



# Office of Mental Health

## Controls Over Prescription Drugs

2007-S-111



Thomas P. DiNapoli



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# State of New York Office of the State Comptroller

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## Division of State Government Accountability

December 17, 2009

Dr. Michael Hogan, PhD  
Commissioner  
NYS Office of Mental Health  
44 Holland Ave.  
Albany, NY 12229-0001

Dear Commissioner Hogan:

The Office of the State Comptroller is committed to helping State agencies, public authorities and local government agencies manage government resources efficiently and effectively and, by doing so, providing accountability for tax dollars spent to support government operations. The Comptroller oversees the fiscal affairs of State agencies, public authorities and local government agencies, as well as their compliance with relevant statutes and their observance of good business practices. This fiscal oversight is accomplished, in part, through our audits, which identify opportunities for improving operations. Audits can also identify strategies for reducing costs and strengthening controls that are intended to safeguard assets.

Following is a report of our audit *Office of Mental Health: Controls Over Prescription Drugs*. This audit was performed pursuant to the State Comptroller's authority under Article V, Section 1 of the State Constitution, and Article II, Section 8 of the State Finance Law.

This audit's results and recommendations are resources for you to use in effectively managing your operations and in meeting the expectations of taxpayers. If you have any questions about this report, please feel free to contact us.

Respectfully submitted,

*Office of the State Comptroller*  
*Division of State Government Accountability*





## State of New York Office of the State Comptroller

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### EXECUTIVE SUMMARY

#### **Audit Objective**

Our audit objective was to determine whether Office of Mental Health-operated pharmacies have implemented appropriate controls over their prescription drugs.

#### **Audit Results - Summary**

The NYS Office of Mental Health (OMH) operates 25 psychiatric centers (Centers) that care for and treat persons with significant psychiatric disabilities. Each of the Centers operates a pharmacy to supply medication to its patients. Current annual costs to procure the prescription drugs maintained at these pharmacies exceed \$60 million.

Prescription drugs can be categorized as “controlled”, such as hallucinogens; or “non-controlled” (less harmful) drugs. The manufacturing, importation, possession, and distribution of controlled drugs are strictly regulated by the federal government due to their potential harmful effects, such as addiction. Non-controlled prescription drugs may also be harmful if misused. Many prescription drugs are quite costly and can result in significant financial waste if over-ordered and left to expire. As such, OMH must have sufficient controls in place to protect its prescription drugs from theft, waste and abuse.

Basic controls over prescription drugs would include storing them in a location where they are inaccessible to unauthorized personnel; and maintaining a perpetual inventory record to account for the purchase, disposition and amount of drugs on hand. OMH policy requires Center directors to develop and implement such protective controls.

We found that, while sufficient controls are in place to protect and account for their controlled drugs, the Centers we visited have not instituted sufficient controls over their non-controlled prescription drugs, which account for the majority of their drug costs.

We visited the pharmacies at three OMH Centers, representing the highest procurers of OMH’s prescription drugs, to determine whether their prescription drugs are adequately controlled. We found that detailed records existed for their controlled substances, which were maintained under lock and key, denoting the procurement, dispensing, balance-on-hand, and disposal thereof. Conversely, although maintained in secured locations and not readily accessible to unauthorized

persons, there were no corresponding perpetual inventory records for their non-controlled drugs. Therefore, we could not perform tests to determine whether the amount of these drugs that were on hand is the amount that should have been on hand.

We also could not determine whether the sampled Centers received the appropriate credits and/or refunds for the unusable drugs they returned to manufacturers.

Our audit report contains five recommendations to improve OMH controls over non-controlled prescription drugs. OMH officials agree with our report recommendations and plan to implement them.

