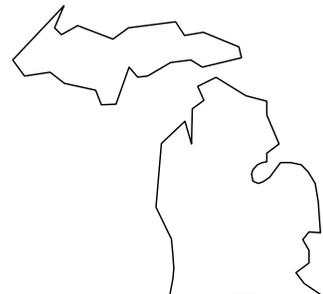


DEPARTMENT OF COMMUNITY HEALTH
AUDIT OF PHARMACY OPERATIONS

Michigan Department of Community Health
Office of Audit
Special Audits, Review and Compliance Section





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JANET OLSZEWSKI
DIRECTOR

March 8, 2006

Ms. Janet D. Olszewski, Director
Department of Community Health
Capitol View Building, 7th Floor
201 Townsend Street
Lansing, Michigan 48933

Dear Ms. Olszewski:

This is our report on our audit of pharmacy operations at the State hospitals/centers for the period October 1, 2002 through September 30, 2004.

This report contains an introduction; audit scope and methodology; objective, conclusion, findings and recommendations.

We appreciate the courtesy and cooperation extended to us during this audit.

Sincerely,

A handwritten signature in cursive script that reads "James B. Hennessey".

James B. Hennessey, Director
Office of Audit
Internal Auditor

TABLE OF CONTENTS

**DEPARTMENT OF COMMUNITY HEALTH
AUDIT OF PHARMACY OPERATIONS**

	Page
INTRODUCTION	1
OBJECTIVE	2
SCOPE AND METHODOLOGY	2
CONCLUSION, FINDINGS, AND RECOMMENDATIONS.....	3
1. Non-Controlled Substance Inventories	4
2. Controlled Substance Perpetual Inventory Records	5
3. Documenting Changes to Inventory Records	7
4. Controlled Substances Physical Inventories	8
5. Excess Medication Inventory (JCAHO Medication Testing).....	9
6. Distribution to the Treatment Units	10
7. Returns and Disposals of Medication	12
8. Authorized Prescribers.....	14
9. Lack of Informed Consent	15
10. Unauthorized Distributions of Flu Vaccinations to Employees	17
11. Reporting and Investigating Medication Errors.....	18
12. Employment of Individuals with Felony Convictions.....	20
13. Lack of Required Pharmacy Supervision	21
14. Storage of Controlled Substances	22
15. Audits of Medication Storage Areas.....	23
16. Pharmacy Purchasing.....	25
17. Inconsistent/Incomplete Pharmacy Policies/Procedures.....	28
Glossary of Acronyms and Terms	30
Corrective Action Plan.....	34

**DEPARTMENT OF COMMUNITY HEALTH
AUDIT OF PHARMACY OPERATIONS**

INTRODUCTION

At the time of our audit the Department of Community Health (DCH) operated the following seven state hospital/centers (facilities): Caro Center, Center for Forensic Psychiatry, Hawthorn Center (a children's facility), Huron Valley Center (operated through a contract with the Department of Corrections (DOC)), Kalamazoo Psychiatric Hospital, Mt. Pleasant Center (primarily a center for developmentally disabled), and Walter Reuther Psychiatric Hospital. These facilities provide treatment to a variety of patients including mentally ill children and adults, developmentally disabled individuals, and mentally ill prisoners (through a contract with the DOC). Each facility operates an in-house pharmacy. On November 17, 2004, the patients/prisoners formerly in the Huron Valley Center (HVC) were transferred to the Huron Valley Men's Facility, now called the Huron Valley Correctional Facility. DOC personnel are now handling the pharmacy operations for the patients/prisoners at that facility.

Pharmacies and pharmacists are subject to the provisions and requirements contained in the Michigan Administrative Code, Board of Pharmacy General Rules, (R338.471 et. seq.). The Michigan Administrative Code, Board of Pharmacy Controlled Substances, (R338.3101 et. seq.) provides additional responsibilities and requirements regarding the acquisition, storage, dispensing, administration and return/disposal of pharmaceuticals classified as controlled substances. For purposes of this report these requirements will be referred to as the Administrative Code.

During FY 03/04 DCH purchased pharmaceutical drugs from AmeriSource Bergen through a statewide contract totaling approximately \$12,648,789. Each of the facilities purchase pharmaceuticals classified as controlled substances; however, the majority of the purchases (\$9,563,034 or 76%) from AmeriSource Bergen pertained to psychotherapeutics. Some psychotherapeutics are also classified as controlled substances.

