The Commonwealth of Massachusetts

AUDITOR OF THE COMMONWEALTH

ONE ASHBURTON PLACE, ROOM 1819

BOSTON, MASSACHUSETTS 02108

TEL. (617) 727-6200

A. JOSEPH DeNUCCI

AUDITOR

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INDEPENDENT STATE AUDITOR'S REPORT ON THE FINANCIAL AND MANAGEMENT CONTROLS OVER CERTAIN PHARMACY OPERATIONS OF THE COMMONWEALTH OF MASSACHUSETTS

OFFICIAL AUDIT REPORT

SEPTEMBER 8, 2003

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During fiscal year 2002, 63 Commonwealth agencies spent more than $50 million on drugs and medicines for use by Commonwealth residents, including human-services consumers, correctional inmates, elder-care and high-risk clients, and college students. The majority of pharmaceutical spending occurred within the Departments of Mental Health, Mental Retardation, Public Health (all within the Executive Office of Health and Human Services [EOHHS] agencies), and the Department of Correction, within the Executive Office of Public Safety.

The Commonwealth enacted Chapter 94C (Controlled Substances Act) of the Massachusetts General Laws to comply with the federal Comprehensive Drug Abuse, Prevention and Control Act of 1970, to deter abuse of drugs and medicines, and to ensure they are used for their intended purposes. The Controlled Substances Act incorporates the requirements of the federal government and adds criteria for regulating controlled substances. It empowers the Commissioner of Public Health to establish rules and regulations and penalties for noncompliance with those rules and regulations.

As authorized by Chapter 11, Section 12, of the General Laws, the Office of the State Auditor conducted an audit of certain pharmacy operations at various state agencies. The objectives of our audit were to determine whether agencies complied with applicable laws, rules, and regulations and to evaluate their effectiveness and efficiency in procuring, purchasing, receiving, storing, issuing, inventorying, dispensing, and safeguarding drugs and medicines, including controlled substances and over-the-counter medications. Our review centered on the activities and operations of the State Office for Pharmacy Services (SOPS), including the Central Distribution Center Pharmacy (CDCP) and the Department of Correction Pharmacy (DOCP). As part of our review, we audited pharmacy-related activities at Bridgewater State Hospital, Medfield State Hospital, Monson Developmental Center, Wrentham Developmental Center, the Soldiers' Home in Holyoke, the Souza-Baranowski Correctional Center, Taunton State Hospital, Tewksbury State Hospital, Western Massachusetts Hospital, and Worcester State Hospital. Our review was undertaken to ensure that federal and state mandated policies and procedures to control the procurement, purchase, receipt, delivery, and dispensing of drugs were being adhered to.

Except as noted in the Audit Results section of the report, we determined that state agencies maintained adequate internal controls over drugs and medicines, including controlled substances and over-the-counter medications, and complied with applicable laws, rules, and regulations. Recommendations are being made to assist state agencies in developing, implementing, and improving internal controls and overall financial and administrative operations to ensure that the delivery system of drugs and medicines to residents of the Commonwealth is economical, efficient, effective, and in compliance with applicable rules, regulations, and laws.

Chapter 94C of the Massachusetts General Laws requires controlled substances to be categorized according to one of six schedules, based on currently accepted medical purposes in the United States and the potential for abuse. Schedule I drugs, such as Heroin and LSD, have a high potential for abuse and no currently accepted medical purpose in the US, and accordingly are not dispensed by state agencies, which distribute only Schedules II through VI controlled substances and over-the-counter medications to their consumers. Schedules II through VI substances do have accepted medical benefits and are rated progressively as to the potential for abuse. Schedule II substances, such as Oxycontin, Percodan, and Ritalin, may lead to severe psychological or physical dependence if abused. Schedule III drugs, such as Anabolic Steroids, Codeine with Aspirin, and Vicodin, also have accepted medical purposes, but if abused could result in moderate to low dependence. Schedule IV and V drugs, which have the potential for limited physical or psychological dependence if abused, include Valium and Xanax (Schedule IV) and Robitussin with Codeine (Schedule V). The last category, Schedule VI medications, includes prescription drugs such as Penicillin and Prilosec, any other drugs not included in Schedules I through V, and over-the-counter medications such as Advil and Nicoderm CQ.

Our audit disclosed that the audited pharmacies maintained adequate inventory records for Schedule II through V controlled substances. However, these pharmacies need to strengthen and improve internal controls over Schedule VI controlled substances and over-the-counter medications. Those prescribed drugs are the least potent, but are still at risk for abuse and theft. We found that the 11 audited pharmacies at 10 Commonwealth agencies - Bridgewater State Hospital, Soldiers' Home in Holyoke, Medfield State Hospital, Monson Developmental Center, Taunton State Hospital, Tewksbury State Hospital, Western Massachusetts Hospital, Worcester State Hospital, Wrentham Developmental Center, and the Central Distribution Center Pharmacy (CDCP) at the State Office for Pharmacy Services (SOPS) did not have adequate accountability systems in place to accurately track inventory activity and balances of Schedule VI controlled substances and over-the-counter medications. Two sample test counts during our audit showed variances of four drugs—as much as 2,611 doses—from physical inventory records. As a result, there is inadequate assurance that $23,385,664 of Schedule VI controlled substances and over-the-counter medications (98% of the total drug and medicine purchases at SOPS) were adequately safeguarded from loss or unauthorized use. In addition, there is inadequate assurance that these drugs and medicines were accounted for in a manner that would readily detect or effectively deter theft, misuse, and abuse. Furthermore, the present accountability system is likely incapable of detecting differences—between recorded inventories and physical counts—for which the pharmacy management vendor should reimburse the Commonwealth. In response to our audit, the SOPS has indicated that steps will be implemented to improve its inventory practices. Finally, the Soldiers' Home in Holyoke, (not part of the SOPS), is

In response to our audit, the SOPS indicated that it will make improvements in the areas cited. An inventory manager has been hired, pharmacies have been notified in writing regarding the proper recording system for medications, including returns, and the recording system will be monitored for compliance. The Soldiers' Home in Holyoke has made improvements in its safeguarding of medications.

We found that seven of the audited pharmacies complied with Generally Accepted Accounting Principles (GAAP) requirements by reporting the value of pharmaceuticals on hand as of June 30, 2002 (at fiscal year's end) to the State Comptroller. However, inventory values of the remaining pharmacies were not reported in accordance with GAAP and instructions issued by the State Comptroller. As a result, approximately $2.5 million, or 90% of inventory, was not included in the Commonwealth's annual financial reports, contrary to GAAP requirements.

In response to our audit, SOPS indicated that it has notified the respective agencies utilizing its drug and pharmaceutical operation regarding the need to improve upon their annual inventory reporting.

INTRODUCTION

Background

The United States Congress enacted the Comprehensive Drug Abuse, Prevention, and Control Act of 1970, recognizing that many drugs and medicines that had useful and legitimate medical purposes, along with other substances with no proven medical purpose, were at times misused or diverted from their original purpose. The Act established regulations to control and regulate drugs and penalize those who did not comply with its provisions. The Act also required states to incorporate five schedules of controlled substances in the federal regulations and set whatever additional guidance over controlled substances as the states deemed necessary.

Chapter 94C of the Massachusetts General Laws, approved on November 11, 1971, established the Controlled Substances Act to comply with this federal mandate. Chapter 94C specifically directs the Commissioner of Public Health to establish rules and regulations for administering and regulating the manufacture, distribution, dispensing, and possession of controlled substances. Chapter 94C further mandates that the Commissioner:

- Establish, through regulations, provisions to incorporate the five schedules of controlled substances under the Comprehensive Drug Abuse, Prevention, and Control Act of 1970;
- Provide regulations to establish a sixth schedule, to include all prescription drugs not included in the first five schedules;
- Consider factors regarding each drug or substance proposed to be controlled or removed from the schedules, as follows: 1) its actual or relative potential for abuse; 2) scientific evidence of its pharmacological effect, if known; 3) the state of current scientific knowledge regarding the drug or other substance; 4) its history and current pattern of abuse; 5) scope, duration, and significances of abuse; 6) what, if any, risk there is to the public health; 7) its psychological or physiological dependence liability; and 8) whether the substance is an immediate precursor already controlled under Chapter 94C; and
- Determine, through regulation and acting jointly with the Board of Registration in Pharmacy, any non-narcotic substance from a schedule that may lawfully be sold over the counter, without a prescription.

