PERFORMANCE AUDIT

MANAGEMENT OF DRUGS
AT THE DEPARTMENT OF MENTAL HEALTH –
DIVISION OF COMPREHENSIVE PSYCHIATRIC
SERVICES' STATE-OPERATED FACILITIES

From The Office Of State Auditor
Claire McCaskill

Better management of the drugs and pharmacies of state-operated mental health facilities is needed from the Department of Mental Health, Division of Comprehensive Psychiatric Services.

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YELLOW SHEET

Better management of pharmacies at state psychiatric service facilities could curb the risk of missing, misused or stolen drugs

This audit reviewed how state-operated psychiatric service facilities manage drugs disbursed to patients. The review focused on the 10 state facilities run by the Department of Mental Health's Division of Comprehensive Psychiatric Services and its internal controls over drug dispensation, inventories, formularies and pharmacy stocks. To test drug management, the audit tracked the drug dispensation from pharmacy to patient in about 60 instances at each facility. The following highlights the audit's findings:

Drugs records: some missing, others had discrepancies

The audit found instances at three facilities in which staff could not locate portions of patient medical records or controlled substance records. One facility could not find two weeks of daily controlled substance inventory records at two wards. In reconstructing some of these records, the audit staff found shortages of drugs, such as Valium, Ativan and Tylenol No. 3. Audit tests could not pinpoint what happened to these drugs. In addition, audit tests showed 15 instances in five facilities where pharmacy records showed one drug dosage charged to a patient, but patient records do not show if they received or refused the drug. (See page 4)

Overstocked pharmacies show need for better drug inventory

Several facilities overstocked pharmacies at the end of the fiscal year to increase reserves of high cost and frequently prescribed drugs. One facility made 77 percent of its drug expenditures in the last two months of fiscal year 2000, which left enough of some drugs to last more than two years. The overstocking seemed unnecessary since the prime drug vendor delivers within two days of an order. In addition, if the drugs expired from non-use, the state would pay 10 percent of the drug cost to return drugs purchased more three months prior. (See page 10)

Better drug formularies could control drug expenditures

Drug formularies, which are continually updated lists of approved medications, promote optimal patient care. The state does not require psychiatric facilities to maintain drug formularies. And of the seven facilities that have developed formularies, many are too broad. One facility had 14 drugs on its list to treat depression and 12 to treat psychosis, but some of these drugs were seldom or never used. Each facility had one or more drugs for either depression or psychosis that had fewer than 100 units dispensed over the fiscal year 2000. In addition, drugs dispensed at places without drug formularies are not properly controlled or tracked. (See page 15)

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SERVICES' STATE OPERATED FACILITIES

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The State Auditor's Office performed an audit of the management of drugs at the Department of Mental Health - Division of Comprehensive Psychiatric Services' 10 state-operated facilities.

The objectives of this audit were to determine whether (1) controls to account for drug inventories and the disposition of drugs dispensed to wards and clients were in place and operating effectively; (2) drug formularies were properly developed and managed; and (3) drug stocks in the pharmacies and wards were efficiently managed.

We concluded that the Division of Comprehensive Psychiatric Services needs to better manage and control pharmacy operations and procedures related to drug inventories, administration, and formularies to ensure that drugs are properly handled and the best patient care is provided at the least cost.

Our audit was conducted in accordance with applicable generally accepted government auditing standards published by the U. S. General Accounting Office and included such procedures we considered necessary under the circumstances.

Claire McCaskill
State Auditor

March 16, 2001 (fieldwork completion)

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RESULTS AND RECOMMENDATIONS

1. Controls Over Drugs Dispensed to the Wards Could Be Improved

The Department of Mental Health, Division of Comprehensive Psychiatric Services (Psychiatric Services) needs to improve the monitoring of administering and accounting for drugs dispensed to the wards at the Psychiatric Services' facilities. Enhanced monitoring could reduce the risk of drug loss, misuse or theft. Audit tests found that:

- ✔ Psychiatric Services' facilities could not locate records that account for the disposition of narcotics and other controlled substances.
- ✔ Numerous discrepancies and omissions were present in the controlled substances records of inventory and administration.
- ✔ Control procedures that document drug wastage and shift counts of controlled substances were not always followed.
- ✔ Discrepancies in recording drug administration were present in the medical records.

Routine procedures did not exist at many of the Psychiatric Services' facilities to review the controlled substance records of inventory and administration for completeness and accuracy. In addition, Psychiatric Services has not developed standard procedures to monitor drug control procedures. As a result, the control procedures in place at most facilities were insufficient to detect deficiencies in the drug administration records.

Background

Controlled substances and other drugs are dispensed from each facility's pharmacy to the wards to be given to patients as prescribed by the doctors. Each facility requires the administering nurse to document administration of medications on the patient's medication administration record. The nurse is also required to document any instances when prescribed drugs are not administered due to patient refusal. Unused drugs, if not contaminated, are returned to the pharmacy.

Controlled substances are drugs subject to additional controls by federal and state law because of their susceptibility to abuse. *(See Appendix III, page 26, for additional information.)* Records of the receipt, administration, wastage, and balance of the controlled substances are prepared by the medication nurses in the wards. These controlled substance inventory and administration records are maintained in addition to the medical administration record and are sent to the pharmacies after completion for billing purposes and filing. During shift changes, the incoming and outgoing medication nurses are required to count the controlled substances in their respective wards. According to Psychiatric Services' procedures, the counts should be documented on the controlled substance inventory and administration records and any discrepancies between the counted amounts and the recorded balances should be investigated.

Audit Methodology

We tested the disposition of drugs from the pharmacy records to the patient medical records and other drug distribution records at the 10 Psychiatric Services' facilities. The records we reviewed included pharmacy billings and order lists, doctors' orders, medical administration records, and when necessary and available, controlled substance inventory and administration records, drug wastage records, and return-to-pharmacy records. For testing, we tracked one or more drugs dispensed for a patient for one dispensing period. The dispensing periods of the facilities varied from 1 day to 1 month. At most facilities, we tracked 60 items. In total, we tracked 560 at the 10 facilities. In addition to these tests, we scanned additional controlled substance inventory and administration records at some facilities and expanded specific tests because of weaknesses found in internal controls identified in our tracking of drug dispositions. The audit results represent conditions noted with these specific tests and do not represent a projection to all drugs dispensed. Issues discussed in the report as a result of these tests represent internal control problems that are systemic.

Missing records were noted at three facilities

Personnel at the Metropolitan St. Louis Psychiatric Center, St. Louis Psychiatric Rehabilitation Center, and Mid Missouri Mental Health Center were unable to locate portions of patient medical records or controlled substance records requested during the audit.

- The Metropolitan St. Louis Psychiatric Center could not locate the medical administration records spanning 3 days for one patient. This facility also could not locate the daily controlled substance inventory and administration record for two wards covering 14 days. The pharmacist speculated these records became missing after he returned the records to the wards for correction of various errors he discovered.