The requirements for medication records pertaining to controlled substances in facilities are set forth in R338.3154 of the Michigan Administrative Code, Board of Pharmacy Controlled Substances. All of the facilities have individually adopted their own internal policies and procedures relating to the maintenance of records for controlled substances.

OBJECTIVE

To assess the effectiveness of the internal control structure over the pharmacy operations at each of the DCH hospitals and centers for selected activities.

SCOPE AND METHODOLOGY

Our audit scope was to examine pharmacy operations at each of the facilities for the period October 1, 2002 through September 30, 2004. We reviewed the Administrative Code as it relates to pharmacies and controlled substances. We reviewed relevant facility policies and procedures. We interviewed selected staff from the DCH Bureau of Health Professions and from each facility.

We selected all seven facilities for the examination of their pharmacy operations. We examined documentation maintained in the pharmacies to determine compliance with policy and procedures governing the purchasing, storing, dispensing, and disposing of controlled substances at each facility. We examined the security of the pharmacy operations. We examined adherence to other policies and procedures relating to the administration of medications after the distribution to the treatment units by the pharmacy. We examined documentation maintained in selected clinical files to determine compliance with the Administrative Code and policies and procedures.

We selected a three-month period of time to test the movement of controlled substances at each facility. Copies of invoices for controlled substance purchases were traced to the pharmacy inventory records. Distributions of doses to medication rooms and other storage areas were traced to the distribution and administration records. Any doses returned to the pharmacy were then traced back to the pharmacy inventory records. Any

reductions in the inventories due to expired medications, etc. were then traced to expired medication logs or other such records when available.

Our audit began with an unannounced inventory of controlled substances at each facility's pharmacy on March 4th and 5th of 2004 and ended with an exit meeting on September 6, 2005.

CONCLUSION

Objective: To assess the effectiveness of the internal control structure over the pharmacy operations at each of the DCH hospitals and centers for selected activities.

Conclusion: The internal control structure over selected pharmacy activities at the DCH hospitals and centers were generally not effective. None of the facilities maintain inventories of non-controlled substances (Finding 1). Three facilities did not maintain perpetual inventory records of their controlled substances (Finding 2). The facilities that did maintain perpetual inventory records for their controlled substances did not always document changes to the inventories in the records (Finding 3). Three facilities did not always report or conduct required physical inventories of their controlled substances (Finding 4). Excess medications held in the treatment units at all of the facilities were not always being identified through regularly scheduled physical inventories (Finding 5).

The facilities were not always adequately documenting the distribution and receipt of controlled substances to the treatment units (Finding 6). The facilities were not adequately documenting returns or disposals of medications (Finding 7). Accurate and current listings of individuals authorized to prescribe medications were not being maintained at all of the facilities (Finding 8). The facilities were not always obtaining the recipients' informed consent before administering psychotropic or other medications (Finding 9). Some of the facilities provided flu vaccinations to its employees free of charge without first obtaining proper authorization (Finding 10). Medication/error reports were not being properly completed and evaluated (Finding 11). One facility knowingly employed a person in their pharmacy that had a felony conviction involving

controlled substances (Finding 12). One facility permitted its pharmacy to be operated without the required supervision (Finding 13).

We also found weaknesses involving the physical storage of controlled substances (Finding 14), a lack of monitoring of medication storage areas (Finding 15), a lack of controls over purchasing (Finding 16), and inconsistent and sometimes incomplete policies and procedures (Finding 17).

FINDINGS AND RECOMMENDATIONS

We believe the recommendations contained in this report will strengthen the hospital/center pharmacy internal controls and improve compliance with the Administrative Code. Establishing and maintaining an internal control structure is an important management responsibility and is necessary to ensure the proper use of resources. Internal controls include the plan of organization, methods, and procedures adopted by management to provide reasonable assurance that goals and objectives are met; resources are used consistent with laws, regulations and policies; resources are safeguarded against waste, loss, and misuse; and reliable data is obtained, maintained, and fairly disclosed in reports.

The processing of pharmacy transactions in seven hospitals/centers differed from each other in some respects. For the most part, each facility instituted their own policies and procedures to reduce management concerns relating to the dispensing of medications.

Finding

1. Non-Controlled Substance Inventories

None of the DCH facilities conducted physical inventories or maintained any kind of inventory records of their non-controlled substance pharmaceuticals purchased and maintained in their pharmacies. Without an inventory control program, the facilities cannot adequately account for their purchases of non-controlled substances.