Controlled substances are required to be scheduled in one of the six classifications identified in Chapter 94C. A controlled substance is generally considered a drug or other substance based on whether 1) it has a potential for abuse; 2) it may have an accepted medical use; 3) abusing it may lead

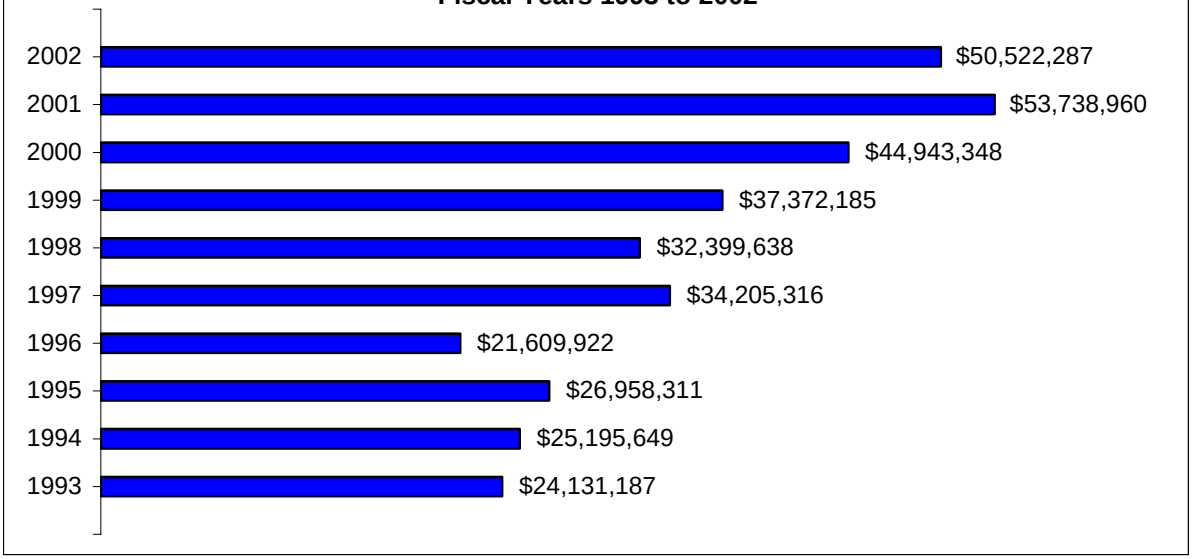
to physical or psychological dependence; 4) or it is a prescription drug. The characteristics of the drug or substance determine in which schedule—Schedule I (high potential for abuse, no medical purpose) to Schedule VI (least potent, prescription drug)—it is placed by the Commissioner of Public Health.

State agencies distribute only Schedules II-VI controlled substances and over-the-counter medications to their consumers. Schedules II-VI controlled substances have a proven medical benefit and require a physician's prescription. Over-the-counter medications are available without a physician's prescription. Examples of controlled substances and over-the-counter medications are provided in Appendix I.

Drug and medicine expenditures by 63 state departments and organizations exceeded $50 million in fiscal year 2002 (see Appendix II). Those drugs and medicines were for use by Commonwealth residents, including human-services consumers, correctional inmates, elder-care and high-risk clients, and college students. The majority of pharmaceutical spending occurred within the Departments of Mental Health (DMH), Mental Retardation (DMR), Public Health (DPH)—all Executive Office of Health and Human Services (EOHHS) agencies—and the Department of Correction (DOC), within the Executive Office of Public Safety. Over the last 10 years, drug and medicine expenditures increased approximately 209% (see Figure 1).

For fiscal year 2002, state agencies procured drugs and medicines both for vaccine-preventable diseases and for ongoing treatment of other illnesses. These agencies spent approximately $19.5 million on inoculating vulnerable children, the elderly, and others at risk with vaccines and immunizations against preventable diseases such as influenza, polio, and measles. According to the State Comptroller's records, an additional $30.96 million was spent on drugs and medicines for ongoing treatment of individuals in the state's care.

Figure 1
Commonwealth Drug and Medicine Spending
Fiscal Years 1993 to 2002



To help ensure that state agencies receive the best drugs and medicines at a reasonable cost, the Commonwealth has contracted with a primary supplier (prime vendor) of drugs and medicines. State agencies order primarily from the prime vendor—at reduced, state-contracted prices—but they occasionally purchase drugs and medicines from other vendors that are 1) sole suppliers of a particular drug or medicine; 2) under contract with the specific state agency; 3) providing what is an emergency procurement; or 4) offering the drugs and medicines at a lower cost.

During fiscal year 2002, state agencies taking advantage of the prime vendor contract bought $27.64 million worth of drugs and medicines (or 89% of purchases, excluding sole-source suppliers of vaccines and immunizations), as reflected in Figure 2. During fiscal year 2002, EOHHS agencies purchased the most drugs and medicines (see Figure 3). EOHHS, concerned about quality and cost issues surrounding healthcare, including the fact that medication costs formed a significant part of the increasing costs, commissioned a study in 1992 to assess pharmacy services in DMH, DMR, and DPH. At that time, the Commonwealth had in its charge approximately 4,000 inpatients housed at 22 facilities in these EOHHS agencies. The study concluded that it was more practical and feasible to standardize, consolidate, and integrate pharmacy services across these agencies. Accordingly, the State Office for Pharmacy Services (SOPS) was established in 1993 to provide comprehensive pharmacy services to these agencies in a cost-effective, clinically responsible manner. In September

1998, SOPS expanded its services to include DOC facilities, bringing the total number of inpatient and residential beds serviced to over 15,000 at 43 state agencies. SOPS again broadened its operations in fiscal year 2003, bringing pharmacy services (for the first time) to the Hampden County Sheriff's Department.

Figure 2
Commonwealth Purchases of Drugs and Medicines by Vendor Type, Fiscal Year 2002

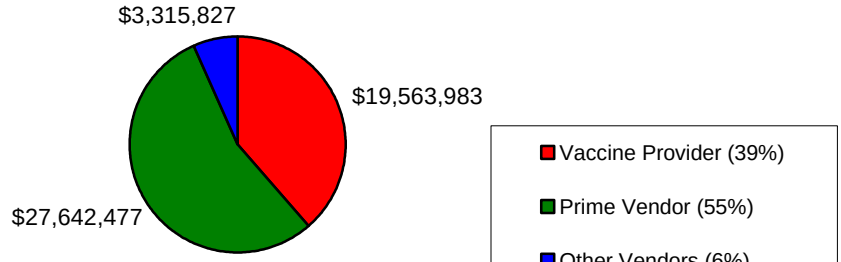
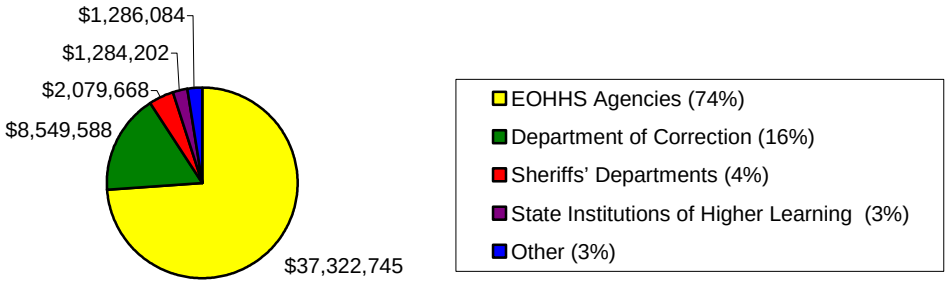


Figure 3
Commonwealth Purchases of Drugs and Medicines by Agency, Fiscal Year 2002



In addition to providing drugs and medicines at a reasonable cost through the use of a prime vendor, SOPS contracts with another private vendor that provides full pharmacy management services to DMH, DMR, DPH, DOC, and the Hampden County Sheriff's Department, along with providing SOPS monitoring and oversight. Under the terms of the contract, the vendor is

responsible for staffing the central distribution centers and all site pharmacies with appropriate pharmacists, technicians, and management and administrative personnel, as necessary. The vendor is also responsible for ordering, receiving, storing, and delivering medications; managing inventory; periodically reporting on medications to SOPS; and complying with all federal and state regulations regarding controlled substances.