Records were missing

- The St. Louis Psychiatric Rehabilitation Center could not locate the doctor's orders and medical administration records spanning 1 month for one patient.

- The Mid Missouri Mental Health Center could not locate 1 day's controlled substance inventory and administration record of one ward.

Missing controlled substance inventory and administration records and other medical records leaves drugs unaccounted for and creates opportunities to conceal theft or misuse of drugs.

Controlled substances records had discrepancies and omissions

Audit tests disclosed discrepancies and omissions were present in the controlled substance inventory and administration records for June 2000. Examples of weaknesses in inventory controls follow:

- Audit staff reconstructed the missing records for the 14-day period at the Metropolitan St. Louis Psychiatric Center using ending balances of the preceding period's records, pharmacy issuances to the wards, and patient medical administration records. There were discrepancies in balances for several drugs. Our calculated drug balance should have represented the ending balance of the 14-day period and been equal to the next period's beginning balance recorded on the controlled substance inventory and administration record. The largest discrepancies were shortages of 18 tablets of Valium 5 mg, 12 tablets of Ativan 2 mg, and 10 tablets of Tylenol No. 3. Audit tests could not disclose whether these drugs were stolen, consumed, or lost.

Shortages of controlled substances were noted

- The administration of controlled substances was not promptly recorded for seven controlled substance inventory and administration records. These records contained one or more entries where the time recorded for giving the drug to the patient was not in proper sequence. For example, by examining the record, a reviewer would see that the fourth entry shows a time of administration earlier than that for the first, second, and third entry. Since entries to the controlled substance inventory and administration record must be made immediately upon administration, there is no viable reason for entries to be out of sequence. For the seven instances, neither facility staff nor we could determine, if these entries were backdated, cover-ups for lost or stolen drugs, or record-keeping errors.

- In 33 instances, the controlled substance inventory and administration record did not agree with medical records that documented drug administration to the patient. Often, the drug administered according to the inventory record was not recorded on the patient's medical record. This raises a question concerning whether the patient received the medication or whether the drug was misappropriated. We also noted instances where (1) the medical record reported the administration of a drug that was not reported on the inventory record, (2) the time of administration was reported differently on the inventory and medical record, and (3) the inventory record and medical record reported the administration of different dosages of the same drug.

Additionally, we noted 11 instances where the signature of the administering or receiving nurse was omitted from the controlled substance inventory and administration record.

These discrepancies and omissions could be indicative of errors in recording the medication administration or potentially more serious errors involving the administration of drugs not in accordance with the orders of the physicians. Additionally, such errors could be part of efforts to conceal fraud or theft of drugs. The St. Louis Psychiatric Rehabilitation Center recently investigated the shortage of a controlled substance in the ward, but was unable to pinpoint the cause of the shortage. The pharmacists responsible for reviewing the controlled substance inventory and administration records did not conduct thorough enough reviews to detect the deficiencies noted above. None of the facilities had a routine procedure to compare controlled substance inventory and administration records to patient medical records to determine if drugs were administered.

Drug records are not adequately reviewed

Documentation requirements for wastage and shift counts of controlled substances were not followed

Two signatures are required when controlled substances are disposed of and for inventory counts when nursing shift changes occur. The purpose for these controls is to guard against fraud and misuse. Audit tests disclosed that these controls were not always working as evidenced by our scan of June 2000 records for controlled substances.

- The witness to the wastage of a controlled substance did not sign the controlled substance inventory and administration record in 18 instances. Therefore, the record does not indicate that there was a witness, and state auditors could not determine if there was a witness or if the drugs were misappropriated.

- The shift count was not documented or only one nurse signed the entry for the shift count in 30, 11, and 9 instances at the St. Louis Psychiatric Rehabilitation Center, Metropolitan St. Louis Psychiatric Center, and Cottonwood Residential Treatment Center, respectively. Additionally, there were two instances at the St. Louis Psychiatric Rehabilitation Center where no explanation was documented for the recorded count shortage of one or two tablets.

Audit tests disclosed discrepancies between drugs dispensed and administered

For the month of June 2000, facility staff could not account for drugs dispensed from the pharmacy. We noted 15 instances at the Cottonwood Residential Treatment Center, Northwest Missouri Psychiatric Rehabilitation Center, Hawthorn Children's Psychiatric Hospital, Southeast Missouri Mental Health Center, and Fulton State Hospital where one dosage of a drug was dispensed from the pharmacy and charged to the patient and not recorded as administered to the patient or refused by the patient. Documentation indicating the drug as wasted or returned to the pharmacy did not exist. One of these instances involved a controlled substance. The nursing and pharmacy personnel at these facilities stated the discrepancies could be due to incorrect execution of procedures as follows:

- The nursing directors at the Cottonwood Residential Treatment Center and Northwest Missouri Psychiatric Rehabilitation Center said the items were omissions by the nursing staff in documenting the administration of drugs.

- The pharmacists at the Hawthorn Children's Psychiatric Hospital and Southeast Missouri Mental Health Center indicated the nursing staff sometimes return the unused drugs of a discharged client to the pharmacy without identifying the client. The pharmacist would not be able to apply a credit in these instances.

- The pharmacist at the Hawthorn Children's Psychiatric Hospital indicated the nurses sometimes borrow a drug tablet from the supply for one patient to make up for a shortage in the supply of another patient.

Lack of clarity in policies and procedures attributed to the conditions noted in this report. For example, for non-controlled substances, the Hawthorn Children's Psychiatric Hospital policy and procedures allows the medication nurse to destroy drugs contaminated during administration without documenting the wastage. To ensure control, drug wastage should be witnessed and documented. These facilities do not employ adequate oversight procedures to ensure that dispensed drugs are properly administered.

Accountability for drug administration is needed

Conclusions

The policies and procedures developed by the Psychiatric Services' facilities have not been sufficient to prevent and detect instances of missing records and discrepancies and omissions within the records related to administration and control over drugs in the nursing wards. Ensuring that controlled substance inventory and administration records agree with patient medical records would provide protection from many of the discrepancies and omissions noted in this report. Additionally, procedures to record the wastage of non-controlled substances along with testing to account for drugs dispensed from the pharmacy as administered or wasted could provide assurance that drugs have been properly handled in the wards. Psychiatric Services staff has not required the development of such procedures by the facilities. Standard procedures for all facilities should be implemented to prevent exposing drugs to risk of loss or theft and to provide assurance that patients are issued appropriate drugs.

Recommendations

We recommend the Director, Division of Comprehensive Psychiatric Services:

1.1 Require facilities to develop controls to (a) ensure controlled substance inventory and administration records are properly completed and retained, (b) ensure wastage and nursing shift counts of controlled substances are properly conducted and documented, and (c) ensure drugs dispensed from the pharmacy are properly accounted for as administered to the patient or returned to the pharmacy.

1.2 Establish an ongoing monitoring function to ensure the above controls are functioning effectively.

Department of Mental Health's responses:

Controls Over Drugs Dispensed to the Wards Could Be Improved.