During our audit we learned that DCH facilities maintain inventory records of only controlled substances purchased and used. No inventory records are maintained regarding purchase, storage, use, or disposal of any other pharmaceuticals, including high value psychotherapeutic drugs. The majority of pharmaceuticals purchased and used in each facility were for psychotherapeutic medications. Accurate and dependable inventory records are necessary to help ensure that pharmaceuticals are safeguarded against waste, loss, and misuse. Inventory systems can provide the pharmacy with information regarding stock of drugs on hand, turnover rates, reorder notification, expiration dates, disposal amounts and dates, and other data useful in the efficient operation of the pharmacy.

The State of Michigan Financial Management Guide requires agencies maintaining warehouses or stock centers to establish and maintain an inventory control program that is verified at least annually by a physical count. An accurate physical inventory is essential to being able to reconcile purchases, disbursements/disposals to the drugs actually on hand. Without an adequate inventory system, DCH cannot be reasonably assured that its pharmaceutical purchases are adequately safeguarded, and protected against waste, loss, and misuse.

Recommendation

We recommend that DCH immediately develop and implement an inventory control program that requires at a minimum, an annual physical inventory of all the pharmaceuticals purchased and maintained by the facilities.

Finding

2. Controlled Substance Perpetual Inventory Records

Three facilities were not maintaining perpetual inventory records for all their controlled substances.

Controlled substances are medications having a potential for abuse, such as narcotics, stimulants, and sedatives. These medications require special handling and security measures. The drugs classified as controlled substances are those

listed in the Controlled Substance Act of 1970 that is administered by the Drug Enforcement Agency (DEA) of the Justice Department. Controlled substances are categorized into five schedules with those classified as Schedule I having the greatest potential for abuse. DCH facilities only maintain Schedule II to V controlled substances on site.

The Administrative Code, R338.3151, indicates, “A licensee shall make and maintain a complete and accurate inventory of all stocks of controlled substances.” Our testing of the controlled substance medication records disclosed that three facilities were not keeping appropriate inventory records for all controlled substances. We found the following deficiencies:

- a. One facility did not maintain inventory records for Phenobarbital, a schedule IV controlled substance.
- b. One facility did not maintain inventory records for any schedule III, IV, and V controlled substances.
- c. One facility did not maintain inventory records for any controlled substances taken from the locked cabinet located in the pharmacy area and placed on open shelving (referred to as the bin area) prior to dispensing. At the time the substances were removed from the locked cabinet, the doses were removed from the inventory records and no separate inventory records for controlled substances were maintained to account for the doses in the bin area.

The failure to maintain perpetual inventory records for all controlled substances is a violation of the Administrative Code and increases the likelihood that loss, misuse, or theft of these drugs could go undetected.

Recommendation

We recommend that DCH ensure that all facilities maintain perpetual inventory records for all controlled substances as required by the Administrative Code.

3. **Documenting Changes to Inventory Records**

The DCH facilities that maintained perpetual inventory records for their controlled substances did not always adequately document changes in their inventory records caused by purchases, returns, and disposals.

The Administrative Code, R338.3154(2)(e), requires that the medication records include “an annual physical inventory and status of any discrepancies between the inventory and the records of acquisition and the dispensing records.” In addition, R338.3154(15) states: “An individual who is responsible for administering a controlled substance or a portion thereof shall record the quantity, disposition, and an explanation of the destruction of the controlled substance on the proper accountability record....”

In a number of instances we found discrepancies between the physical inventory and perpetual inventory records due to purchase, return, or disposal of controlled substances that were not identified or adequately disclosed. The following are examples of issues found at the various facilities audited:

- a. A purchase of 21 doses of Adderal was made at a local pharmacy and never recorded on the inventory records, resulting in an understatement on the perpetual inventory records.
- b. There were 28 milliliters of Lorazepam returned to the pharmacy by a unit and never recorded as a return on the perpetual inventory records. This resulted in an understatement on the inventory record.
- c. There were five doses of Estazolam sent to a unit, but not subtracted from the inventory balance, resulting in an overstatement on the perpetual inventory record.
- d. One dose of Vicodin that was returned to the pharmacy by a unit did not appear on the perpetual inventory record.
- e. Fifteen doses of Ambien were not recorded on the expired medication log as required by facility policy even though they were listed as expired and removed from the pharmacy perpetual inventory. Instead of being returned

or destroyed, we subsequently learned that these expired medications were given to a doctor at the facility.

- f. Five different medications (a total of 448 doses) listed as expired and removed from the pharmacy perpetual inventory records were not recorded on the expired medication log as required by facility policy. This facility did not use Guaranteed Returns, so we were unable to determine what happened to the medication.