In fiscal year 2002, SOPS spent $18,910,705 on drugs and medicines for 43 agencies within DMH, DMR, DPH, and DOC, as detailed in the following table:

SOPS Expenditures for Medicine and Drugs Fiscal Year 2002

Agency	Amount
Department of Correction	$ 8,546,000
Department of Public Health	3,204,871
Department of Mental Retardation	2,798,554
Department of Mental Health	4,361,280
Total	$18,910,705

In addition, SOPS paid $7,013,096 during fiscal year 2002 to the private vendor under contract to provide pharmacy management services at DOC, DPH, DMR, and DMH facilities, as detailed in the following table:

SOPS Payments for Pharmacy Management Services Fiscal Year 2002

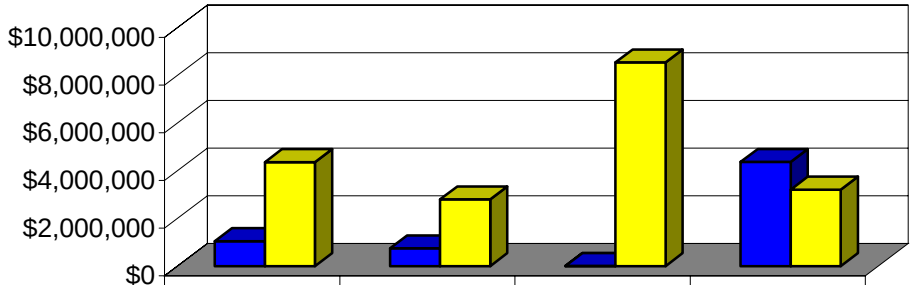
Agency	Amount
Department of Correction	$1,372,626
Department of Public Health	1,943,049
Department of Mental Retardation	1,872,740
Department of Mental Health	1,824,681
Total	$7,013,096

Funding for these SOPS initiatives came either directly from DPH appropriations or indirectly from DMR, DMH, and DOC appropriations via interdepartmental service agreements. Such an

agreement is a contract between two state agencies that documents the terms and conditions of their relationship; funds are transferred from the buyer department—in this case, DMR, DMH, and DOC—as compensation for goods and services provided by the seller department, SOPS.

Although DMH, DMR, DPH, and DOC receive the majority of medications based on an agreement with SOPS, these agencies also purchase medications if they are not available through SOPS or consumers require them before the next scheduled delivery from SOPS. Figure 4 summarizes drug and medicine purchases by DMR, DMH, DPH, and DOC, made on their own and through SOPS, during fiscal year 2002.

Figure 4
Fiscal Year 2002 Medicine and Drug Expenditures by DMH, DMR, DOC, and DPH



	DMH	DMR	DOC	DPH
Local Purchases	$1,043,483	$741,660	$3,588	$4,367,608
SOPS Purchases	$4,361,280	$2,798,554	$8,546,000	$3,204,871

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 financial and management controls over certain pharmacy operations of the Commonwealth of Massachusetts. The scope of our audit included various administrative and operational activities of the State Office for Pharmacy Services and related state departments and organizations for the period July 1, 2001 to August 31, 2002.

Our audit was conducted in accordance with applicable generally accepted government auditing standards for performance audits and, accordingly, included audit procedures and tests that we considered necessary under the circumstances.

Our audit objectives were (1) to conduct an assessment of the adequacy of controls that state agencies had established for procuring, purchasing, receiving, storing, issuing, inventorying, dispensing, and safeguarding drugs and medicines, including controlled substances and over-the-counter medications, and (2) to determine the extent of controls established for measuring, reporting, and monitoring effectiveness and efficiency in compliance with applicable federal and state laws, rules and regulations, other guidelines, and their own policies and procedures.

Our review centered on the activities and operations of SOPS. We also audited pharmacy-related activities at 12 EOHHS and DOC locations (see Appendix III) to determine whether federal and state mandated policies and procedures to control the procurement, purchase, receipt, delivery, and dispensing of drugs are being adhered to for full accountability.

To achieve our objectives, we reviewed applicable federal and state laws, rules, and regulations; evaluated internal policies and procedures; interviewed selected agency personnel; tested and reviewed accounting records and transactions; analyzed various administrative, personnel, budgetary, and related activity reports and documents; examined pharmaceutical inventory records; reviewed vendor contracts; and performed audit tests of drug and medicine expenditures, medical administration records, and physical inventory counts of controlled substances and over-the-counter medications. The purpose of our review was to determine whether adequate and proper controls existed over pharmacy operations to ensure that public funds are expended in a proper and reasonable manner and consistent with applicable federal and state laws, rules, and regulations.

Except as noted in the Audit Results section, we determined that for the areas tested, state agencies (1) maintained adequate internal controls over procuring, purchasing, receiving, storing, issuing, inventorying, dispensing, and safeguarding drugs and medicines, including controlled substances and over-the-counter medications, and (2) complied with applicable laws, rules, and regulations. Our recommendations are intended to assist state agencies in developing, implementing, or improving internal controls and overall financial and administrative operations to ensure that the delivery system of drugs and medicines to residents of the Commonwealth is done in an economical, efficient, and effective manner, in compliance with applicable rules, regulations, and laws.

AUDIT RESULTS

1. IMPROVEMENTS NEEDED IN INVENTORY CONTROLS OVER DRUGS AND MEDICINES AT STATE PHARMACIES

Chapter 94C of the Massachusetts General Laws requires controlled substances to be categorized according to one of six schedules, based on currently accepted medical purposes in the United States and the potential for abuse. Schedule I drugs, such as Heroin and LSD, have a high potential for abuse and no currently accepted medical purpose in the US, and accordingly are not dispensed by state agencies, which distribute only Schedules II through VI controlled substances and over-the-counter medications to their consumers. Schedules II through VI substances do have accepted medical benefits and are rated progressively as to the potential for abuse. Schedule II substances, such as Oxycontin, Percodan, and Ritalin, may lead to severe psychological or physical dependence if abused. Schedule III drugs, such as Anabolic Steroids, Codeine with Aspirin, and Vicodin, also have accepted medical purposes, but if abused could result in moderate to low dependence. Schedule IV and V drugs, which have the potential for limited physical or psychological dependence if abused, include Valium and Xanax (Schedule IV) and Robitussin with Codeine (Schedule V). The last category, Schedule VI medications, includes prescription drugs such as Penicillin and Prilosec, any other drugs not included in Schedules I through V, and over-the-counter medications such as Advil and Nicoderm CQ.

Our audit disclosed that the audited pharmacies maintained adequate inventory records for Schedule II-V controlled substances. However, these pharmacies need to (1) strengthen and improve internal controls over Schedule VI controlled substances and over-the-counter medications, and (2) maintain documentation of perpetual inventory records. During fiscal year 2002, these agencies purchased from the prime vendor Schedule VI controlled substances and over-the-counter medications valued at $23,385,664. In accordance with the General Accountability Guidelines of Controlled Substances in Hospitals and Clinics, issued by the Department of Public Health (DPH) of the Executive Office of Health and Human Services (EOHHS), departments are required to maintain an accountability system that would deter and detect drug theft, misuse, and abuse. These guidelines also allow departments to track inventory using a computer, if they also maintain a hardcopy of the perpetual inventory record. Additionally, provisions of Chapter 647 of the Acts of 1989 (the Internal Control Act) require

that agencies have an accountability system in place that will reduce the risk or unauthorized use or loss of resources.

Our review of 11 pharmacies (one audited site did not have a pharmacy) at 10 agencies as of August 30, 2002, identified that all 11 pharmacies (including two located at the State Office of Pharmacy Services [SOPS]) did not fully comply with applicable regulations. We found that 10 of the 11 pharmacies—Bridgewater State Hospital, Soldiers' Home in Holyoke, Medfield State Hospital, Monson Developmental Center, Taunton State Hospital, Tewksbury State Hospital, Western Massachusetts Hospital, Worcester State Hospital, Wrentham Developmental Center, and the Central Distribution Center pharmacy (CDCP) at SOPS—did not have an adequate accountability system to track inventory balances of Schedule VI controlled substances and over-the-counter medications. We also identified that at the remaining pharmacy, the Department of Correction pharmacy (DOCP) at SOPS, the automated accountability system (for recording the receipt and dispensing of drugs, establishing medication reorder levels, and maintaining a record of balances on hand) did not accurately account for the stock of controlled substances and over-the-counter medications. Although we found that hardcopies of the perpetual inventory records were mathematically accurate and in balance with periodic physical inventory counts, these records were maintained in a loose-leaf notebook—not in a permanent, prenumbered bound book. This subjects these records to manipulation or alteration, and therefore to undetected theft, abuse, and misuse of drugs and medicines.

The pharmacies acquired the bulk of all prescription and nonprescription drugs from a primary supplier under state contract—the prime vendor, which supplies all levels of medication (see Appendix I). All drugs must be dispensed to clients in accordance with the written prescriptions of their physicians.