While the Division of Comprehensive Psychiatric Services acknowledges that processes may always be improved, we disagree with the general conclusion that our facilities have failed to insure that drugs are not exposed to increased risk of loss, misuse, or theft. CPS facilities dispense over half a million doses of medication each month, and each month perform over 3,400 control inventory counts to assure accountability.

A. Regarding missing records that were noted at 3 facilities:

- *Auditors note that Metropolitan St. Louis Psychiatric Facility could not locate medication administration records for 3 days for 1 patient. The record identified was in transfer between the unit and the pharmacy for quality control re-check and was sent to the Auditor at a later date. Metropolitan St. Louis Psychiatric Center generates 2,400 medication administration records per month.*

- *At Metropolitan Psychiatric Center regarding the 2 wards missing 14-days of controlled substance inventory and administration records, we agree that discrepancies exist. While we cannot prove that the drugs were <u>not</u> lost or stolen, nor is there evidence that the drugs were not consumed by patients as intended. Additional monitoring has been put into place.*

- *Regarding the Medication Administration Record and doctor's orders for one patient for one month at St. Louis Psychiatric Rehab Center. Since St. Louis Psychiatric Rehab Center generates 850 medication administration records per month this is an error rate of 0.1%.*

- *Regarding the one-day, one ward Controlled Substance Administration record at Mid Mo Mental Health Center. Since Mid Mo Mental Health Center generates 120 controlled substance inventories a month this is an error rate of 0.8%.*

B. *Discrepancies and omissions in controlled substance records. The auditors identify a total of 44 errors of documentation that occur on controlled substance and administration records. CPS facilities inventory controlled substances 3 times a day, on each unit. In a 1-month period CPS facilities generate 3,473 controlled substance administration records. This represents a documentation error rate of less that 1.3%.*

C. *Documentation of wastage and shift counts.*

The auditor's identify 18 incidences of errors of documentation of wastage. As previously noted, CPS facilities generate 3,473 inventory counts including wastage documentation monthly. This is a documentation error rate of approximately 0.5%. Regarding shift counts, the auditors identify only 2 instances of actual discrepancy at St. Louis Psychiatric Rehab Center. For St. Louis Psychiatric Rehab Center, which administers 1400 doses of controlled substances a month this represents an error rate of 0.14%.

D. *Audit tests disclose discrepancies between dispensing administration*

The auditor's note 15 instances, in 5 facilities, where records of pharmacy dispensing do not match records of administration. These 5 department facilities administer over 350,000 doses of medication each month and generate 2,173 medication administration records for individual patients monthly. This represents a documentation error rate of .004% per doses administered.

E. *Conclusions: CPS facilities are constantly engaged in continuous quality improvement to prevent and reduce errors of documentation and improve their medication management process. We agree with auditors that such processes may always be improved further.*

CPS has standard procedures in place that prevent exposing drugs to risk of loss and theft and assure that patients receive the appropriate drugs.

F. Recommendations:

1.1 & 1.2 CPS will conduct a pilot audit of a random sample at each facility to monitor, and verify that controlled substances dispensed from pharmacy and issued to nursing units are administered to patients as intended. Data sources will include controlled substance administration records, medication administration records, and pharmacy controlled substance inventory records. The results from the initial pilot will be used to determine whether the improvements achieved merit continued periodic audits.

State Auditor Comments:

Psychiatric Services calculated "error rates" based on the total population of events possible in a given month. We did not test all transactions for any given month. As a result the error rates calculated by Psychiatric Services are wrong. As explained in our audit methodology, we generally tested approximately 60 items at each facility and scanned additional transactions at some facilities. These tests were patient specific and for a single episode of administration. They were not projected to a total month's activity for all patients and all medical administration episodes.

While pilot audits may be beneficial, the report clearly shows there are procedural weaknesses that need to be corrected as recommended in recommendation 1.1.

2. Controls Over Drug Inventories Should Be Improved

Drug inventories were exposed to increased risk of loss, misuse, theft, and expiration due to the purchasing and dispensing practices and inventory controls of Psychiatric Services' facilities. The Department of Mental Health allocated funds to Psychiatric Services' facilities to acquire drugs near the end of the fiscal year 2000. As a result, significant overstocking of drugs at some of the facilities occurred. Additionally, there were inconsistencies among the facilities in procedures to control drug inventories and dispense drugs to the patient care areas as follows:

- ✓ Some facilities maintained perpetual drug inventory records for all drugs, while other facilities maintained perpetual inventory records for only some of their drugs.
- ✓ The perpetual records, where they were maintained, were often inaccurate.
- ✓ Complete physical drug inventory counts were not conducted regularly by most facilities.
- ✓ Some facilities dispense drugs infrequently to the patient care areas and consequently maintain significant stocks of drugs in those areas.

Psychiatric Services staff has not established consistent drug inventory controls and has not reviewed the adequacy of controls currently in place at Psychiatric Services' facilities. As a result, the facilities have developed inconsistent and often ineffective controls over drug inventories and drugs are vulnerable to theft.

Background

Psychiatric Services' facilities use their individual budget appropriations to purchase drugs. Psychiatric Services also allocated funds for medications to facilities. Psychiatric Services' facilities that maintain pharmacy inventories, order drugs from the state's prime vendor. The prime vendor delivers drugs within 48 hours of receiving the order. The concept of prime vendor is to provide "just-in-time" delivery and reduce the need for large inventories of products.

Except for the Southwest Missouri Psychiatric Rehabilitation Center, Mid Missouri Mental Health Center, and Cottonwood Residential Treatment Center, each facility has a pharmacy where drugs are stored after purchase. Drugs prescribed to patients are dispensed from these pharmacies to the wards, usually according to a regular schedule. The drugs dispensed for patients are housed in medication rooms in the wards until administered to the patients by nursing staff. Drugs for patients of Southwest Missouri Psychiatric Rehabilitation Center, Mid Missouri Mental Health Center, and Cottonwood Residential Treatment Center are dispensed to the wards of the facilities from contracted off-site pharmacies.

Year-end drug purchases resulted in overstocked drugs

The drug inventories for certain drugs in the pharmacies of the Psychiatric Services' facilities were excessive on June 30, 2000, because drugs were acquired near the end of the state fiscal year to expend remaining appropriations. Although Psychiatric Services staff could not quantify the amount of funds allocated to facilities to acquire drugs near the end of the fiscal year 2000,

the amounts were significant. The facilities used the allocations to increase their reserves of high cost and frequently prescribed drugs, the most prevalent of which was Olanzapine in various strengths. As a result, the facilities' stocks of this anti-psychotic drug at June 30, 2000, were in excess of immediate needs. The Western Missouri Mental Health Center, Fulton State Hospital, and St. Louis Psychiatric Rehabilitation Center all held stores of Olanzapine on June 30, 2000, that were particularly excessive.