Periodic physical inventories need to be reconciled to the perpetual inventory records in order to maintain an accurate inventory of controlled substances. Discrepancies should be identified, investigated and explained immediately. Implementing such a process would help ensure that changes to the inventories are being accurately identified and posted to the inventory records. Failure to maintain adequate documentation of changes in inventory amounts increases the likelihood that the controlled substances could be lost, misused, or stolen without detection.

Recommendation

We recommend that DCH facilities reconcile the physical inventory counts to the perpetual inventory records whenever a physical inventory is conducted and explain any discrepancies fully.

4. Controlled Substances Physical Inventories

Pharmacists did not always perform or report scheduled inventories of controlled substances as required by their facilities' policy and procedures, the Administrative Code, and the Michigan Public Health Code.

Each facility has a policy requiring performance of a weekly, monthly, or yearly inventory of all controlled substances. In addition, Administrative Code, R338.3152, also requires that: "...an inventory shall be taken annually of all stocks of controlled substances in the possession or control of the licensee...." The Michigan Public Health Code, Section 7321, requires completion of these annual inventories and submission of the results to the Board of Pharmacy within 90 days

of May 1. Failure to do so may be punishable by a civil fine of not more than \$25,000.

Three out of seven hospitals did not perform a regular controlled substance inventory (on a weekly, monthly, or yearly basis) in accordance with their facilities' policies. Of the 75 inventories that should have been conducted by these three facilities, 22 (29%) were not conducted, ranging from 1 to 17 missing inventories. One facility did not perform counts/inventories on all of the controlled substances in their possession. This facility only inventoried 16 of 45 (36%) of their controlled substances for the period tested. In addition, one facility failed to report the results of their annual 2004 inventory as required by the Michigan Public Health Code.

Failure to complete timely inventories may result in errors remaining undetected for longer periods of time and increase the likelihood that once detected the errors may not be as easily explained. The facilities also may be at risk of administrative sanctions if they fail to meet the requirements of the administrative and public health codes.

Recommendation

We recommend that DCH establish and implement policies and procedures to ensure inventories are conducted in accordance with their internal policies/procedures, the Administrative Code, and the Public Health Code.

5. Excess Medication Inventory (JCAHO Medication Testing)

The facilities did not have controls in place to monitor and detect excess medication supplies that were being maintained in the treatment units.

During our examination of the latest Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accreditation at one facility, we discovered that JCAHO had made a finding stating that excess medications were being kept in the hospital treatment units. The actual finding made by JCAHO did not specify the quantities of medication that were excessive, but they did note that the amounts in the individual patient medication drawers did not correlate accurately with the

amounts that should have been dispensed from the pharmacy and the amounts administered to patients as indicated by a patient administration record. Generally, facility pharmacies dispense sufficient doses of medications to the unit that should be administered until the next delivery date, generally weekly. If any doses from a delivery are refused or otherwise not administered to the patient the treatment unit may have doses on hand in excess of what is required to be administered up to the time the next delivery is received.

As a follow-up to the issue identified by JCAHO, we reviewed the medications for 30 patients at five of the seven facilities. These patients were receiving 204 different medications. Our results were similar to that of JCAHO. We found 21 instances, ranging from 3 to 6 per facility (approximately 10%), where the doses in the treatment units exceeded what was needed until the next medication delivery.

Dispensing medications to the treatment units in quantities that exceed the amount necessary to provide treatment represents a control weakness and increases the likelihood that the medications may not be used appropriately.

Recommendation

We recommend that DCH establish policies/procedures to ensure that only medications necessary for the immediate care needs of the patients be held/maintained in the treatment units.

6. Distribution to the Treatment Units

The facilities did not all have controls in place to adequately account for the distribution and receipt of controlled substances between the pharmacy and the treatment unit.

DCH facilities did not always obtain the signatures of the pharmacist or the treatment unit when controlled substances were dispensed by the pharmacy to the treatment unit as required by facility policy. In addition, dual signatures were not always obtained when a count is completed of controlled substances in the unit at shift change or when they have been destroyed/disposed of.

The Administrative Code, R338.3154 (3)(c)(vi & vii), requires that the distribution record maintained for the doses distributed to a treatment unit contain both the name of the distributing pharmacist and the name of the individual in the nursing unit who receives the substance. Each facility also has policies requiring the signature of both the pharmacist distributing (deliverer) and the unit receiving (recipient) whenever controlled substances are dispensed from or returned to the pharmacy. Each facility also has a policy requiring a verification/count of controlled substances within the unit by both the outgoing and incoming nurses at each shift change and policies requiring two signatures when a controlled substance is wasted or destroyed.

