Yes	Opium poppy capsules, Poppy heads
Poppy Straw Concentrate	Yes	Concentrate of Poppy Straw, CPS
Racemethorphan	Yes	-
Racemorphan	Yes	Dromoran
Remifentanil	Yes	Ultiva
Secobarbital	No	Seconal, Tuinal
Sufentanil	Yes	Sufenta
Thebaine	Yes	Precusor of many narcotics

Source: U.S. Drug Enforcement Administration

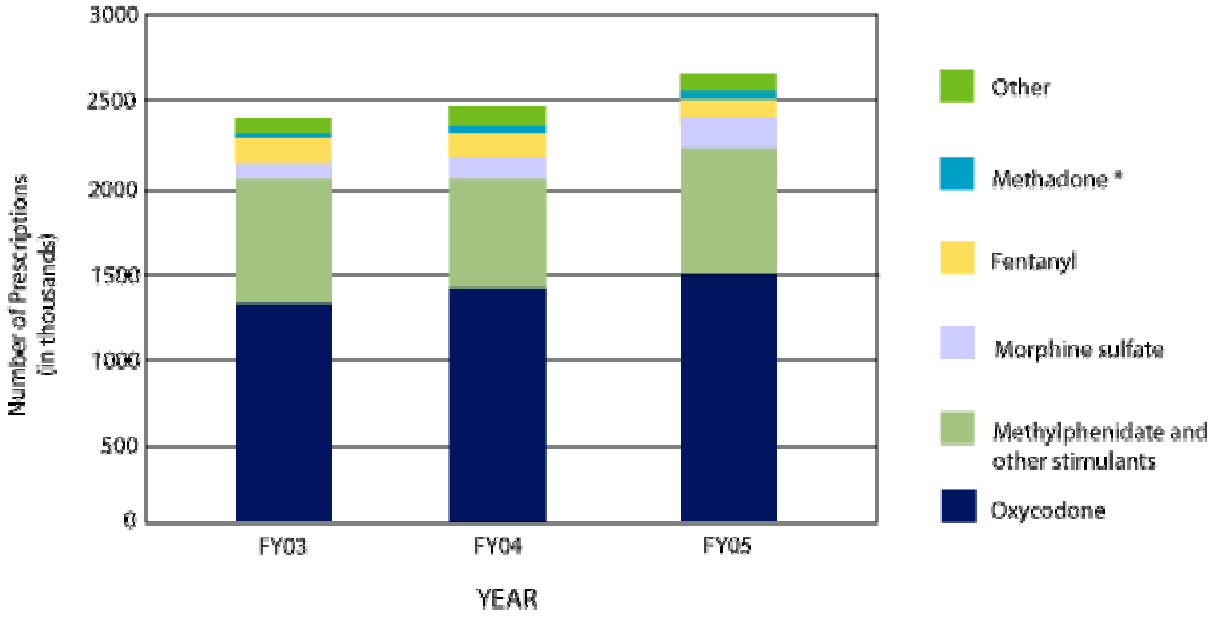
APPENDIX II

Prescription Monitoring Program
Schedule II Prescriptions by Year
Fiscal Year 1993 to Fiscal Year 2005



APPENDIX III

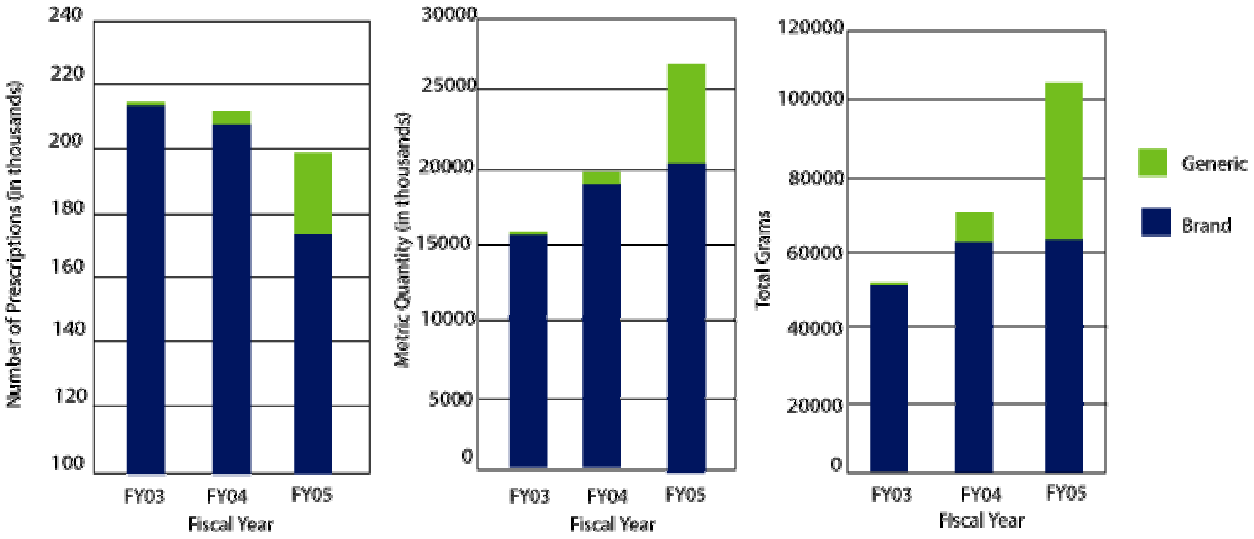
Prescription Monitoring Program
Schedule II Prescriptions by Year
Fiscal Years 2003, 2004 and 2005