This report, dated December 17, 2009, is available on our website at: <http://www.osc.state.ny.us>.  
Add or update your mailing list address by contacting us at: (518) 474-3271 or  
Office of the State Comptroller  
Division of State Government Accountability  
110 State Street, 11<sup>th</sup> Floor  
Albany, NY 12236



## Introduction

### Background

OMH operates 25 psychiatric centers (Centers) that care for and treat persons with mental illnesses. Each of these Centers operates a pharmacy to supply medication to its patients. Patients can be either inpatients (patients who sleep at the Centers) or outpatients (e.g., those who visit the Centers for psychiatric services or to have prescriptions filled). OMH, either directly or indirectly through contracted parties, provides care for approximately 12,000 inpatients and about 600,000 outpatients.

Controlled drugs, such as methadone and amphetamines, are strictly regulated by the federal government and have been declared by federal and state law to be illegal for sale or use except by order of a licensed physician or other authorized licensed professional. The basis for such stringent control and regulation is the potential danger of addiction, abuse, or physical and mental harm that could result in death when the drugs are misused. Non-controlled prescription drugs, according to OMH, are frequently more expensive than controlled drugs but not as dangerous if abused.

OMH central office responsibilities include overseeing the pharmacies at the Centers. The OMH Policy Manual requires that:

- Each State-operated psychiatric center shall have a fully-licensed and operational pharmacy.
- Each OMH pharmacy shall have a director for the appropriate provision of pharmacy services throughout the Center.
- Each director shall formulate procedures for controlling and accounting for all drug products.

All dispensed medications require an order from the attending doctor, nurse practitioner or physician's assistant.

Center drugs are purchased from a wholesaler. When received, they are secured in the Center's pharmacy. Individual patient prescriptions are filled under the direction of pharmacists using the OMH pharmaceutical database called Meds Manager. When an order is placed, Meds Manager electronically records the medication(s) as being dispensed to the named patient(s) and a charge is generated for each individual dose dispensed. Most drugs for inpatients are packaged in unit doses and placed into carts to be delivered to a locked and secure area in the appropriate nursing unit.

Carts have drawers for patient-specific drugs, as well as space for non-patient-specified drugs for use as needed.

Outpatients receive prescribed drugs from the pharmacy in the quantity ordered by their physician. Outpatient medications are not unit-dosed but are dispensed in quantities ordered by the prescriber. As required by law, written prescriptions are maintained in the pharmacy for a minimum of five years. Records of all dispensed outpatient medications are also available in the Meds Manager system.

In calendar year 2007, the OMH purchased \$66.9 million in prescription drugs for use by the 25 Centers. According to OMH records, expenditures for prescription drugs have tripled over a ten-year period, from \$22 million in 1997, to \$66.9 million in 2007. OMH attributes this increase in cost to the use of six newer, more expensive, antipsychotics. These six medications account for roughly two thirds of all pharmacy prescription procurement costs.

## **Audit Scope and Methodology**

We audited the controls in place over OMH prescription drugs at selected Centers for the period January 1, 2007 through April 17, 2008. To accomplish our objectives, we reviewed OMH and Center prescription drug policies and procedures, interviewed OMH and Center officials, and reviewed available prescription drug inventory records and records relating to unused, disposed of, and returned drugs. To determine whether the centers were adhering to federal requirements for controlled substances, we performed inventory tests on a sample of these items at each of the Centers visited. We also verified the existence of prescription forms supporting the dispensing of drugs to patients.

We conducted our performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained during our audit provides a reasonable basis for our findings and conclusions based on our audit objectives.

In addition to being the State Auditor, the Comptroller performs certain other constitutionally and statutorily mandated duties as the chief fiscal officer of New York State. These include operating the State's accounting system; preparing the State's financial statements; and approving State contracts, refunds, and other payments. In addition, the Comptroller appoints members to certain boards, commissions and public authorities, some of whom have minority voting rights. These duties may be considered management functions for purposes of evaluating organizational independence under

generally accepted government auditing standards. In our opinion, these functions do not affect our ability to conduct independent audits of program performance.