Each facility has developed a form to be used within their treatment units to track the delivery and administration of controlled substances. These forms are referred to by various names including the Controlled Substance Disposition and Audit Report, the Controlled Substance Medication Sign-Out Sheet, the Controlled Substance Sign-Out and Count Sheet, etc. Each of these forms includes the medication, quantity, date, receiver signature, and deliverer signature. A signature by two different individuals is required as verification of the quantity. When a shift ends and another nurse comes on duty, a count is performed of the controlled substances and both nurses verify the accuracy of this count, generally by initialing the count form.

At one facility we found thirty-six instances where the deliveries were not documented by the pharmacy personnel (deliverer) and/or documented by the nurse in the unit (receiver). At another facility we found seven instances where the nurses (receiver) signature was not present. At a third facility we found 12 instances where there was no documentation of a count of controlled substances at the time of a shift change.

When a medication has been wasted (dropped on the floor, spit out by the patient, etc.) facility policies generally require that two employees attest to the fact that the

item was wasted. We found 94 (23%) instances out of 404 wasted items reviewed at two facilities, which contained no second signature attesting to the waste.

These dual signatures and/or initials provide assurance about the accuracy of the amount of medication delivered/received/counted/destroyed. Without these assurances, DCH cannot be reasonably assured that it is accurately accounting for wasted medications. Exploring the reasons for the large discrepancies between facilities could also provide DCH with some valuable insight on how to minimize the amount of medications that are being wasted.

Recommendations

We recommend that appropriate signatures be obtained at the time of medication transfer, unit shift change, and disposal of wasted medications to ensure the accuracy of controlled substances on hand.

We also recommend that DCH review the policies and procedures at facilities with little waste and determine whether those procedures could be applied at the facilities experiencing a large amount of waste.

7. Returns and Disposals of Medication

DCH has not implemented controls to ensure an accurate accounting of medications that are returned for refund or otherwise disposed of. None of the DCH facilities maintain accurate records documenting the medications that are being distributed/released to a licensed disposal company.

DCH, through its purchase contract with AmeriSource Bergen, also has a relationship with a company called Guaranteed Returns. Guaranteed Returns is licensed by the Drug Enforcement Administration (DEA) to dispose of expired drugs, including controlled substances. When a facility has accumulated a quantity of medications that it cannot use because the expiration date has passed, the medications were damaged (dropped on floor, broken, etc.), or other reasons they can contact Guaranteed Returns. Guaranteed Returns will pick up the medications

from the facility and determine what items can be returned to the manufacturer for a refund and what items must be destroyed. Guaranteed Returns will destroy the non-returnable items and process refund amounts from the manufacturer for the returnable items, taking a percentage of the refund for their handling fee. Normally medications that are unopened and for which the pharmaceutical company has a demand are the returnable medications. The facility will receive two manifests from Guaranteed Returns, one listing the returnable medications and the corresponding refund amount, and the other listing the non-returnable destroyed medications. The refund may be paid directly to the facility or be recorded as a credit toward future purchases from AmeriSource Bergen. Guaranteed Returns is not reimbursed separately for this service as they receive a percentage of the total amount of the refunds.

The Administrative Code, R338.3153 (7), requires that: "Records of controlled substances distributed to another licensee, shall include all of the following information and be maintained in an appropriate file...(c) name and quantity of controlled substance distributed." This type of documentation must be maintained for controlled substances per the Administrative Code. Maintaining accurate records of medications returned through Guaranteed Returns would provide the facilities with a means to determine whether they had received appropriate credit or refunds for returned medications. Without this documentation, DCH has no way of knowing of whether they are receiving appropriate refunds.

The facilities maintained little documentation to support the return of non-controlled substances; therefore we focused our examination on documentation for disposal of controlled substances. Six of the seven facilities did not maintain accurate inventory records regarding disposals and one facility did not maintain any records to document the disposal of controlled substances. For this facility we were not able to determine whether the controlled substances were appropriately destroyed. For the other six facilities we found instances where the perpetual inventory records listed the controlled substances as expired, wasted, or disposed of; however, the disposals were not listed on the expired medication records.

Consequently, we were unable to determine the final disposition of over 1,300 doses of controlled substances that were identified from either the inventory records or the expired medication logs.