* Does not include methadaone dispensed by opioid treatment programs

APPENDIX IV

Prescriptions for Long Acting Oxycodone by Fiscal Year



APPENDIX V

List of Controlled Substance Classification

Schedule I

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

Schedule II

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

Schedule III

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in Schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

Schedule IV

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in Schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substance in Schedule III.

Schedule V

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in Schedule IV.

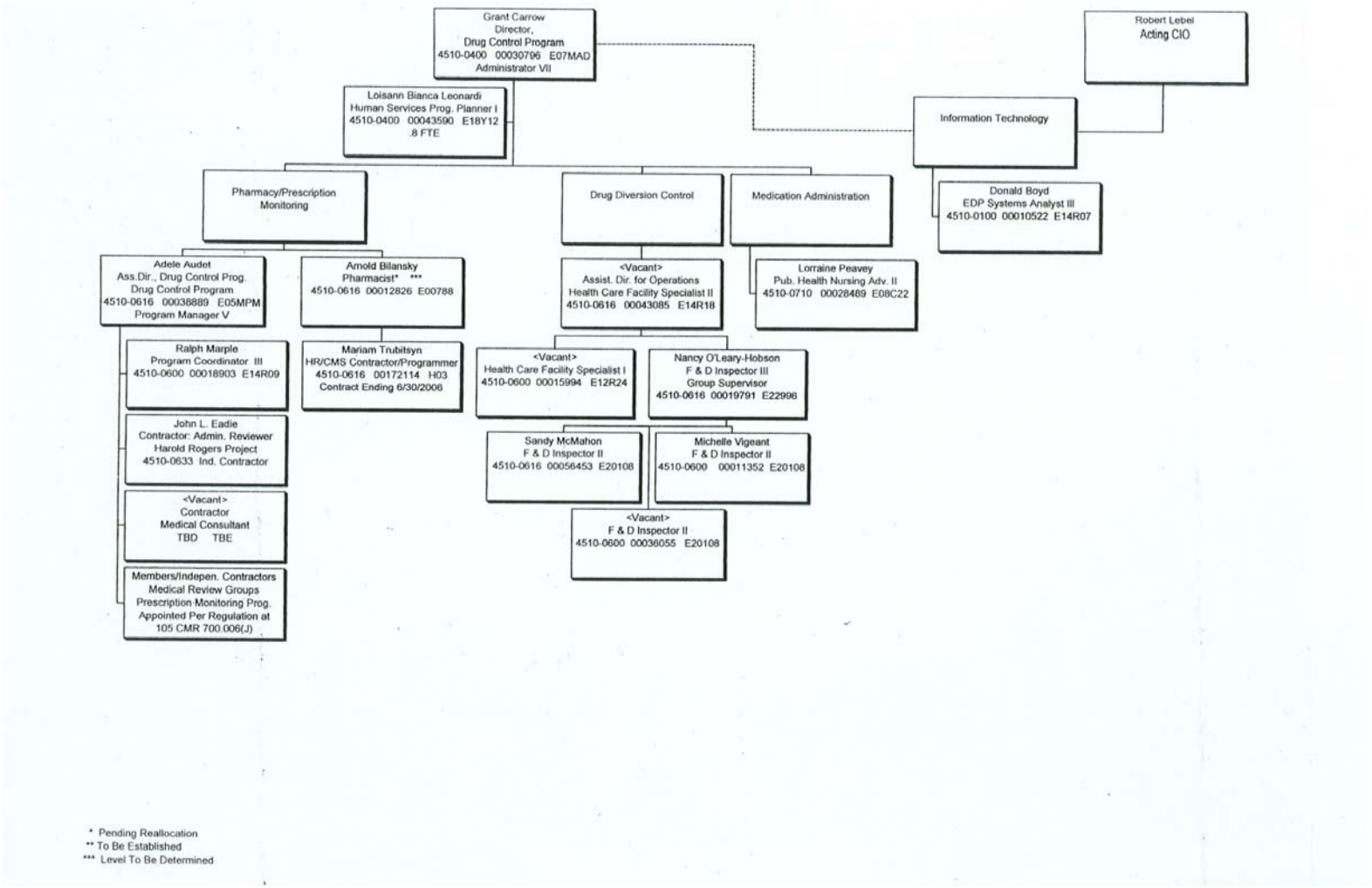
(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule IV.