- The Western Missouri Mental Health Center spent $368,000 on drugs of which $287,000 was spent in the final 2 months of the fiscal year ending June 30, 2000. It held total stocks of Olanzapine on June 30, 2000, with a value of $202,669. Based on usage of this drug during the preceding year, the Western Missouri Mental Health Center held supplies on June 30, 2000, of the 5 mg, 7.5 mg, and 10 mg tablets equivalent to usage for 28, 19, and 16 months, respectively.

Large year-end purchases resulted in overstocking

- On June 30, 2000, the Fulton State Hospital held supplies of Olanzapine 7.5 mg tablets equivalent to usage of about 9 months.

- The St. Louis Psychiatric Rehabilitation Center held supplies of all dosages of Olanzapine equivalent to usage of about 4 months.

The drug quantities on hand in the pharmacies on June 30, 2000, were much larger than necessary to meet the needs of the facilities. Because the prime vendor delivers within 2 days of ordering, it should not be necessary to maintain more than a few days' supply of drugs on hand at any time. Given the reorder time frames, the drug stocks could be reduced significantly. Overstocking of drug inventories unnecessarily commits state funds and increases the potential for misuse, theft, or expiration of drugs. Such overstocking also does not account for the possibility of introducing a new drug that could have an impact on historical issue rates of the current drug.

Psychiatric Services' staff indicated that the year-end purchases were made to obtain drugs at cheaper prices due to an annual drug inflation rate of approximately 12 percent. However, our review of Olanzapine prices indicated no change from June 2000 prices through February 2001. Staff also indicated that no wastage of drugs due to expiration is possible because expired drugs can be returned to the prime vendor for full credit. While it is true that expired drugs may be returned to the prime vendor, a fee of at least 10 percent is charged for returns made more than 90 days after purchase.

Large differences between perpetual inventory records and physical inventory counts existed

Psychiatric Services' staff has not established inventory procedures or guidelines for the facilities. The facilities have independently developed various policies related to perpetual inventory systems and physical inventory counts. However, Psychiatric Services has not reviewed the adequacy of those procedures or routinely monitored facility compliance with those procedures.

Perpetual drug inventory records are maintained to varying degrees at the facilities. All facilities maintain perpetual inventory records for Schedule II controlled substances (drugs that have high severe psychic or physical dependence liability) due to the high risk of abuse and misuse for these drugs. Additionally, the St. Louis Psychiatric Rehabilitation Center, Metropolitan St. Louis Psychiatric Center, Hawthorn Children's Psychiatric Hospital, and Southeast Missouri Mental Health Center maintain perpetual inventory records for all other drugs, and the Fulton State Hospital maintains perpetual records for only all other controlled substances (Schedule III-V drugs). The Fulton State Hospital previously had maintained perpetual records for some of its most costly drugs to provide additional controls over these drugs, but stopped tracking these drugs because it found the procedure to be ineffective and labor intensive.

Drug inventory records are not reliable

The perpetual inventory records contained numerous inaccuracies for three of the four facilities maintaining perpetual records for all drugs. The individual drug balances maintained in the perpetual records of St. Louis Psychiatric Rehabilitation Center, Metropolitan St. Louis Psychiatric Center, and Hawthorn Children's Psychiatric Hospital often varied significantly from the quantities counted during the most recent physical inventory count, and negative balances were recorded for many drugs.

The wide disparity in counts compared to records made the records unreliable. The facilities' staffs investigated the variances between the counted and recorded quantities and determined that errors had been made in entering transactions into the perpetual records. Examples of these errors were: (i) recording the wrong unit for the drug in the records, and (ii) recording a "date received" as a "quantity" in the records. The occurrence of these discrepancies indicates that accurate record keeping is not a priority. The following table shows some of the drugs with variances between the recorded and counted quantities.

Table 2.1 - Selected Drugs with Quantity Variances

		Quantity	
Facility	Metropolitan St.Louis Psychiatric Center	Recorded	Counted
Drugs	Lithium Carbonate 150 mg	-413,057	131
	Acetaminophen 325 mg (Tylenol)	382	1,068
	Citalopram 10 mg (Celexa)	956	26
	Divalproex 500 mg (Depakote)	827	457
	Haloperidol 5mg/ml (Haldol)	-914	126
Facility	St. Louis Psychiatric Rehabilitation Center		
Drugs	Lithium Citrate 8meq/5ml	7,213	0
	Acetaminophen 325 mg (Tylenol)	-825	3,000
	Bupropion SR 100 mg	-3,918	718
	Carbamazepine 200 mg (Tegretol)	-7,235	3,000
	Divalproex 500 mg (Depakote)	4,628	2,300
Facility	Hawthorn Children's Psychiatric Center		
Drugs	Risperidone 1 mg	494	62
	Carbamazepine 200 mg unit dose	-1,974	232
	Clonidine HCL .1 mg	1,212	238
	Benztropine 1 mg unit dose	-1,324	207
	Methylphenidate HCL 10 mg	1,082	1,390

Source: Facility records

While each facility conducted physical inventory counts of controlled substances at least annually, some facilities were not conducting periodic physical inventory counts for all other drugs. The most recent complete physical inventory counts of St. Louis Psychiatric Rehabilitation Center, Metropolitan St. Louis Psychiatric Center, Northwest Missouri Psychiatric Rehabilitation Center, and Hawthorn Children's Psychiatric Hospital were conducted more than 1 year following the previous count. More than 3 years had elapsed between complete physical inventory counts at Hawthorn Children's Psychiatric Hospital. By contrast, Fulton State Hospital, Southeast Missouri Mental Health Center, and Western Missouri Mental Health Center have conducted complete physical inventory counts annually and compared the total counted value to an expected value based on the previous year's count and total purchases and usages during the year. Pharmacy inventories are exposed to increased risk of loss and theft when perpetual records are not maintained correctly and periodic physical inventory counts are not properly conducted.

Drug inventory procedures are not consistent

Psychiatric Services' staff could assist the facilities in developing appropriate methods of controlling pharmacy inventories. The procedure development process could be facilitated by a sharing of experiences among the facilities of the advantages and disadvantages of the various systems. While differing procedures may be appropriate at the various facilities, Psychiatric Services should review and approve each facility's procedures and then establish an ongoing monitoring function to ensure compliance with those procedures. One of the highest priorities in any inventory procedure is the reconciliation of records to physical counts.

Untimely dispensing intervals to the wards caused excessive stocks of drugs

Some facilities maintain excessive stocks of drugs in the wards because the pharmacies do not dispense drugs to the wards often enough. Drugs are dispensed on a daily cycle to the wards of the Western Missouri Mental Health Center, Southeast Missouri Mental Health Center, and Mid Missouri Mental Health Center. The other facilities have adopted dispensing intervals of various frequencies ranging from three times each week to once each month. Psychiatric Services has not developed policies or guidelines for the facilities regarding dispensing intervals.

Drug quantities in wards are too large

The quantity of drugs maintained in the wards should be maintained at minimal levels to reduce the risk of theft or loss of drugs and to reduce the record keeping burden over ward stocks. Psychiatric Services should develop and institute policies for the facilities to maintain minimal drug stores in the wards. This is especially important because of the problems noted in Issue 1 of this report regarding accountability of drugs on wards and records of administration of drugs to the patients.