We found five facilities that did not reconcile their expired medication logs to the manifests received from Guaranteed Returns. One facility used Michigan Waste Services to dispose of their medications, so they did not receive any manifests for comparison purposes nor did they receive any refund or credit for the disposal of their medications. One of the six did not retain their expired medication logs after the disposal company picked up the medications.

Without the use of appropriate disposal documentation and reconciliation to Guaranteed Return manifests, there is no assurance that the facilities are properly disposing of all medications and/or receiving the appropriate credit for those returned.

Recommendation

We recommend that DCH facilities maintain documentation of disposals and reconcile that documentation to the returnable/non-returnable manifests received from Guaranteed Returns.

8. Authorized Prescribers

Two DCH facilities did not maintain certain information pertaining to the individuals authorized to prescribe controlled substance medications as required by the Administrative Code.

The Administrative Code, R338.3153a, states: “prescriptions for controlled substance medications to be dispensed for administration to an inpatient in a medical institution shall contain all of the following information...the prescriber’s name, address and drug enforcement administration (DEA) number. In place of including the address and DEA number on each medication order, the pharmacy may maintain a separate list of authorized prescribers. The list shall contain the prescriber’s name, address, and DEA number.”

One of the facilities did not have a current list of the individuals authorized to prescribe medications. This facility had experienced many changes in staff authorized to write prescriptions/medication orders that were not reflected on the listing. Prescriptions/medication orders were being written by physicians who were not on the list and physicians no longer at the facility were still on the authorized prescriber list. One other facility did not maintain any list of individuals authorized to prescribe/write medication orders. Neither of these facilities used the alternative procedure of including the address and DEA number of the prescribers on the individual medication orders.

Because of the potential for abuse with controlled substances, DCH needs to ensure that it accurately monitors the individuals authorized to prescribe controlled substances in its hospitals and centers. Maintaining an accurate and up-to-date list would also help ensure that controlled substances are only dispensed or prescribed by individuals with the proper authorization.

Recommendation

We recommend that DCH ensure that each facility maintain an appropriate authorized prescriber list in accordance with the Administrative Code.

9. Lack of Informed Consent

Six out of the seven facilities could not always document that they had explained the specific risks of the most common adverse side effects associated with a particular psychotropic medication before it was administered to recipients as required by the Mental Health Code. In addition, the facilities could not document that informed consent forms had been obtained from the recipient before the drugs were administered as required by facility policy.

The Mental Health Code, Section 330.1719, states, “The prescriber or, if the prescriber is not on site, the individual administering a drug shall explain to a recipient the specific risk, if any, to the recipient of the most common adverse effects that have been associated with any psychotropic medication prescribed for

the recipient. A written summary of the most common adverse effects shall be provided to the recipient by the person dispensing the drug.”

In addition, each of the facilities has a policy requiring the prior informed consent for treatment by the recipient before psychotropic and/or other specified medications can be administered. Each facility has developed forms that when signed by the patient and/or guardian authorizes the administration of the medication and acknowledges that they have been informed of potential side effects associated with the medication.

There are situations where it is not necessary to obtain the informed consent from the patient/guardian. An example would be the use of a psychotropic drug that is necessary to prevent physical injury to the individual or to others. In this situation, the informed consent of the individual is not required; however, the prescriber is still required to explain the risks and adverse effects associated with the medication.

We examined 282 instances where patients were receiving medications requiring an informed consent. In six of the seven facilities we found 66 (23%) instances, ranging from 1 to 34 per facility, in which the documentation of the informed consent of the patient and/or guardian was not located in the patient’s file.

The failure to document the communication of the risks and adverse effects associated with psychotropic medications and/or that the patient has consented to the administration of the medication is a violation of the Michigan Mental Health Code and the facilities’ policy/procedures. In addition, DCH could be exposing itself to increased risk of liability by not ensuring that recipients/guardians are informed of the potential adverse side effects.

Recommendation

We recommend that documentation of the communication of adverse side effects and/or the informed consent be retained in the patients’ record as required by Mental Health Code and facility policy.

10. Unauthorized Distributions of Flu Vaccinations to Employees

Four facilities provided its employees with an additional benefit in the form of flu vaccinations that lacked any formal authorization.

Flu vaccinations were provided by the four facilities without cost to 747 DCH facility employees during fiscal year 03/04 at a total cost to the facilities of \$5,472. This practice has never been officially authorized as an employee benefit and DCH Personnel has not developed a policy authorizing free flu vaccinations for facility employees. We discovered that this topic had been discussed at a Management Leadership Meeting with all DCH hospital/centers on October 22, 1996. The minutes of that meeting stated that, “This year each hospital and center will proceed according to the past practice. A consistent policy of availability will be proposed to the director of the department and Office of State Employer by DCH Personnel given contract issues and need for consistent practice.” DCH Personnel has not yet created a policy to propose to the director of the department and Office of State Employer (8 years later).