Source: U.S. Drug Enforcement Administration

APPENDIX VI

Drug Control Program
Center for Quality Assurance and Control
Organization Chart
As of March 23, 2006



APPENDIX VII

Drug Control Program
Fiscal Year 2005 Expenditures by Appropriation

	Appropriation Account				
	4510-0600	4510-0616	5046-0000	5920-2010	Totals
State Employee Compensation					
Salaries: Regular	$63,061.01	$336,653.87	$39,374.71	$79,798.61	$518,888.20
Overtime Pay	-	432.37	-	-	432.37
Holiday Pay	-	395.64	-	241.71	637.35
Employee Related Expense					
Out-of-State Travel – Other	-	17.50	-	-	17.50
In-State Travel	12.88	144.71	190.36	-	347.95
Conference, Training and Registration	-	285.00	150.00	-	435.00
Exigent Job-Related Expenses	-	19.99	-	-	19.99
Out-of-State Travel – Hotel/Lodging	-	108.92	-	-	108.92
Employee Reimbursement Accounts Payable Non-Tax	-	-	1,080.00	-	1,080.00
Special Employees/Contracted Services					
Management, Business Professionals and Administrative Services	-	33,842.10	-	-	33,842.10
Reimbursement for Travel and Other Expenses	-	96.92	-	-	96.92
Administrative Expenses					
Office and Administrative Supplies	-	9,084.27	-	1,475.85	10,560.12
Printing Expenses and Supplies	-	1,082.47	-	1,569.82	2,652.29
Postage	-	3,750.00	-	2,267.00	6,017.00
Telecommunications Services Voice	-	8.730.20	-	-	8,730.20
Software and Information Technology Licenses	-	5,441.73	-	-	5,441.73
Information Technology Chargeback	-	510.10	-	-	510.10
Subscriptions, Memberships and Licensing Fees	-	2,298.86	-	-	2,298.86
Bottled Water	-	820.99	-	-	820.99
Temporary Use of Space, Conferences and Conference Incidentals Including Reservations Fees	-	-	-	192.60	192.60
In-State Travel and Related Expenses on Behalf of State Employees	-	150.00	-	-	150.00

APPENDIX VII (CONTINUED)

Drug Control Program
Fiscal Year 2005 Expenditures by Appropriation

	Appropriation Account				
	4510-0600	4510-0616	5046-0000	5920-2010	Totals
Energy Costs and Space Rental Expenses			-		
Electricity	-	-	$ 1,046.00	-	$ 1,046.00
Fuel for Vehicles	-	$ 8,000.00	-	-	8,000.00
Heating and Air Conditioning, Water Treatment, Chemicals and Supplies	-	-	4,354.00	-	4,354.00
Consultant Service Contracts					
Information Technology (IT) Professionals	-	84,504.00	-	-	84,504.00
Health/Medical Consultants	-	450.00	-	-	450.00
Operational Services					
Temporary Help Services	-	10,096.11	10,047.96	$10,596.57	30,740.64
Equipment Purchase					
Informational Technology (IT) Equipment	-	21,567.32	-	-	21,567.32
Equipment Tax Exempt Lease-Purchase, Lease and Rental, Maintenance and Repair					
Printing, Photocopying and Micrographics Equipment Rental or Lease	$ 694.66	-	-	-	694.66
Printing, Photocopying and Micrographics Equipment Maintenance or Repair	201.68	4,380.00	-	-	4,581.68
Total	$63,970.23	$532,863.07	$56,243.03	$96,142.16	$749,218.49

Appropriation Number	Appropriation Descriptions
4510-0600	For an environmental and community health hazards program, including control of radiation and nuclear hazards, consumer products protection, food and drugs, lead poisoning….
4510-0616	For a drug registration program; provided, that the department may expend an amount not to exceed $551,110 from revenue collected from fees charged to register … for controlled substance registration….
5046-0000	For adult mental health and support services….
5920-2010	For state-operated community-based residential services for adults, including community-based health services for adults.

APPENDIX VIII

Harold Rogers Grant for Prescription Monitoring Programs Budget Category Data

Budget Summary Category	Total Cost
Personnel	N/A
Fringe Benefits	N/A
Travel	$13,980
Equipment	35,195
Supplies	18,300
Construction	N/A
Consultants/Contracts	829,125
Other Costs	23,400
Indirect Costs	N/A
Total Project Costs	$920,000

APPENDIX IX

PMP Cases for Calendar Year 2006
By Requesting Entity

Requesting Entity	Number	Percentage
Board of Registration in Medicine	20	19.2%
Diversion Investigative Unit, Massachusetts State Police	37	35.6%
Drug Control Program, DPH	36*	34.6%
Board of Registration in Dentistry	3	2.9%
Office of the Attorney General	3	2.9%
U.S. Drug Enforcement Administration	5	4.8%
	104	100.0%

*

Release** Date (2006)	Number of Cases	Source
02/07	1	DCP investigative case
03/20	1	DCP investigative case
04/19	1	DCP investigative case
04/20	3	DCP investigative case
05/31	12	PMP data analysis
12/28	18	PMP data analysis
	36	

The increase was due to an increase in the number of cases generated by DCP through analysis of PMP data. This increase was in turn due largely to the application of technological enhancements, specifically the acquisition, deployment and use of data analysis software. This effort is one of the effects of implementation of the DCP's federally funded efforts to enhance the PMP through increased efficiency of the program and increased use of data.

**Disposition