For fiscal year 2002, SOPS acquired $23,826,214 of pharmaceuticals from the prime vendor. Schedule VI prescription drugs and over-the-counter medications, approximately 1,941 and 595 items, respectively, accounted for 98% ($23,385,664) of total drug and medicine purchases, as detailed in the following table:

SOPS Drug and Medicine Expenditures by Category
Fiscal Year 2002

Category	Amount Purchased	Share of Total
Schedule II	$ 181,688	1%
Schedule III	6,910	0%
Schedule IV	249,099	1%
Schedule V	2,853	0%
Schedule VI	23,099,794	97%
Over the counter	285,870	1%
Total	$23,826,214	100%

A private vendor under contract with SOPS operates 10 pharmacies that we audited. Two of these pharmacies serve as distribution centers and provide the majority (75-100%) of drugs and medicines to the pharmacies of the various state departments and organizations providing medical services to their patients and consumers (site pharmacies). Site pharmacies can also purchase, directly from the prime vendor, most of the pharmaceuticals not provided by the distribution centers.

According to the contract, the vendor is responsible for (1) providing adequately trained pharmacy and administrative staff; (2) dispensing medications; (3) specific periodic reporting to SOPS; (4) ordering, receiving, and storing medications and managing inventory; (5) performing biannual physical inventory counts; and (6) reimbursing the Commonwealth for any difference between recorded inventory and the physical inventory count.

In accordance with the terms of the agreement, the vendor performed physical inventory counts on December 30, 2001 and June 28, 2002—the most recent physical inventory, which reported $2,389,258 of pharmaceuticals on hand at the 10 pharmacies and is summarized in the following table:

Drug and Medicine Inventory Values at Selected Sites as of June 30, 2002

Location	Value
CDCP (at SOPS)	$1,414,952
DOCP (at SOPS)	687,733

Location	Value
Tewksbury State Hospital	55,408
Taunton State Hospital	51,817
Western Massachusetts Hospital	43,176
Medfield State Hospital	31,961
Bridgewater State Hospital	31,466
Worcester State Hospital	30,874
Monson Developmental Center	27,608
Wrentham Developmental Center	14,263
Total	$2,389,258

SOPS could not verify the accuracy of the physical counts for Schedule VI controlled substances and over-the-counter medications at the first nine pharmacies listed in the table, since there was no perpetual inventory record maintained to compare to the physical counts. To verify physical counts at any given period, each pharmacy would have to be able to determine the beginning balance of inventory on hand, add purchases made during the period, then subtract items dispensed; the result would be the inventory on hand at the end of the period being measured. This control procedure was not in place at any of those nine pharmacies. We also found that the Automated Inventory Management System (AIMS) used by the vendor at the remaining pharmacy—DOCP at SOPS—was unreliable for reporting inventory balances on hand. On two occasions we observed the count of four Schedule VI controlled substances (Aricept, Buspirone, Celexa, and Cipro) and found that the physical counts were substantially different from what AIMS reported, as summarized in the following table:

Variances Identified during Test Counts of Schedule VI Controlled Substances June 19 and October 10, 2002

Drug	For Treating	June 19 Physical Count	June 19 Quantity According to AIMS	June 19 Variance	October 10 Physical Count	October 10 Quantity According to AIMS	October 10 Variance
Aricept	Alzheimer	150	120	30	90	60	30
Buspirone	Anxiety	1,604	2,280	(676)	73	1,810	(1,737)
Celexa	Depression	12,676	10,065	2,611	1,618	(580)	2,198
Cipro	Bacterial Infections	97	77	20	100	123	(23)

Note: Dollar amount of June 19 variance is $4,256. Dollar amount of October 10 variance is $2,497.

Neither vendor nor SOPS personnel were able to reconcile or account for these differences. SOPS staff and vendor representatives stated that there is a problem with the automated program and they are attempting to work out the glitches with the software maker.

We also reviewed the pharmacy at the Soldiers' Home in Holyoke (not operated by the private vendor under contract with SOPS) and found that it did not have a system in place to account for its Schedule VI and over-the-counter medications. The pharmacy also had not performed periodic physical counts or maintained a perpetual inventory record of Schedule II-V drugs until it had been told to do so in March 2002, following an internal review by SOPS at the request of the EOHHS. At that time, a physical count of all controlled substances and over-the-counter medications was conducted. As of March 13, 2002, the physical inventory counted was valued at $72,852.

The Soldiers' Home in Holyoke has subsequently put into place a policy requiring semiannual physical counts. However, this practice will not prove effective until there is a perpetual inventory system in place to validate the physical counts and thus detect shortages, overages, potential thefts, misuse, or abuse of drugs and medicines. The current inventory process is not adequate as an accountability mechanism and is not in compliance with the Internal Control Act, which states, in part:

> *Access to resources and records is to be limited to authorized individuals as determined by the agency head…. Periodic comparisons shall be made between the resources and the recorded accountability of the resources to reduce the risk of unauthorized use or loss and protect against waste and wrongful acts.*

The DPH Drug Control Program's general accountability guidelines for controlled substances in hospitals and clinics with pharmacies state, in part:

> *General: Regulations of the Department of Public Health at 105 CMR 700.005 require every registrant to provide effective physical security controls against theft and diversion of controlled substances. Access to all controlled substances must be restricted to authorized personnel. In order to reduce the likelihood of diversion and enable timely identification of potential problems, hospitals and clinics must maintain strict accountability of controlled substances in Schedules II-V and an effective level of accountability for those controlled substances in Schedule VI. All controlled substances must be dispensed pursuant to a legal prescription or medication order.*

As a result, SOPS has inadequate assurance that $23,385,664 of Schedule VI controlled substances and over-the-counter medications purchased during fiscal year 2002 were adequately safeguarded from loss or unauthorized use. Moreover, there is inadequate assurance that these pharmaceuticals were accounted for in a manner that would readily detect and effectively deter drug theft, misuse, and abuse. Furthermore, the present accountability system is likely incapable of detecting differences between recorded inventories and physical counts for which the Commonwealth should be reimbursed by the pharmacy management vendor under the terms of its contract.

Recommendation

All pharmacies should establish an accountability system that maintains accurate and timely inventories of Schedule VI drugs and medicines and over-the counter medications. Each should also maintain accountings of Schedule II-V drugs in a permanent bound book. Furthermore, physical inventory counts should be done semiannually. Those counts should be verified against the perpetual inventory record; any losses should be properly reported, and the Commonwealth should be reimbursed for any inventory shrinkage.

Auditee's Response

The current pharmacy software system is inadequate to maintain a perpetual inventory on medication (C-II thru C-VI) currently inventoried at SOPS pharmacies. The SOPS initiative has grown significantly since its inception from approximately 4,000 to 13,000 patients serviced. As a result, the pharmacy software system's inventory management module cannot satisfactorily meet the complexity and uniqueness of the dispensing systems that comprise the SOPS operation. SOPS has attempted to implement computer assisted inventory management in the DOC (punch card distribution) part of its operation, but has determined that the system cannot accurately maintain the on hand inventory quantities. The auditor's findings support this fact.

In an attempt to improve inventory control and satisfactorily meet the recommendations of the audit, SOPS is currently reviewing a system for maintaining perpetual inventory of C-VI and OTC medications in the central pharmacy stock supply. The proposed system would be implemented in the PDC. The process would involve maintaining a perpetual inventory of the central stock medications with adjustments made daily for medication issued to work station locations within the PDC. The inventory specialist would enter medication received from the wholesaler into the computer system. Staff would complete hard copy requisition slips to sign out medication from a central stock inventory to work stations. The inventory specialist would enter the information from the slips into the computer system daily, which would deduct amounts from quantity on hand and record the work location to which the medication was assigned. In addition, medication location movement summary reports for inventory will be generated to track issues. An

ongoing random quality assurance audit process will be implemented to access accuracy of the system. This process will be an interim measure until a new pharmacy software system that can maintain a perpetual inventory can be acquired.

The DPH is currently in the process of acquiring a pharmacy software system, pending funding, with a proven inventory management module that would address the inventory concerns of the audit. The implementation process is scheduled to begin in the early part of calendar year 2004 with full implementation tentatively scheduled for fiscal year 2005.

Medications (C-II – C-V) are currently maintained on a manual perpetual inventory. An audit of all C-II - C-V medications inventory will be completed weekly. Instead of maintaining the inventory in pre-numbered bound books as recommended in the audit report, SOPS will implement the use of sequentially pre-numbered perpetual inventory sheets with control and record of issuing, thereby not subjecting these records to manipulation or alteration.

Semiannual inventories are currently being done within pharmacies under the SOPS initiatives. All pharmacy inventories will be supported by back up data.

The Soldier's Home in Holyoke stated that records will be maintained in permanent pre-numbered bound books. These records will provide the inventoried amount and will be reconciled on a regular basis. The Soldiers' Home in Holyoke is meeting with an outside vendor (EXP Pharmaceutical Services) to conduct an on-site evaluation of the possibility of computerization of the process. The program will provide for the drug being inventoried, reporting the same for distribution and any drugs being returned for credit.