Conclusions

Psychiatric Services' oversight and management of the drug inventories and policies of the Psychiatric Services' facilities has not been sufficient to provide for consistent and effective control over drugs. At Psychiatric Services' facilities, the inventories of drugs in the pharmacies and wards have been overstocked, perpetual inventory records have been maintained

inaccurately, and complete physical inventory counts have been conducted infrequently. Consequently, drugs have been exposed to increased risk of loss, misuse, theft, and expiration.

Recommendations

We recommend the Director, Division of Comprehensive Psychiatric Services:

2.1 Curtail fiscal year-end drug purchasing of excessive quantities of drugs.

2.2 Review and approve pharmacy procedures at each facility and then establish an ongoing monitoring function to ensure compliance with those procedures.

2.3 Review dispensing intervals at pharmacies to reduce the quantities of drugs stored in the ward areas.

Department of Mental Health's responses:

Controls Over Drug Inventory Should Be Improved

A. Year-end drug purchases result in overstocked drugs. CPS agrees that in some years it purchases advance inventory of drugs, but disagrees that this represents overstocking. Medication prices are subject to unpredictable cost increases. While Olanzapine did not change its price during the time period noted by the auditors the practice of purchasing advance medications has yielded significant savings for other medications for other periods of time. It is not possible to predict precisely which medication will increase in price and at exactly what time.

B. Differences between perpetual inventory records and physical inventory counts exist. CPS agrees that these discrepancies render the perpetual inventories unusable and is discontinuing perpetual inventories for all except controlled substances. The smaller number of drugs that are controlled substances and the much smaller volume of doses of controlled substances utilized make perpetual inventories possible to do in an accurate manner within a reasonable commitment of manpower. The additional risk of controlled substances merits continuing perpetual inventories. Regarding timely physical inventories CPS agrees that Hawthorn's Children Psychiatric Hospital's inventory for the period between the last 2 inventories was excessive. However, all other facilities were in acceptable limits for annual audit.

C. Untimely Dispensing Intervals – CPS agrees that dispensing intervals vary and they should given the variety of types of facilities. Dispensing intervals at acute hospitals where patients only stay a few days and new patients are admitted and discharged everyday, short dispensing intervals are appropriate. At long-term facilities where patients stay for years and medications are changed only infrequently, longer dispensing periods are appropriate. All CPS facility units except two dispense at least once a week. Fulton State Hospital has a transition to community unit where patients are particularly stable that dispenses every 14 days. Cottonwood Residential Treatment Center dispenses monthly, this is the usual practice for residential treatment centers.

D. Conclusions

Psychiatric Services disagrees with the conclusion that it has not provided consistent and effective control over medications and that its pharmacies and wards are overstocked.

E. Recommendations

2.1 CPS has not purchased advance stock during the current fiscal year but reserves the right to do so in future fiscal years if in its judgment this would result in savings to the State of Missouri.

2.2 CPS agrees that perpetual inventories are not helpful for non-controlled medications and will discontinue them. CPS will maintain perpetual inventories for controlled substances. CPS will require physical inventories annually.

2.3 CPS has reviewed its facilities' dispensing intervals and finds them appropriate. CPS will refer the auditor's comments on dispensing periods to the facility pharmacy and therapeutics committees and safety committees for consideration.

State Auditor Comments

Psychiatric Services states that its year-end drug purchases do not represent overstocking. Our concern is borne out by Psychiatric Services' comments to the report where they acknowledge, "It is not possible to predict precisely which medication will increase in price and at exactly what time." Without this knowledge, Psychiatric Services' cannot justify the year-end purchases.

3. Better Management of Drug Formularies Is Needed

Drug formularies were not being used effectively to control drug expenditures while ensuring the best drug therapy to Department of Mental Health clients. While seven Psychiatric Services' facilities had developed a drug formulary, three facilities had not. For those facilities that had developed a drug formulary, there were deficiencies in the drug formulary development and control as follows:

- ✔ The drug formularies were often broad and contained some drugs that were seldom or never used.

- ✔ Written justification and approval for the non-formulary prescriptions was not required by many of the facilities.

- ✔ Many of the facilities did not formally monitor the amount of non-formulary drug usage.

Psychiatric Services' staff has not established consistent policies and procedures regarding formulary management at the facilities. As a result, there is less assurance Psychiatric Services is realizing the intended benefits of a properly managed drug formulary – to improve the quality and control the cost of drug therapy.

Background

A Pharmacy and Therapeutics (P&T) Committee and drug formulary are two important components of drug management in a health-care organization. The health-care organization's P&T committee, which is composed of physicians, pharmacists, nurses, administrators, and other health professionals, is responsible for evaluating the clinical use of drugs, developing policies for managing drug use and drug administration, and developing and managing the drug formulary. A drug formulary is a continually updated list of medications approved by the P&T committee for use by the patients of the health-care organization. Drug products included on the formulary are routinely available for use in the organization. The drug formulary promotes optimal patient care because it restricts the drug treatments to only those drugs judged to be in the best interest of the patient's health needs in terms of efficacy and cost.

Drugs on formularies represent a decision by trained professionals regarding the quality of the drug, frequency of use of the drug for patients, and cost of the drug. Provisions are always made for prescribing drugs not on formulary for those instances where the formulary drugs are not suited for a particular patient's needs. These provisions generally require approval from the Chief of Staff or P&T committee before prescribing. Approvals are necessary because they require a justification as to why a drug on the formulary is not appropriate and can give cause for the approval authorities to consider adding the new drug to the formulary if there is a projected recurring need for it.

Some facilities have not developed drug formularies specific to the facilities' needs

Drug formularies are needed at all facilities

Psychiatric Services' staff has not required the facilities to establish and maintain drug formularies. Seven facilities have independently developed their own drug formularies, but the Mid Missouri Mental Health Center, Cottonwood Residential Treatment Center, and Southwest Missouri Psychiatric Rehabilitation Center have not developed drug formularies specific to the needs of these facilities. Consequently, these facilities have less assurance that their patients have received the most efficacious and cost effective drug therapy.

The Cottonwood Residential Treatment Center has not developed a drug formulary. The physician at this facility may prescribe drugs without regard to the restrictions of a drug formulary.

The Southwest Missouri Psychiatric Rehabilitation Center and the Mid Missouri Mental Health Center have not developed drug formularies specific to the needs of these facilities. The Southwest Missouri Residential Treatment Center's formulary consists of a 253 page drug catalog that lists nearly 1,000 drugs. The Mid Missouri Mental Health Center physicians prescribe drugs from the formulary of the University of Missouri Hospital and Clinics' pharmacy from which it obtains its drugs. Although the Mid Missouri Mental Health Center may recommend changes to the formulary of the hospital, it has no members on the P&T committee of the hospital, and consequently is not directly involved in the development and approval of the hospital's formulary.