DCH should immediately suspend this practice until it seeks and receives guidance concerning the appropriateness of providing vaccinations to its employees at state expense. At a minimum, DCH needs to determine whether this practice is considered an employee benefit that needs specific statutory approval.

Recommendations

We recommend that the DCH determine whether it needs specific authority to provide flu vaccinations to its employees.

We also recommend, if DCH has the authority and wishes to continue this program, that it develop a policy regarding the administration of flu vaccinations for all DCH facility employees.

11. Reporting and Investigating Medication Errors

The facilities had not implemented an effective review process to ensure that medication error/incident reports were being completed and evaluated in accordance with the facilities' policies and procedures.

Each facility has policies and procedures regarding the reporting and investigation of medication errors or medication incidents. Generally, any medication error or incident must be reported when discovered. The facilities are not consistent in terms of how they treat and classify errors. For instance, some facilities classify both dispensing and administration errors as medication errors, while others classify only the incorrect administration of a dose as a medication error. For those facilities, errors not resulting in the actual administration of a dose to the patient are classified as medication incidents. These facilities track medication incidents separately from medication errors.

Each facility has developed its own form that must be used when reporting a medication error or incident such as the date and time of discovery, who discovered the error, if the medication was actually administered to the patient, when the doctor was notified, any harm to patient (level of severity), notification to patient/parent/guardian, levels of review, etc. The Pharmacy and Therapeutics Committee, or similarly named committee, ultimately reviews the reports.

The Mental Health Code, Section 330.1143a, requires that the facilities establish a review process "for the purpose of improving the quality of patient care provided in the facility. This review shall include the quality and appropriateness of the care provided." These incident reports/medication error reports are one of the tools developed by the facilities to evaluate and improve patient care.

We examined 112 medication error or incident reports completed at the seven facilities. We identified 155 deficiencies with how these reports were completed, ranging from 1 to 65 per facility. The deficiencies included the following:

- a. There were 26 instances involving 3 facilities where there was no documentation that the patient, guardian, or parent was notified of the error. Twenty-one of these instances occurred at one facility.
- b. There were 52 instances involving five facilities where there was no documentation that the errors had been reviewed by the Pharmacy and Therapeutics Committee. These deficiencies ranged from a low of 1 to a high of 17 instances.
- c. There were 16 instances involving 4 facilities where there was no evidence that the severity of the error had been assessed.
- d. There were 21 instances involving 3 facilities where there was no evidence that the physician had reviewed the error.
- e. There were 11 instances involving three facilities where the date and time that the physician was notified of the error was not documented.
- f. There were 2 instances involving 1 facility where there was no documentation that the error had been communicated to the pharmacy.
- g. There were 6 instances involving 2 facilities where the date and time that the error occurred was not documented and 9 other instances, also involving two facilities, where the date and time the error was discovered was not documented. These situations were only common to one facility.
- h. There were 8 instances involving 3 facilities where the person that discovered the error did not complete the report. Six of these instances occurred at 1 facility.
- i. There were 4 instances at 1 facility where the report was not filed during the shift when the error was discovered.

An accurate and complete assessment of medication errors is essential to an effective quality review program. These reports should help the facilities assess why errors are being made and identify ways to ensure that they are not repeated.

Recommendation

We recommend that DCH ensure that medication error/incident reports are properly completed and utilized in the assessment of patient care within the facilities.

12. Employment of Individuals with Felony Convictions

One DCH facility knowingly permitted an individual with a felony conviction involving controlled substances to work in its pharmacy even though the position was subject to the policies and procedures of the Department of Corrections, which prohibited hiring anyone with a felony conviction.

In addition to being a psychiatric hospital, one of the facilities was also a correctional facility, funded through the DOC appropriation. As a correctional facility this facility was required to follow DOC policies and procedures. DOC employment policies prohibit the hiring of anyone who has a controlled substance violation in any jurisdiction. The Corrections Code of 1953, Public Act 232, states, “An individual who has been convicted of a felony, or who is subject to any pending felony charges, shall not be employed by or appointed to a position in the department.”