2. IMPROVEMENTS NEEDED IN PROCUREMENT PRACTICES AT CENTRAL DISTRIBUTION PHARMACIES

Our audit found that nine pharmacies—those at Western Massachusetts Hospital, Bridgewater State Hospital, Taunton State Hospital, Medfield State Hospital, Monson Developmental Center, Tewksbury State Hospital, Wrentham Developmental Center, Worcester State Hospital, and the Soldiers' Home in Holyoke—generally purchased only those drugs and medicines that were immediately needed to fill prescriptions. However, the procurement practices of the two central distribution pharmacies at SOPS—CDCP and DOCP—lacked adequate internal controls for allowing measured forecasts of pharmaceutical needs during the fiscal year. The absence of controls allowed increasingly excessive spending practices and stockpiling of prescription drugs at fiscal year's end that would not be consumed by site pharmacies until far into the subsequent fiscal year. In accordance with Chapter 29, Section 12, of the General Laws and guidance issued by the Office of the State Comptroller (OSC), state appropriations are for the ordinary maintenance of a department for the current fiscal year and should not be used to fund the subsequent year's expenses.

Our review of drug and medicine purchases made by the two central distribution pharmacies indicated an inappropriate trend in the ordering and stockpiling of large quantities of high-cost drugs during the final weeks of the 2002 fiscal year. Some prescription drugs were purchased during the final weeks of June 2002 (the final month of the fiscal year) in amounts as much as quadruple those of earlier weeks. Our test sample of six commonly prescribed drugs purchased in June 2002 indicated excess spending of $729,276. The following table cites examples of June 2002 orders that exceeded previous weeks' averages:

Drug	Description	Average Weekly Spending, July 1, 2001 to May 31, 2002	Average Weekly Spending, June 1, 2002 to June 30, 2002	Increase in Weekly Average	Excess Purchasing* in June 2002
Depakote	For the treatment of manic episodes associated with bipolar disorder	$13,430	$ 25,258	188%	$ 47,312
Neurontin	An anti-epileptic drug as well as mood stabilizer also used for the prevention of migraine headaches, social phobia, and panic disorders	$ 8,529	$ 30,576	358%	$ 88,188
Risperdal	For the treatment of disorganized or psychotic thinking; also used to treat aggression, false perceptions, tourette's syndrome, and behavioral problems in persons with mental retardation	$27,163	$ 59,795	220%	$130,528
Seroquel	For the treatment of schizophrenia	$13,153	$ 30,843	234%	$ 70,760
Zyprexa	For the treatment of schizophrenia; also used to treat bipolar disorder (manic depression)	$36,803	$114,258	310%	$309,820
Lamictal	An anti-epileptic drug and mood stabilizer also used for the prevention of migraine headaches, social phobia, and panic disorders	$ 6,060	$ 26,727	441%	$ 82,668
Total					$729,276

*Calculated by taking the difference in weekly spending averages and multiplying it by 4 weeks.

The central distribution pharmacies are responsible for supplying the bulk of drugs and medicines to the Department of Mental Retardation (DMR), Department of Mental Health

(DMH), Department of Correction (DOC), and DPH. These two pharmacies have established procedures to ensure that there are sufficient supplies of drugs and medicines in stock to meet consumers' needs. The CDCP is required to fill orders weekly, based on orders from the site pharmacies at DMR, DMH, DPH agencies, and DOC's Bridgewater State Hospital. The orders are based on a "pick list" submitted by each site pharmacy. The pick list is an automated record of what is needed for site-pharmacy consumers for the upcoming week. If the CDCP does not have sufficient inventory on its shelves to fill the site pharmacy's weekly order, it places an order for the medications from the supplier, which in turn delivers these orders to the CDCP on the same or the next day. CDCP orders are mostly in unit-dose form, which eliminates the need for repackaging before transmittal to the site pharmacies. The DOCP fills the prescription drug and over-the-counter medicine orders of the DOC facilities that do not have site pharmacies. DOC facilities fax their consumers' prescription orders directly to DOCP, where the orders are filled and delivered to the DOC sites on a weekly basis via courier. DOCP prescriptions are blister packaged—a form of non-reclosable packaging that consists of foil laminated to PVC, which is molded into areas that contain tablets. A tablet is released by pushing the molded area, causing the pill to emerge through the foil. DOCP purchases pharmaceuticals in bulk, and its staff prepares the blister packaging. To ensure that sufficient supplies of medicines exist to meet the needs of the DOC facilities and to allow adequate lead time for repackaging medications, DOCP has established reorder levels in its automated inventory tracking system. Daily queries are made to the system by vendor staff to determine and place drug orders for that day. The orders are placed with the supplier, which delivers them on the same or next day.

The purchasing practices at the central distribution pharmacies are not in compliance with state law and OSC regulations that specifically prohibit spending state-appropriated funds in this manner. Chapter 29, Section 12, of the General Laws, as amended, states:

> *Appropriations by the general court, unless specifically designated as special, shall be for the ordinary maintenance of the several departments, offices, commissions and institutions of the Commonwealth and shall be made for the Fiscal Year unless otherwise specifically provided therein.*

The State Comptroller has also instructed state agencies on fiscal year closing/opening. In an April 24, 2002 memorandum to department heads, the OSC provided the following guidance regarding disbursement management:

> *Under no circumstances should FY [fiscal year] Closing funds be used for FY Opening expenditures or vice-versa, unless specifically allowed with appropriate legislative language.*

Current fiscal year spending for subsequent fiscal year liabilities potentially deprives DPH, DMR, DMH, and DOC agencies use of state funds for more appropriate and allowable purposes in the current period. In addition, any monies left over at fiscal year's end are to be returned to the state's general fund, with the legislature finding suitable uses for the funds no longer needed for the ordinary maintenance of the departments for that fiscal year.

Recommendation

The central distribution center pharmacies (CDCP and DOCP) should refrain from purchasing medications in excess of immediate needs. Funds not committed at fiscal year's end should be returned to the Commonwealth's General Fund as required by law and OSC regulations.

Auditee's Response

> *The SOPS purchases medication based on previous historic utilization data, which is driven by prescribing practices. Every effort is made to purchase medication for the immediate need of the population served, based on utilization, prescribing trends and consideration of repacking lead time for medications. It is important to note, however, that prescribing practices can change abruptly at any time, thereby influencing purchasing and inventory levels in order to meet the demand.*
>
> *The SOPS inventory currently turns over 16 times a year, compared to the national average of 8 to 10 times a year. This high number of inventory turns results in having only several weeks of inventory on hand during the year. The national average of eight turns, on the other hand, results in a six week inventory. In order for SOPS to ensure a continuation of inventory early into the next fiscal year, it is often necessary to order additional inventory at the end of the year sufficient to meet a six week demand. SOPS consults with its agency clients whenever such year-end purchases become necessary.*
>
> *At times, SOPS is also forced to purchase greater quantities at the end of fiscal year because funds were not available earlier. For instance, it may take time to negotiate and process an increase to an Interagency Service Agreement (ISA) needed to fund an agency's drug purchases through June 30.*

Auditor's Reply

We concur that SOPS drug purchase can be dictated by fluctuations or unusual prescribing that may abruptly alter utilization norms of certain drugs, thereby increasing the need to purchase above immediate needs. However, SOPS did not demonstrate with any specific examples or corroborating data, the need to address the unusual, abnormal, or emergency inventory purchase

requirements, which resulted in excessive purchasing of certain drugs at year-end. Therefore, we have concluded that the inventory purchases that we cited were excessive and more likely occurred as a result of the decision to spend down available funds.

3. INADEQUATE MANAGEMENT CONTROLS OVER THE SAFEGUARDING OF PHARMACEUTICALS

Our review found that six of audited locations—Taunton State Hospital, Wrentham Developmental Center, Western Massachusetts Hospital, Medfield State Hospital, Tewksbury State Hospital, and Bridgewater State Hospital—had controls to properly safeguard medications. However, at the remaining audited sites, we observed internal control deficiencies that could leave medications susceptible to misuse or misplacement that may not be detected in a timely manner. Guidance issued by OSC requires that state agencies have in place an internal control plan to ensure that the Commonwealth's resources are adequately protected from misappropriation.