Drug formularies were too broad

Some formulary drugs are never used

The drug formularies developed by the facilities could have more drugs than needed to provide adequate care to their patients. For example, the drug formularies of the facilities contained at least 14 drugs to treat depression and 12 to treat psychosis. Some of these drugs were seldom or never used indicating that they might not be needed. Whether they are needed would have to be determined through a review by the P&T committee.

Each facility had one or more drugs in these two drug classes (depression and psychosis) that had fewer than 100 units dispensed during the year ending June 30, 2000. The Hawthorn Children's Psychiatric Hospital and St. Louis Psychiatric Rehabilitation Center had seven and five formulary drugs, respectively, in these two drug classes that were not dispensed. The medical director of the St. Louis Psychiatric Rehabilitation Center indicated that these unused drugs are usually not needed and should be removed from the formulary. Most facilities did not routinely review the formularies to consider seldom or never used drugs for removal from the formulary.

Psychiatric Services has not compared formularies

Psychiatric Services' staff did not compare facility formularies to possibly identify drugs that are not efficacious or cost effective. The facilities indicated a large number of formulary drugs were necessary because some of the drugs produce different results in certain patients. However, by reducing the size of the formularies and removing seldom used drugs from

the formularies where possible, better control over the drugs prescribed could be achieved, as the use of marginally effective drugs would be discouraged. Also, because the pharmacies generally maintain some stock of all formulary drugs, eliminating seldom and never used drugs from the formularies would reduce the risk of loss from expiration and reduce the overall costs of inventories.

Non-formulary drug usage was not adequately controlled

Psychiatric Services has not established procedures for facilities to control non-formulary drug usage. Each facility has developed its own procedures for allowing physicians to prescribe non-formulary drugs. The procedures at most facilities for justifying, approving, and monitoring non-formulary drug usage provided insufficient control. At most facilities, the physicians were permitted to prescribe non-formulary drugs without providing a written justification or obtaining written approval from another member of the medical staff. Psychiatric Services' staff indicated that verbal approval is obtained at some facilities and that this is sometimes noted in P & T Committee meeting minutes. Most facilities required the pharmacist to suggest formulary alternatives upon receiving non-formulary prescription orders, however, the pharmacist generally filled the prescription if the physician believed the drug was needed. Additionally, most facilities do not formally track the amount of non-formulary drug usage.

Better controls are needed for non-formulary drug use

To ensure the drug formularies are not being circumvented, guidelines are needed for non-formulary drug usage. The guidelines should require written justification and approval. That could include the following criteria:

- Patient experiences an adverse reaction to a formulary alternative.
- Formulary alternatives have been tried and were therapeutic failures.
- Formulary alternative do not exist.
- Patient has previously responded to a non-formulary drug and risk is associated with a change to a formulary alternative.
- Other circumstances exist with compelling evidence-based clinical reasons.

Non-formulary approvals should be subsequently re-evaluated based upon the clinical response of the patient. The guidelines should also require periodic monitoring of the amount of non-formulary drugs dispensed.

Conclusions

Psychiatric Services' oversight and management of drug formularies of facilities has not been sufficient to ensure the best drug therapy is provided to its patients at the least cost. Three facilities have not developed drug formularies. The formularies that have been developed are broad and contain drugs that are seldom or never prescribed. Non-formulary drug usage is

not properly controlled and tracked. Consequently, the benefits of properly developed and managed drug formularies have not been fully realized.

Recommendations

We recommend the Director, Division of Comprehensive Psychiatric Services:

3.1 Require all facilities to develop drug formularies.

3.2 Review facility formularies for drugs that are seldom or never used and determine whether these drugs should be removed. In addition, Psychiatric Services should periodically compare facility formularies to determine whether more efficacious and cost effective drugs should be added.

3.3 Develop procedures for facilities to better manage and control non-formulary drug usage.

Department of Mental Health Responses:

Better Management of Drug Formulary

A. "Some facilities have not developed drug formularies" – CPS agrees that the Cottonwood Residential Treatment Center has not developed a drug formulary. Cottonwood Residential Treatment Center is intended to function as a residential treatment center and not as a hospital facility. Residential treatment centers are not required by standard or license to develop and maintain drug formularies. Residential Treatment facilities do not, as a general practice, develop or maintain drug formularies. There is only 1 physician practicing at Cottonwood Residential Treatment Center for a few hours a week. Use of a formulary would make no more sense than with an individual practitioner operating in solo practice in the community or at a nursing home. Regarding Mid Mo Mental Health Center, they utilize the formulary of University Hospital. The Pharmacy and Therapeutics Committee of Mid Mo Mental Health Center has evaluated and accepted the University Hospital formulary as being appropriate to the needs of Mid Mo Mental Health Center. We disagree that any changes are necessary for Mid Mo Mental Health Center.

B. "Drug formularies are too broad"- We disagree that the drug formularies at CPS facilities are too broad. As noted above, development of a formulary is the purview of the licensed professional pharmacist and physicians of the medical staff. It is appropriate for CPS facilities to have formularies that contain all available medications for treatment of mental illness since we are tertiary referral specialty facilities for the treatment of mental illness. The acute care facilities need to maintain broad formularies in non-psychiatric areas due to their patients only staying a few days and the non-psychiatric medication being prescribed by outside physicians. It would be poor patient care to change a persons asthma medicine during their 3 to 5 day stay at a CPS acute facility only to have it changed back again once in the community. This would expose the patient to additional risk of developing new drug interactions and is also potentially confusing to

patients and a likely source of additional errors in continuity between facility and community.

C. *"Conclusion" – Psychiatric Services disagrees that it has not ensured the best drug therapy. We do not believe that therapy is improved by taking a restrictive approach to formularies and believe that these decisions are best made by pharmacist and physicians. The minutes of the CPS facilities' Pharmacy and Therapeutics Committees document adequate formulary management.*

D. *Recommendations:*

3.1 CPS will continue to require facilities that are designed and function as hospitals to develop and maintain formularies. We do not believe it is useful or appropriate to require residential treatment facilities to develop drug formularies.

3.2 The Medical Director of CPS with the support of DMH and new appropriations provided by Missouri legislature has worked to assure that all the newer, more effective psychiatric medications are available at CPS in-patient facilities. Facilities have been provided with practice guidelines for most effective usage of some medications. We will refer the auditor's findings and recommendations to the individual facilities pharmacy and therapeutics committee for their consideration regarding formulary development and maintenance.

3.3 We will refer the auditor's findings and recommendations to the individual facility's pharmacy and therapeutics committee where authority rests regarding approval and monitoring of non-formulary usage.

State Auditor Comments

Psychiatric Services states that a drug formulary is not useful or appropriate for patients in a residential treatment facility setting. However, drug formularies restrict drug treatments to drugs judged to be in the best interest of the patients' health needs in terms of efficacy and cost.

We did not advocate that persons with short-term stays for psychiatric care should have their non-formulary drugs changed upon admission. Rather, this condition would be a viable reason for justifying continuance of the drug even though it is not on the facility's formulary.