**Authority**

This audit was performed pursuant to the State Comptroller's authority as set forth in Article V, Section 1 of the State Constitution, and Article II, Section 8 of the State Finance Law.

**Reporting  
Requirements**

A draft copy of this report was provided to OMH officials for their review and comment. Their comments were considered in preparing this final report and are attached in their entirety.

Within 90 days of the final release of this report, the Commissioner of OMH shall report to the Governor, State Comptroller, and the leaders of the Legislature and fiscal committees, explaining the actions taken by OMH officials to implement the recommendations contained herein, and where not implemented, the reasons therefor.

**Contributors  
to the Report**

Major contributors to this report include Frank Patone, Michael Solomon, Todd Seeberger, John Lang, Legendre Ambrose, Dmitri Vassiliev, and Sue Gold.



## Audit Findings and Recommendations

We found that the Centers we visited did not have sufficient controls in place over their non-controlled prescription drugs to protect them from theft, waste and abuse. We also found that unused prescription drugs returned to manufacturers for refunds were not properly accounted for. As such, we could not determine whether the dollar amount of refunds that should have been received by OMH for these returns was in fact collected.

### **Inventory Controls Over Prescription Drugs**

To determine whether OMH Centers could properly account for their prescription drugs, we visited the pharmacies at the three OMH Centers (Bronx Psychiatric Center, Pilgrim Psychiatric Center [located on Long Island], and Rockland Psychiatric Center) with the highest amount of prescription drug expenditures during calendar year 2007. Drug purchases for these Centers during this period totaled \$5.2 million, \$7.7 million, and \$8.4 million, respectively.

The OMH Policy Manual requires Centers to maintain detailed records for all drug-related pharmacy transactions. However, during our audit, OMH officials informed us that they did not believe that the risk of misappropriation or diversion of Center drugs was sufficient to warrant concern as to the type of inventory records that were maintained by their pharmacies. Therefore, they did not provide active guidance to their Centers in this area. As a result, the pharmacies at the Centers we visited did not employ standard methods to track, inventory and account for all of their prescription drugs.

### **Controlled Drugs**

OMH pharmacies are required to follow the United States Drug Enforcement Administration's (DEA) Office of Diversion Control Manual (Manual) for their controlled prescription drugs. The Manual stipulates that every pharmacy must maintain complete and accurate up-to-date records to document each controlled drug purchased, received, distributed, dispensed or otherwise disposed of. Required records also include a perpetual inventory record tracking the movements of each controlled substance.

Our first test was to compare a vendor-supplied list of controlled drugs purchased by the visited Centers during two judgmentally-selected months (June and December 2007) to determine whether those purchases had been recorded properly in Center inventory records. We were able to trace all 60,500 of the sampled purchased drugs to the appropriate Center records.

We also selected a judgment sample of 20,152 doses of controlled drugs that, according to inventory records, had been withdrawn from the visited pharmacies for the same two-month periods. Here, too, we were able to

verify that each dose dispensed was supported by a physician's order and signed for by the appropriate nursing station representative or outpatient. In addition, we observed that the controlled drugs at each of the visited Centers were properly secured in a locked area not accessible to unauthorized persons.

### **Non-Controlled Drugs**

We did not find the same level of controls and recordkeeping over OMH's non-controlled drugs. Although non-controlled drugs were also maintained in an area not accessible to unauthorized persons, none of the visited Centers maintained a perpetual inventory record for them. Thus, we were unable to determine the amount of non-controlled drugs that should have been on hand at the respective pharmacies. Although Meds Manager illustrates the drug dosages that were ordered by physicians, it does not report how many drugs were in stock before the order, nor does it document receipt and dispensing of the drugs by nursing stations.

Thus, these non-controlled drugs, which OMH officials estimate account for at least 85 percent of OMH's total annual drug costs (approx. \$56 million for 2007, and \$54 million for 2008), are subject to theft, waste and abuse.