Medications were not adequately safeguarded at the following six locations—CDCP and DOCP at SOPS, Monson Developmental Center, the Soldiers' Home in Holyoke, Worcester State Hospital, and the Souza Baranowski Correctional Center in Shirley. The lack of proper safeguards at these facilities exposes drugs and medicines to misappropriation, misuse, and abuse. We identified one or more of the following internal control weaknesses at those sites: inadequate segregation of duties, physical security breaches, and inadequate recording and handling of returned medications.

a. Inadequate Segregation of Duties

We found that two of the vendor's employees at CDCP and DOCP had too much control and responsibility for various critical aspects of their operations, a condition contrary to adequate segregation of duties for the proper control of operations. This lack of segregated responsibilities could interfere with the timely detection of intentional or unintentional errors, thus leaving medications vulnerable. At DOCP, Schedule II-V controlled substances are kept in a restricted area accessible only by pharmacists. We found that one pharmacist is responsible for filling prescriptions, receiving inventory, maintaining perpetual inventory records, and conducting weekly physical counts. These responsibilities should be distributed

among the other pharmacists to achieve segregation of duties. The purchasing technician, who works at both CDCP and DOCP, ordered and recorded all drug purchases, received all Schedule VI and over-the-counter medications, and maintained drug inventories at CDCP and DOCP. One individual's ordering, receiving, recording, and inventorying of pharmaceuticals is contrary to sound business and industry practice, and contradicts Chapter 647 of the Acts of 1989 (The Internal Control Act), which states, in part:

> *Key duties and responsibilities, including (1) authorizing, approving, and recording transactions, (2) issuing and receiving assets, (3) making payments and (4), reviewing or auditing transactions, should be assigned systematically to a number of individuals to ensure that effective checks and balances exist.*

Proper internal control procedures advocate that key duties and responsibilities be divided or segregated among several people to reduce the risk of error or fraud. Such duties and responsibilities include authorizing transactions, processing and recording them, reviewing them, and handling any related assets. No one individual should be responsible for all key aspects of a transaction or event.

b. Physical Security Breaches

We found physical security breaches at the Monson Developmental Center and the Soldiers' Home in Holyoke that could potentially jeopardize physical safeguarding of pharmaceuticals. At Monson Developmental Center, the site pharmacy alarm system was not working at the time of our audit. According to staff, the alarm system was damaged by a lightning strike in June 2002 and is awaiting repair or replacement. Nevertheless, metal grates secure pharmacy windows, and all doors leading to and within the pharmacy are locked. However, 247 Code of Massachusetts Regulations (CMR) 6.02 requires a pharmacy to have a separate working alarm that is activated when the pharmacy is closed or unattended. Specifically, the CMR states:

> *A pharmacy department must be secured by a floor to ceiling barrier, securely locked and separately alarmed at all times when the pharmacy department is closed.*

At the Soldiers' Home in Holyoke, we found that after the site pharmacy fills prescriptions, they are delivered on a dumbwaiter that is accessible to too many individuals. The dumbwaiter contains separate bins for each of the nursing stations on the various floors, but

the bins are not securely locked for each nursing unit; anyone with a dumbwaiter key has access to the prescriptions of other wards.

Proper internal control procedures would preclude the practice of delivering medications in such an unsecured environment, requiring either that bins be locked or that an authorized individual from each station pick up prescription orders at the pharmacy.

c. Inadequate Recording and Handling of Returned Medications

We found that the Monson Developmental Center, Worcester State Hospital, and the Soldiers' Home in Holyoke did not maintain written records of discarded drugs (those that have expired or have been damaged) awaiting pick up by its drug disposal contractor. At Monson and Worcester State we identified approximately 3,045 doses of drugs and medicines awaiting disposal. Some of these expired or damaged drugs had been awaiting return for more than five months. The Soldiers' Home staff was unable to provide an accounting of any discarded drugs in its possession prior to their return. Although the supplier and disposal contractor provide subsequent accountings of what was taken from the specific location, the agency has no way to verify their accuracy.

Proper internal control procedure requires prompt and accurate recording of transactions in order to establish accountability. Also, the Internal Control Act requires the following:

> *All transactions and other significant events are to be promptly recorded, clearly documented and properly classified. Documentation of a transaction or event should include the entire process or life cycle of the transaction or event, including (1) the initiation or authorization of the transaction or event, (2) all aspects of the transaction while in process and (3), the final classification in summary records.*

Accountability deters theft, misuse, and abuse and assists in the subsequent reconciling of vendor reports of discarded drugs.

After we addressed this issue during our audit, Monson and the Soldiers' Home started maintaining a log of medications awaiting returns; however, this practice should be permanently made part of their written policies and procedures.

Recommendation

Procedures and practices should be put into place to reasonably ensure the prevention and detection of unauthorized acquisition, use, and disposition of medications, specifically as follows:

- The duties of the pharmacist at DOCP and the pharmacy technician working at both CDCP and DOCP should be realigned so that neither position has control over an entire transaction. Responsibilities should be distributed so that the work of one employee serves as a check against another's.

- The security system at Monson Developmental Center should be immediately repaired or replaced. The Soldier's Home in Holyoke should ensure that before drugs and medicines are placed on the dumbwaiter for delivery, medications are secured in locked bins accessible only to the appropriate nursing station and pharmacy staff.

- Pharmacies should implement a standardized recording system to maintain a log of medications awaiting return.

Auditee's Response

As of March 1, 2003, SOPS relocated into a new central pharmacy referred to as the PDC. Previous inventories were separate as DOCP and CDCP: the inventory is now under one PDC. Duties within the PDC have been realigned to meet the auditor recommendations. Staff assigned to ordering medication will no longer take part in verifying the receipt of such orders. The responsibility for receipt and verification of ordered deliveries will be assigned to a different staff member. An inventory manager has been hired and will be in place as of July 14, 2003, to oversee and assist with the process.

The pharmacist currently assigned to maintain the C-II – C-V perpetual inventory will no longer receive orders into inventory. Another staff member will assume this responsibility.

A new security system at the Monson Developmental Center has been installed and tested as February 7, 2003.

Pharmacies under the SOPS initiative have been notified in writing as of June 24, 2003, as to the proper recording system for maintaining a log of medications awaiting return.

SOPS will routinely monitor the recording system for compliance.

The Soldier's Home in Holyoke has purchased and has incorporated the use of opaque lockable containers. These containers will be filled with the prescriptions, deliverable to the care centers. A combination lock is placed on the container during transportation. Authorized staff has access to the combination. Upon receipt to the floor, an inventory is conducted to verify and acknowledge the contents. Upon return, the container will be inventoried for any returned or discarded drugs.

4. NONCOMPLIANCE WITH GAAP REPORTING REQUIREMENTS

At the close of each fiscal year, state agencies are required to report year-end financial activity and obligations for inclusion in the Commonwealth's annual financial report in accordance with Generally Accepted Accounting Principles (GAAP) to the Office of the State Comptroller (OSC). OSC provides guidance to departments by issuing annual GAAP packages, which include instructions, reporting forms, and a timetable for completion. Specific instruction is given for accurately reporting the dollar value of materials and supplies on hand at the end of the fiscal year. OSC instructions relating to materials and supplies include the following:

> *Materials and supplies are consumable items used in departmental operations. Examples include office supplies, medical supplies and repair materials. Materials and supplies are ordinarily maintained in a central storage area where they can be physically safeguarded, and where they can also be counted (inventoried) efficiently.*
>
> *On a statutory basis, they are recorded as expenditures when purchased. For GAAP, however, any materials and supplies on hand at year-end, and intended for use in future operations, are considered assets. Special GAAP reporting is necessary to adjust expenditures and report these assets.*

We found that seven pharmacy sites—Bridgewater State Hospital, Monson Developmental Center, Taunton State Hospital, Tewksbury State Hospital, Western Massachusetts Hospital, Wrentham Developmental Center, and Worcester State Hospital—complied with the GAAP inventory-reporting requirement. However, two sites—Medfield State Hospital and the Soldiers' Home in Holyoke—and the two central distribution center pharmacies did not report the value of pharmaceutical inventories on hand as of June 30, 2002. Consequently, approximately 90% of the $2,462,110 pharmaceutical inventory on June 30, 2002 at the 11 audited pharmacy locations was not reported (see the following table), contrary to GAAP reporting requirements.

Pharmacies	Pharmaceutical Inventory as of June 30, 2002	GAAP Reporting Compliance	GAAP Reporting Non-Compliance
Bridgewater State Hospital	$ 31,466	$ 31,466	-
Taunton State Hospital	51,817	51,817	-
Medfield State Hospital	31,961	-	$ 31,961
Monson Developmental Center	27,608	27,608	-
Soldiers' Home in Holyoke*	72,852	-	72,852
Tewksbury State Hospital	55,408	55,408	-

Pharmacies	Pharmaceutical Inventory as of June 30, 2002	GAAP Reporting Compliance	GAAP Reporting Non-Compliance
Western Massachusetts Hospital	43,176	43,176	-
Wrentham Developmental Center	14,263	14,263	-
Worcester State Hospital	30,874	30,874	-
	$ 359,425	$254,612	$ 104,813
Central Distribution Center			
Central Distribution Center Pharmacy	$1,414,952	-	$1,414,952
Department of Correction Pharmacy	687,733	-	687,733
	$2,102,685	-	$2,102,685
Total	$2,462,110	$254,612	$2,207,498

*The amount reflected is as of March 13, 2002—the last time a physical inventory of the pharmacy was performed.