4. Pharmacy Arrangements Need Reconsideration

Psychiatric Services could save money by ensuring facilities participate in the state's prime vendor drug contract. In addition, a reevaluation of the current pharmacy operations may reveal that cost savings, increased efficiency, and improved controls could be achieved through consolidation of some or all of the pharmacies. The facilities have developed different methods of obtaining drugs and pharmacy services as follows:

- ✓ Four facilities have contracted with a pharmacist to provide pharmacy services and manage the drug inventories at these facilities.

- ✓ Three facilities have contracted with a pharmacist to provide drugs and pharmacy services. Two of these pharmacists did not acquire their drugs from the prime vendor and charged the facilities a drug unit price that was often significantly higher than the unit price of the prime vendor.

- ✓ Three facilities have managed their own drug inventories and received pharmacy services from employees of the facility.

Some facilities have independently evaluated the economy of their method and a statewide analysis of a centralized pharmacy was considered. But these analyses were conducted years ago and documentation could not be located by Psychiatric Services' facilities for most of these analyses. Psychiatric Services has not required the facilities to (i) re-evaluate the merits of their current arrangements and (ii) study the feasibility of consolidating some or all pharmacy operations. Consequently, the value of the current pharmacy arrangements has not been supported with documented analyses and there is no assurance that pharmacy operations are economical.

Background

In 1997, the state of Missouri joined a multi-state drug purchasing alliance. Currently, 36 states participate in the alliance. The member states obtain their drugs using contracts with drug manufacturers established by the alliance. The alliance uses its large buying power to negotiate favorable contract prices with the drug manufacturers. The alliance also contracts with drug wholesalers, one of which each member state chooses as its prime vendor for obtaining drugs. Member states are expected to buy their drugs from the contracts of the alliance.

The pharmacy arrangements of each facility are summarized as follows:

- The St. Louis Psychiatric Rehabilitation Center, Metropolitan St. Louis Psychiatric Center, and Hawthorn Children's Psychiatric Hospital, have jointly contracted with a healthcare company to provide pharmacy services and manage their drug inventories. The Fulton State Hospital also separately contracts with this company. Each facility maintains a distinct pharmacy with drug inventories and acquires its drugs from the prime vendor.

- The Southwest Missouri Psychiatric Rehabilitation Center, Mid Missouri Mental Health Center, and Cottonwood Residential Treatment Center each have separately contracted

with external pharmacies to provide drugs and pharmacy services. Because the facilities acquire their drugs from an external pharmacy, they do not use the services of the prime vendor. The Mid Missouri Mental Health Center and Cottonwood Residential Treatment Center are charged the average wholesale price for the drugs they receive from their pharmacies. The Southwest Missouri Psychiatric Rehabilitation Center is charged drug prices equivalent to those of the prime vendor, although its current contracted pharmacy does not acquire its drugs from the prime vendor.

- The Southeast Missouri Mental Health Center, Western Missouri Mental Health Center, and Northwest Missouri Psychiatric Rehabilitation Center have managed their own drug inventories and received pharmacy services from employees of the facility. Each of these facilities acquires its drugs from the prime vendor.

Cost savings could be achieved by using the state's prime vendor

The Mid Missouri Mental Health Center and Cottonwood Residential Treatment Center have paid higher unit costs for their drugs than the unit costs charged by the prime vendor. The drug prices charged by the prime vendor were often significantly lower than the average wholesale price charged these facilities by their contracted pharmacies. For example, the average unit drug costs paid by the Mid Missouri Mental Health Center for its most costly drugs for the fiscal year ending June 30, 2000, exceeded the average unit costs of those drugs charged by the prime vendor for that period. If the Mid Missouri Mental Health Center had acquired these drugs at the prices charged by the prime vendor, it would have reduced its total expenditures for these drugs by approximately $60,000 for fiscal year 2000.

One facility could have saved $60,000

Additionally, the Mid Missouri Mental Health Center has not solicited bids for its contracted pharmacy. It negotiated a contract for the purchase of drugs, pharmacy services, and other services from the University of Missouri Hospital and Clinics' pharmacy. Psychiatric Services' staff indicated that the potential savings noted above may be offset by increased pharmacy fees if a separate drug inventory needed to be maintained.

Psychiatric Services should ensure its facilities are taking appropriate measures to receive the best prices for their drugs. Measures such as soliciting bids and purchasing drugs from the prime vendor are available to help reduce costs. Because these activities have not always been conducted, some facilities have incurred increased drug costs.

The economy of current pharmacy operations has not been evaluated

Psychiatric Services has not recently evaluated the merits of the different pharmacy arrangements of the facilities and considered other alternatives. In addition, adequate consideration has not been given to determining what methods may be best for Psychiatric Services and all facilities collectively:

- The Fulton State Hospital, Metropolitan St. Louis Psychiatric Center, and Southeast Missouri Mental Health Center have independently compared expected costs for a contracted pharmacy and a state-operated pharmacy (the Metropolitan St. Louis Psychiatric Center analysis covered all three St. Louis facilities). The most recent of

these analyses was conducted approximately 3 years ago. Each facility concluded the cost of a contracted pharmacy exceeded the cost of a state-operated pharmacy. The Southeast Missouri Mental Health Center used the analysis as a basis for continuing with its state-operated pharmacy. The Fulton State Hospital and Metropolitan St. Louis Psychiatric Center continued to contract for the pharmacy services because they concluded that other benefits from contracting - like service quality, computerization, and recruitment and retention of pharmacists - outweighed the additional operating costs.

- The St. Louis Psychiatric Rehabilitation Center indicated it had concluded about 8 years ago that it was best to maintain separate pharmacy and drug inventories for the three St. Louis facilities because of transportation issues.

- The other facilities maintain they acquire their drugs and pharmacy services in the best and most practical method, although most of these facilities had no recent documented study of the issue.

More than 10 years ago, Psychiatric Services concluded that consolidation of its pharmacies was not feasible due to logistics and the loss of some of the clinical consultative function of the on-site pharmacists; but Psychiatric Services has no documentation of this study and has not considered the issue in recent years. Some significant changes since then such as the availability of a drug prime vendor, the ability of the prime vendor to make timely deliveries, and advances in electronic communications may now make some consolidation of the pharmacies feasible. Consolidation of some or all of the pharmacies would eliminate the need for drug inventories at many facilities, which could provide benefits such as:

Economy of pharmacy operations needs study

- Reducing costs for space and staff time in maintaining the inventories,

- Reducing the total statewide investment in inventories by maintaining a smaller total stock of inventories in a centralized location, and

- Increasing efficiency by eliminating the need for separate drug inventory records and controls at each facility.

Additionally, because several facilities have concluded that state-run pharmacies offer potential cost savings over contracted pharmacies, a consolidated state-operated pharmacy may offer significant savings over the current methods. The drawbacks to operating solitary state-run facility pharmacies noted by some facilities may be overcome when considered on a consolidated basis.