### **Unusable Drugs**

The OMH Manual also requires Centers to account for all of their unusable drug products. Unusable drugs are those that have expired, been contaminated or otherwise returned from a nursing station; they are not fit for reissuing to a patient. Where possible, these unusable drugs are returned to their respective manufacturers for a credit or refund. In the case of OMH, considering the volume of drugs it procures, credits and refunds can amount to a significant number of dollars. In fact, according to OMH records, during 2007 OMH received \$208,000 worth of manufacturer credits and/or refunds for the drugs returned from our three sampled Centers. We found that two of the three Centers we visited did not account for their unusable drugs properly. To dispose of unusable drugs, the Centers use private companies known as reverse distributors. Reverse distributors are responsible for destroying drugs with no associated dollar value and returning others that are eligible for a manufacturers' credit or refund.

We found that neither the Bronx nor Pilgrim centers had prepared or maintained a list of the drugs they turned over to their reverse distributor. Instead, they relied on the distributor to itemize the quantity and types of drugs that they picked up at their respective facilities. Conversely, Rockland prepared its own list of unusable drugs and shipped its unusables to its reverse distributor along with a copy of the list. However, it did not have any procedures in place to reconcile the actual credits and refunds it received to what it should have received based on its listings. Due to the lack of detailed records maintained at the centers we could not test the appropriateness of the credits actually received.

When we discussed these issues with OMH officials, they agreed that some level of accountability over their non-controlled prescription drugs needs to be established. At a minimum, they plan to inventory a small percentage of their inventory, such as the 25 prescription drugs which make up the largest dollar value (approximately 85 percent) of the drugs the Centers purchase annually.

We believe that OMH officials' reliance on each Center to control its prescription drugs, without effective central office oversight to assess Center compliance with the OMH policy manual, has resulted in the deficiencies identified in this report.

- Recommendations**
1. Provide guidance to centers on how to properly control and account for their prescription drug inventory.
  2. Ensure that each Center pharmacy implements and maintains an accurate, up-to-date, perpetual inventory record for its prescription drugs. These records should be complemented by periodic physical inventory counts.
  3. Ensure that each Center prepares its own listing of unusable drugs, differentiating between those that are discarded versus those that are given to their reverse distributors.
  4. Reconcile the amount of credits and/or refunds received from manufacturers for returned drugs, as well as the bills received from reverse distributors, to the prepared listings noted in recommendation 3.
  5. Periodically evaluate the effectiveness of the controls in place at OMH Center pharmacies, and make revisions and improvements as appropriate.





## Agency Comments



State of New York  
David A. Paterson  
Governor



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November 19, 2009

Frank Patone, CPA  
Audit Director  
Office of the State Comptroller  
Division of State Government Accountability  
123 William Street, 21st Floor  
New York, NY 10038

Dear Mr. Patone:

The Office of Mental Health has reviewed the draft audit report entitled, Office of Mental Health: Controls over Prescription Drugs (2007-S-111). Our comments to the findings and recommendations contained in the report are enclosed.

The Office of Mental Health appreciates the Office of the State Comptroller's efforts to recommend improvements in our operations.

Many thanks for your continued help and cooperation.

Sincerely yours,

Bruce E. Feig  
Executive Deputy Commissioner

Enclosure

AN EQUAL OPPORTUNITY/AFFIRMATIVE ACTION EMPLOYER



OMH 26.01 (5/08)

**OFFICE OF MENTAL HEALTH  
RESPONSE TO OFFICE OF THE STATE COMPTROLLER  
DRAFT REPORT 2007-S-111  
CONTROLS OVER PRESCRIPTION DRUGS**

**OMH Comments**

**OSC's AUDIT**

OMH officials have reviewed the findings and recommendations in the Office of the State Comptroller's draft report entitled, Office of Mental Health: Controls Over Prescription Drugs. OMH is appreciative of OSC having identified areas where improvements can be made to OMH's controls over non-controlled prescription medications and has begun implementing OSC's recommendations.