Inaccurate GAAP departmental information potentially jeopardizes the fair and accurate presentation of the Commonwealth's financial statements.

Representatives of the Soldiers' Home in Holyoke indicated that staffing shortages prevented them from physically inventorying pharmaceuticals on hand at fiscal year's end. The Soldiers' Home is in the process of having an inventory prepared by an external group and plans to conduct physical inventories twice a year, including June 30.

Representatives of the Medfield State Hospital Pharmacy informed us during our audit that the facility was in the process of closing and its clients were being transferred to other facilities.

Representatives of the State Office for Pharmacy Services, the agency that oversees the central distribution center pharmacies, which store the majority of pharmaceuticals for the Departments of Mental Health, Mental Retardation, Public Health, and Correction, stated that they allocated the value of its year-end inventory to those Departments for GAAP reporting, but that the respective departments did not report the value of their share of the inventory on hand as of June 30, 2002.

Recommendation

The Departments of Mental Health, Mental Retardation, Public Health, and Correction should report their share of the inventory balance at the State Office for Pharmacy Services on hand as

of June 30, 2002. This accounting should include detailed documentation on how the value was determined, should there need to be a follow-up in the future. The Soldiers' Home in Holyoke should continue with its efforts to conduct physical counts on a semiannual basis, making sure that a count occurs on or about June 30, in accordance with GAAP instructions. It should retain all detailed documentation regarding how the June 30 figures were calculated.

Auditee's Response

SOPS will notify agency fiscal contacts that it is their agency's responsibility to include pharmaceutical drug inventory assigned to them on their year-end GAAP report. SOPS will provide the agencies' fiscal contacts with information regarding the dollar value of PDC inventory required for GAAP reporting. Site pharmacies will notify SOPS and the facility administration of the dollar value of the site's inventory. Also, the SOPS is currently recruiting for a budget analyst whose duties will include assisting agencies in completing GAAP reporting.

APPENDIX I

Examples of Drugs and Medicines by Schedule/Category

Category Type	Common Drugs in Category	Common Example Description/Characteristics
Schedule I Drug or substance with high potential for abuse. No currently accepted medical use in United States. Lacks accepted safety for use under medical supervision.	Heroin, LSD, Marijuana, Methaqualone, Mescaline	Lysergic acid diethylamide, also known as "LSD" or "acid": One of the major hallucinogenic drugs having the most potent mood-changing chemicals. It is manufactured from lysergic acid and is sold on the street in tablets, capsules, and, occasionally, liquid form. It is odorless, colorless, and has a slightly bitter taste and is usually taken by mouth. Often LSD is added to absorbent paper, such as blotter paper, and divided into small decorated squares, with each square representing one dose.
Schedule II Drug or substance with high potential for abuse. Currently has an accepted medical use in treatment in United States or a currently accepted medical use with severe restrictions. Abuse of drug or substance may lead to severe psychological or physical dependence.	Codeine, Morphine, Cocaine, Dexedrine, Methamphetamine, Ritalin, Percodan, Demoral, Opium, Percocet, Oxycontin	Methylphenidate, also known as Ritalin: A medication prescribed for individuals (usually children) who have an abnormally high level of activity or attention-deficit hyperactivity disorder (ADHD), which is characterized by agitated behavior and an inability to focus on tasks. It is occasionally prescribed for treating narcolepsy. It is a central nervous system (CNS) stimulant. It has effects similar to, but more potent than, caffeine and less potent than amphetamines. It has a notably calming effect on hyperactive children and a "focusing" effect on those with ADHD. Because of its stimulant properties, however, methylphenidate is abused by people for whom it is not a medication. Some individuals abuse it for its stimulant effects: appetite suppression, wakefulness, increased focus/attentiveness, and euphoria. When abused, the tablets are either taken orally or crushed and snorted.
Schedule III Drug or substance has potential for abuse less than drugs or substances in Schedules I and II. Drug or substance has current accepted medical use in treatment in United States. Abuse of drug or substance may lead to moderate or low physical dependence or high psychological dependence.	Anabolic steroids, Codeine with aspirin, Vicodin, Lorcet, Talbutal, Testosterone	Anabolic steroids, or "body building" drugs: These are man-made substances related to male sex hormones. "Anabolic" refers to muscle building, and "steroids" refers to the class of drugs. It is available legally only by prescription, to treat conditions that occur when the body produces abnormally low amounts of testosterone, such as delayed puberty and some types of impotence. Athletes and others abuse anabolic steroids to enhance performance and also to improve physical appearance. Anabolic steroids are taken orally or injected, typically in cycles of weeks or months (referred to as "cycling"), rather than continuously. Cycling involves taking multiple doses of steroids over a specific period of time, stopping for a period, and starting again. In addition, users often combine several different types of steroids to maximize their effectiveness while minimizing negative effects (referred to as "stacking").

Examples of Drugs and Medicines by Schedule / Category

Category Type	Common Drugs in Category	Common Example Description/Characteristics
Schedule IV Drug or substance has low potential for abuse relative to drugs or substances in Schedule III. Drug or substance has a current accepted medical use for treatment in the United States. Abuse of drug or substance may lead to limited physical dependence or psychological dependence relative to drugs in Schedule III.	Xanax, Valium/Diazepam, Phenobarbital, Darvon, Chloral Hydrate	Alprazolam, also known as Xanax: A CNS depressant used to treat anxiety or sleep disorders. Often the abuse of CNS depressants occurs in conjunction with the abuse of another substance or drug, such as alcohol or cocaine.
Schedule V Drug or substance has low potential for abuse relative to drugs or substances in Schedule IV. Drug or substance has current accepted use for treatment in the United States. Abuse of drug or substance may lead to limited physical dependence or psychological dependence relative to drugs in Schedule IV.	Buprenorphine, Robitussin with Codeine, Kapectolin PG	Buprenorphine: A treatment medication for narcotic drug dependence.
Schedule VI The drug or substance is a prescription drug and has not been included in Schedule I-V.	Omeprazole, Penicillin, Cimetidine	Omeprazole, also known as Prilosec: A controlled substance used to treat various stomach or esophagus problems related to excess stomach acid (e.g., GERD, certain types of ulcers, Zollinger-Ellison Syndrome, H pylori).
Over-the-counter drugs and medicines available without physician's prescription and not considered a controlled substance.	Advil, Benadryl, Caladryl, NICODERM CQ	NICODERM CQ: A stop-smoking aid that is a small, nicotine-containing patch, which when worn on the skin will help reduce cravings for nicotine.

APPENDIX II

Fiscal Year 2002 Medicine and Drug Expenditures By Department

Departments	Amount	Total
EOHHS Agencies		
Department of Mental Health	$ 5,404,763	
Department of Mental Retardation	3,540,214	
Department of Public Health	27,136,462	
Department of Youth Services	1,134	
Soldiers' Home in Chelsea	510,933	
Soldiers' Home in Holyoke	729,239	$37,322,745
Department of Correction		8,549,588
Sheriffs' Departments		
Hampshire	$ 84,520	
Berkshire	151,310	
Hampden	957,119	
Middlesex	408,280	
Worcester	478,439	2,079,668
State and Community Colleges and University of Massachusetts System		
Berkshire Community College	$ 362	
Cape Cod Community College	2,137	
Fitchburg State College	158	
Mass College of Liberal Arts	4,745	
Worcester State College	2,913	
Westfield State College	204	
University of Massachusetts System	1,273,683	1,284,202
Other Department and Agencies		
Emergency Management Agency	$ 670	
Office of the State Comptroller	188	
County Expenses	1,280,914	
Fisheries and Wildlife	1,582	
Division of Operational Services	187	
Department of Police	2,543	1,286,084
		$50,522,287

Note: Expenditures data is from Office of the State Comptroller (OSC) records. We obtained this data from the OSC Information Warehouse by querying the statewide expenditure detail report for all payments made under the F04 classification.