Conclusions

Psychiatric Services should reconsider alternatives and analyze the entire pharmacy operation service. The prime vendor concept is widely used in the federal sector and private sector and has proven to create cost savings. Some Psychiatric Services' facilities are benefiting from the prime vendor concept. More widespread use of the prime vendor to acquire drugs would result in reduced drug costs. A study of the feasibility of operating a consolidated state-run pharmacy, if

state-run pharmacies pass the scrutiny of the entire pharmacy operation analysis, may reveal improvements in operating efficiencies.

Recommendations

We recommend the Director, Division of Comprehensive Psychiatric Services:

4.1 Require facilities to obtain drugs under the state's prime vendor contract and solicit bids for contracted pharmacy services when contracts are warranted.

4.2 Reevaluate its current pharmacy arrangements including the feasibility of a consolidated state-operated pharmacy.

Department of Mental Health Responses:

Pharmacy Arrangements Need Reconsideration.

CPS agrees that it arranges for pharmacies in different manners at different sites.

A. "Cost savings could be achieved by using the State's prime vendor." Regarding Cottonwood Residential Treatment Center the majority of its residents are Medicaid eligible and their pharmacy benefit is provided by Medicaid. Only a few residents receive medications directly purchased by DMH. The volume is so small it would not be feasible to run a separate prime vendor location. Regarding Mid Mo Mental Health Center they reviewed their arrangement for pharmacy services subsequent to the auditor's visit and have found that their savings on pharmacy personnel costs out weigh their increased ingredient costs. Their current contract is the most advantageous currently available.

Recommendation 4.1: CPS disagrees that it should require all facilities to obtain drugs under State's prime vendor. CPS has re-evaluated Mid Mo Mental Health Centers current arrangement. CPS has determined that it is not feasible to use prime vendor with Cottonwood due to the extremely low volume.

Recommendation 4.2: We will consider evaluating the feasibility of a consolidated state operated pharmacy. A major reason for CPS contracting for pharmacy services has been its inability to recruit and retain pharmacists. Currently the state salary for pharmacist is approximately $15,000 less than the community rates offered for new hires. Staffing a consolidated state-operated pharmacy may not be possible until the state employed pharmacist's salaries would allow us to recruit and retain sufficient pharmacists to staff such an operation.

State Auditor Comments

Psychiatric Services stated that the current contract for pharmacy services at the Mid Missouri Mental Health Center is the most advantageous currently available. It is difficult for Psychiatric Services to support this statement given that the pharmacy arrangement has not been competitively bid.

APPENDIX I

OBJECTIVE, SCOPE AND METHODOLOGY

Objective

The objective of this audit was to evaluate the management of drugs at Psychiatric Services' facilities. Specifically, our objectives included determining whether (1) controls to account for drug inventories and the disposition of drugs dispensed to the wards and clients were in place and operating effectively; (2) drug formularies were properly developed and managed; and (3) drug stocks in the pharmacies and wards were efficiently managed.

Scope and Methodology

The audit included interviews of Psychiatric Services' staff at the central office in Jefferson City and on-site reviews at each of the 10 state-operated mental health facilities. The audit focused on current procedures, and procedures and records for fiscal year 2000. At Psychiatric Services' facilities, we:

- Interviewed pharmacy, administrative, and medical personnel about procedures for dispensing, administering, and controlling drugs.

- Tested the disposition of drugs from the pharmacy records of dispensed drugs to the patient medical records and other records of the disposition of the drugs as necessary. The records we reviewed included pharmacy billings and pick lists, doctors orders, medical administration records, and when necessary and available, controlled substance inventory and administration records, drug wastage records, and return-to-pharmacy records. For testing, we selected one or more drugs dispensed for a patient for one dispensing period. The dispensing periods of the facilities varied from one day to one month. The items tested for all facilities totaled 560.

- Scanned, in addition to the tests noted above, additional controlled substance inventory and administration records at some facilities.

- Reviewed policy manuals, drug formularies, detailed drug usage reports, physical inventory counts, pharmacy contracts, and other records.

- Reviewed applicable federal and state laws related to controlled substances.

APPENDIX II

BACKGROUND

The Department of Mental Health - Division of Comprehensive Psychiatric Services (Psychiatric Services) is responsible for providing comprehensive psychiatric services. Comprehensive psychiatric services are services to persons affected by mental disorders other than mental retardation or developmental disabilities and include inpatient, outpatient, day program or other partial hospitalization, emergency, diagnostic, treatment, liaison, follow-up, consultation, education, rehabilitation, prevention, screening, transitional living, medical prevention and treatment for alcohol and drug abuse.

Psychiatric Services directly supervises the following 10 state-operated facilities:

Name	*Location*	*Capacity (beds)*
Cottonwood Residential Treatment Center (CRTC)	Cape Girardeau	32
Hawthorn Children's Psychiatric Hospital (HCPH)	St. Louis	60
Fulton State Hospital (FSH)	Fulton	508
Metropolitan St. Louis Psychiatric Center (MPC)	St. Louis	125
Mid Missouri Mental Health Center (MMMHC)	Columbia	69
Northwest Missouri Psychiatric Rehabilitation Center (NMPRC)	St. Joseph	120
Southeast Missouri Mental Health Center (SMMHC)	Farmington	206
Southwest Missouri Psychiatric Rehabilitation Center (SWMPRC)	El Dorado Springs	30
St. Louis Psychiatric Rehabilitation Center (SLPRC)	St. Louis	212
Western Missouri Mental Health Center (WMMHC)	Kansas City	110

During the fiscal year 2000, Psychiatric Services provided inpatient services to 7,762 individuals.

APPENDIX III

CONTROLLED SUBSTANCES

A controlled substance is a drug or drug product that comes under the jurisdiction of the federal Controlled Substances Act of 1970. The narcotic, depressant, stimulant, hallucinogenic and anabolic steroid drugs that are covered by the Controlled Substances Act are listed in one of five schedules. Schedule I substances have no accepted medical use in the U.S. and have high abuse potential. Schedule II drugs have high abuse potential with severe psychic or physical dependence liability, and in general are substances that have therapeutic utility. Schedules III-V include drugs with decreasing levels of abuse potential.

The Comprehensive Drug Control Act of 1989, administered by the Bureau of Narcotics and Dangerous Drugs in the Missouri Department of Health, closely parallels the federal law. In some instances, however, Missouri's law is more stringent and takes precedence over federal law.

The federal and state laws related to controlled substances include the following:

- Records of controlled substances must be maintained for at least 2 years.

- Inventories and records of all controlled substances listed in Schedules I and II are to be maintained separately from all other records, and inventories and records of controlled substances listed in Schedules III, IV, and V are to be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records.

- An inventory must be conducted that contains a complete and accurate record of all controlled substances on hand on the date the inventory is taken. Federal law requires inventories be taken at least biennially. State law requires inventories be taken at least annually.

- For contaminated controlled substances, when disposal of controlled substances is in patient care areas, the controlled substances are to be destroyed by a physician, nurse, or pharmacist in the presence of another hospital employee. The destruction must be recorded and signed by both the physician, nurse, or pharmacist and the witnessing employee.