OMH is also appreciative of OSC's acknowledgment that its audit of 20,152 doses of controlled drugs found that all doses were properly "supported by a physician's order and signed for by the appropriate nursing station representative." OMH is also pleased that the audit found that all drugs, both controlled and non-controlled, were properly secured "in a locked area not accessible to unauthorized persons."

**OMH'S HOSPITAL PHARMACY SYSTEM**

OMH dispensed over 23 million doses (over 30 million individual units) of medication across the 26 hospital pharmacy system in calendar year 2008. Current inventory control policies for this system meet or exceed all federal and New York state laws as well Joint Commission standards for hospitals.

OMH psychiatric hospital pharmacies rely on multiple electronic systems and a significant manual component for inventory management of pharmaceuticals. Cardinal Health is the contracted wholesale vendor for receiving pharmaceuticals, McKesson MedsManager is the contracted pharmacy systems software and Guaranteed Returns is the contracted reverse distributor. The three systems do not currently interface.

When medications leave the secure pharmacy environment they are securely transported to locked and secured areas of the hospital (locked nursing units). Unused medication is then securely transported back to the pharmacy.

Currently medications are manually ordered by the physician and manually administered and documented by a nurse. Current plans are for OMH to implement both a computerized prescription order entry system for physician medication ordering and an electronic bar code administration program to electronically document administered doses. The initial stages of implementation have already begun. The end result will be a closed loop medication system which will enable an accurate accounting of medication ordering and administering.

OMH is also addressing the challenge of having an inventory system comprised of multiple electronic non interfacing systems. OMH plans to develop a single system that brings these separate systems together. This will facilitate inventory management at both the facility and Central Office levels.

#### **OMH Responses to OSC Recommendations**

##### **OSC Recommendation No. 1**

Provide guidance to centers on how to properly control and account for their prescription drug inventory.

##### **OMH Response**

OMH will develop and implement a specific policy regarding pharmacy inventory management at the facility. The policy will address receiving, storing, administering and recording of inventory.

##### **OSC Recommendation No. 2**

Ensure that each Center pharmacy implements and maintains an accurate, up-to-date, perpetual inventory record for its prescription drugs. These records should be complemented by periodic physical inventory counts.

##### **OMH Response**

OMH plans to implement an electronic inventory management system that includes bar code identification of pharmaceuticals in an electronic environment. This system will provide a perpetual inventory record of prescription drugs. Until this process is complete, OMH will identify high cost medications and require pharmacies to do routine counts (minimally every 6 months). Information from these counts will be sent to Central Office for review against electronic purchasing and dispensing data. Outliers will be examined, addressed and corrected.

##### **OSC Recommendation No. 3**

Ensure that each Center prepares its own listing of unusable drugs, differentiating between those that are discarded versus those that are given to their reverse distributors.

##### **OMH Response**

OMH Inventory Management policy will require that records be maintained for all unusable medications. OMH Central Office will work with its state approved vendor, "Guaranteed Returns" to track all credits and/or refunds electronically. Disposed medications, that are determined to have no redeemable value, will be listed separately

##### **OSC Recommendation No. 4**

Reconcile the amount of credits and/or refunds received from manufacturers for returned drugs, as well as the bills received from reverse distributors, to the prepared listings noted in Recommendation No.3.

**OMH Response**

As noted in OMH's response to OSC Recommendation No. 3, the amount of credits and/or refunds received from manufacturers for returned drugs, as well as the bills received from reverse distributors, will be reconciled to the records maintained by OMH.

**OSC Recommendation No. 5**

Periodically evaluate the effectiveness of the controls in place at OMH Center pharmacies, and make revisions and improvements as appropriate.

**OMH Response**

OMH will evaluate controls which will include periodic physical cycle counts of medications in the facilities. A focus will be on high cost medications. Issues that arise will be corrected as needed.