APPENDIX III

Audited Locations

Executive Office	Agency	Audited Location	Number of Pharmacies	Serviced by SOPS
Executive Office of Health and Human Services				
	Department of Mental Health			
		Medfield State Hospital	1	Yes
		Taunton State Hospital	1	Yes
		Worcester State Hospital	1	Yes
	Department of Mental Retardation			
		Monson Developmental Center	1	Yes
		Wrentham Developmental Center	1	Yes
	Department of Public Health			
		Tewksbury State Hospital	1	Yes
		Western Massachusetts Hospital	1	Yes
		State Office for Pharmacy Services	2	Yes
	Soldiers' Home in Holyoke			
		Soldiers' Home in Holyoke	1	No
Executive Office of Public Safety				
	Department of Correction			
		Bridgewater State Hospital	1	Yes
		Souza-Baranowski Correctional Center	0	Yes

APPENDIX IV

Chapter 647, Acts of 1989, An Act Relative to Improving the Internal Controls within State Agencies

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Chapter 647

THE COMMONWEALTH OF MASSACHUSETTS

In the Year One Thousand Nine Hundred and Eighty-nine

AN ACT RELATIVE TO IMPROVING THE INTERNAL CONTROLS WITHIN STATE AGENCIES.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

Notwithstanding any general or special law to the contrary, the following internal control standards shall define the minimum level of quality acceptable for internal control systems in operation throughout the various state agencies and departments and shall constitute the criteria against which such internal control systems will be evaluated. Internal control systems for the various state agencies and departments of the commonwealth shall be developed in accordance with internal control guidelines established by the office of the comptroller.

(A) Internal control systems of the agency are to be clearly documented and readily available for examination. Objectives for each of these standards are to be identified or developed for each agency activity and are to be logical, applicable and complete. Documentation of the agency's internal control systems should include (1) internal control procedures, (2) internal control accountability systems and (3), identification of the operating cycles. Documentation of the agency's internal control systems should appear in management directives, administrative policy, and accounting policies, procedures and manuals.

(B) All transactions and other significant events are to be promptly recorded, clearly documented and properly classified. Documentation of a transaction or event should include the entire process or life cycle of the transaction or event, including (1) the initiation or authorization of the transaction or event, (2) all aspects of the transaction while in process and (3), the final classification in summary records.

(C) Transactions and other significant events are to be authorized and executed only by persons acting within the scope of their authority. Authorizations should be clearly communicated to managers and employees and should

Chapter 647, Acts of 1989, An Act Relative to Improving the Internal Controls within State Agencies

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include the specific conditions and terms under which authorizations are to be made.

(D) Key duties and responsibilities including (1) authorizing, approving, and recording transactions, (2) issuing and receiving assets, (3) making payments and (4), reviewing or auditing transactions, should be assigned systematically to a number of individuals to ensure that effective checks and balances exist.

(E) Qualified and continuous supervision is to be provided to ensure that internal control objectives are achieved. The duties of the supervisor in carrying out this responsibility shall include (1) clearly communicating the duties, responsibilities and accountabilities assigned to each staff member, (2) systematically reviewing each member's work to the extent necessary and (3), approving work at critical points to ensure that work flows as intended.

(F) Access to resources and records is to be limited to authorized individuals as determined by the agency head. Restrictions on access to resources will depend upon the vulnerability of the resource and the perceived risk of loss, both of which shall be periodically assessed. The agency head shall be responsible for maintaining accountability for the custody and use of resources and shall assign qualified individuals for that purpose. Periodic comparison shall be made between the resources and the recorded accountability of the resources to reduce the risk of unauthorized use or loss and protect against waste and wrongful acts. The vulnerability and value of the agency resources shall determine the frequency of this comparison.

Within each agency there shall be an official, equivalent in title or rank to an assistant or deputy to the department head, whose responsibility, in addition to his regularly assigned duties, shall be to ensure that the agency has written documentation of its internal accounting and administrative control system on file. Said official shall, annually, or more often as conditions warrant, evaluate the effectiveness of the agency's internal control system and establish and implement changes necessary to ensure the continued integrity of the system. Said official shall in the performance of his duties ensure that: (1) the documentation of all internal control systems is readily available for examination by the comptroller, the secretary of administration and finance and the state auditor, (2) the results of audits and recommendations to improve departmental internal controls are promptly evaluated by the agency management, (3) timely and appropriate corrective actions are effected

Chapter 647, Acts of 1989, An Act Relative to Improving the Internal Controls within State Agencies

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by the agency management in response to an audit and (4), all actions determined by the agency management as necessary to correct or otherwise resolve matters will be addressed by the agency in their budgetary request to the general court.

All unaccounted for variances, losses, shortages or thefts of funds or property shall be immediately reported to the state auditor's office, who shall review the matter to determine the amount involved which shall be reported to appropriate management and law enforcement officials. Said auditor shall also determine the internal control weaknesses that contributed to or caused the condition. Said auditor shall then make recommendations to the agency official overseeing the internal control system and other appropriate management officials. The recommendations of said auditor shall address the correction of the conditions found and the necessary internal control policies and procedures that must be modified. The agency oversight official and the appropriate management officials shall immediately implement policies and procedures necessary to prevent a recurrence of the problems identified.

House of Representatives, December 21, 1989.

Passed to be enacted, George Fingold, Speaker.

In Senate, December 22, 1989.

Passed to be enacted, William M. Bulger, President.

January 3, 1990.

Approved,

Michael Dukakis Governor.

APPENDIX V

Chapter 647 Awareness Letter from the State Auditor and the State Comptroller

The Commonwealth of Massachusetts

Office of the State Auditor
State House
Boston, MA 02133

Office of the Comptroller
One Ashburton Place
Boston, MA 02108

September 19, 2000

Legislative Leadership
Judicial Branch Administrators
Elected Officials
Secretariats
Department Heads

The State Auditor and the Comptroller are both committed to departmental improvements in the Internal Control structure of the Commonwealth. A good system of controls, as you know, assists management in meeting objectives while avoiding serious problems. Chapter 647 of the Acts of 1989, *An Act Relative To Improving Internal Controls Within State Agencies*, establishes acceptable Internal Control systems for state government operations and constitutes the criteria against which we will evaluate internal controls. With the passage of this law, we began a campaign to educate all department staff on the significant role of internal controls in department operations.

In the past few years, departments have made significant progress in the area of internal controls. Every department has certified that they have documented internal controls in the form of an Internal Control Plan. In Fiscal Year 2001, we are focusing our Internal Control Campaign on the review of department risk assessments, as documented within the departments' internal control plans. Internal control plans must, of course, include all aspects of a department's business, programmatic operations as well as financial.

A major requirement of Chapter 647 is that "an official, equivalent in title or rank to an assistant or deputy to the department head, shall be responsible for the evaluation of the effectiveness of the department's internal controls and establish and implement changes necessary to ensure the continued integrity of the system". This official, whom we refer to as the Internal Control Officer, is responsible for ensuring that the plan is evaluated annually or more often as conditions warrant.

During this annual Statewide Single Audit, we continue with our review of the Commonwealth's internal controls. We analyze and evaluate information obtained during the audit process in our continuing effort to educate agencies regarding both the need for internal controls and the risks of not having adequate internal controls in place.

Chapter 647 Awareness Letter from the State Auditor and the State Comptroller

To assist departments with this effort, we provide the following support activities:

- The Office of the Comptroller offers departments free monthly training on internal controls. These classes are listed in the *OSC Training Bulletin*.
- The Office of the Comptroller provided a new document entitled the *Internal Control Guide for Managers* on the Office of the Comptroller's Web page: http: www.osc.state.ma.us/. Part II of the guide will be available shortly and will replace the current *Internal Control Guide for Departments*, currently available on the Web.
- Upon request, the Office of the Comptroller provides assistance to departments in the process of redefining or reviewing their internal control plans.
- As part of the Statewide Single Audit, auditors will review and comment upon departments' internal control plans, risk assessments, and the reporting level of the Internal Control Officers.
- We have updated and automated the Internal Control Questionnaire (ICQ) for easier submission. These changes to the ICQ will enable OSA and OSC to evaluate department internal controls and monitor their progress.

Chapter 647 also requires that "all unaccounted for variances, losses, shortages, or thefts of funds or property be immediately reported to the Office of the State Auditor" (OSA). The OSA is required to determine the amount involved and the internal control weaknesses that contributed to or caused the condition, make recommendations for corrective action, and make referrals to appropriate law enforcement officials. In order to comply with this law instances must be reported on the *Report on Unaccounted for Variances, Losses, Shortages, or Thefts of Funds or Property* and be submitted to the OSA. Reporting forms can be obtained by contacting the Auditor's office, Room 1819, McCormack State Office Building, or Web Site: http://www.magnet.state.ma.us/sao/.

In conjunction with the above requirement, please note that management is responsible for financial records and systems and must inform, disclose and make representations to the auditors with regards to their management of funds, account activities, programs and systems.

The Offices of the State Comptroller and the State Auditor are committed to the goal of improving the Internal Control structure of the Commonwealth. Thank you for your cooperation and attention on this worthwhile task. Please do not hesitate to call upon the staff of either office for assistance.

A. JOSEPH DeNUCCI
Auditor of the Commonwealth

MARTIN J. BENISON
State Comptroller