A criminal background check was performed for this facility on a pharmacist provided by a contract agency. This background check revealed that the pharmacist had two felony convictions involving controlled substances. The facility director was informed of these convictions and still authorized this individual to perform duties within the pharmacy. As a condition of this individual’s probation, the pharmacist’s license became limited and restricted. The court order stated that the pharmacist could only practice under the direct supervision of another pharmacist. Depending on the size of the pharmacy staff at the facility, it could be difficult for a pharmacist with a limited and restricted license to be supervised 100% of the time.

DCH has not established any formal policies and procedures with respect to any hiring restrictions based on a person’s criminal history. The DOC requires criminal background checks be performed on all prospective hires. DCH needs to consider adopting requirements and standards for all its prospective new hires. Sound business practice and judgment suggest that individuals with controlled substance felony convictions would not be ideal candidates for a position in a pharmacy that

routinely deals with controlled substances. In addition, in this particular instance, a person known to have a felony conviction involving controlled substances was hired in direct violation of DOC policy. The Bureau of Hospitals and Centers immediately had this person removed upon being notified of the situation by the audit staff.

Recommendation

We recommend that DCH develop formal policies and procedures regarding the hiring of convicted felons, which at a minimum should consider requiring criminal background checks for any prospective employee that will have access to pharmaceuticals.

13. Lack of Required Pharmacy Supervision

One facility did not always ensure that its pharmacy operation was being directed and supervised by a licensed pharmacist as required by the Administrative Code.

The Administrative Code, R 338.486 states, “pharmacy services shall be directed and provided by a licensed pharmacist. Pharmacy personnel who assist the pharmacist by performing delegated functions in the care of the inpatients shall be supervised by a pharmacist who is on the premises of the medical institution.” We inquired with personnel at DLEG (Department of Labor and Economic Growth) regarding the operation of a pharmacy by a person, such as a doctor, who holds a controlled substance license. They advised us that any controlled substance license would only allow the performance of activities associated with the type of license issued such as the authorization to write prescriptions for controlled substances and would not include the operation of a pharmacy.

There are occasions when a State of Michigan employed pharmacist may not be available to personally supervise the pharmacy operations. This would occur due to vacations and sick days where the facility’s pharmacy department is not large enough to have more than one pharmacist on staff. Generally, facilities have

pharmacists under a contractual agreement that will operate the pharmacy in the absence of the regular pharmacists.

One facility did not use a contractual pharmacist to direct the pharmacy operations when the regular pharmacists were unavailable. Instead, the facility used the medical director whose controlled substance license did not authorize this person to supervise and direct the operations of the pharmacy. By not complying with the terms of the Administrative Code, the facility could be subjecting itself to possible regulatory sanctions that could impact its accreditation.

Recommendation

We recommend that DCH ensure that only persons that hold the proper license supervise and direct the operations of the pharmacies at the facilities.

14. Storage of Controlled Substances

Two DCH facilities had not implemented adequate physical controls over the storage of controlled substances.

The Administrative Code, R338.3143, states: “A controlled substance that is listed in schedules 2, 3, 4, and 5...shall be stored in a securely locked, substantially constructed cabinet, room, or cart. However, in a pharmacy, the controlled substances may be dispersed throughout the stock of non-controlled substances in a manner to obstruct the theft or diversion of controlled substances.”

All of the controlled substances at one facility were stored together on an open shelf, separate from the other drugs in the pharmacy. The Bureau of Health Professions advised us that if controlled substances are not stored in a securely locked area, the controlled substances must be mixed together with the non-controlled substances to make it more difficult to remove only the controlled substances. At another facility we discovered five vials of Diazepam 10 ml located in a box, inside an unlocked drawer holding the seals and logs for the emergency drug box.

The failure to properly store controlled substances violates the Administrative Code and increases the likelihood that any loss or misuse, including theft of these medications could go undetected.

Recommendation

We recommend that DCH ensure that facility pharmacies implement procedures to ensure that all of their controlled substances are stored in a secure location in accordance with the Administrative Code.

15. Audits of Medication Storage Areas

None of the facilities have implemented effective monitoring procedures for the storage areas of medications throughout the facility, particularly in the treatment units.

Most facilities, in addition to the medication rooms located in the various treatment units, also store medications in night drug cabinets and emergency drug boxes. All seven facilities utilize a night drug cabinet and six of seven facilities maintain emergency drug boxes. The night drug cabinet is in an area within the facility where certain medications are stored and can be obtained so a medication not stored in the medication room can be obtained and administered at times when the pharmacy is closed. The emergency drug boxes may be located in secure locations in the treatment units or other areas in the facility used by patients. Within the emergency drug box there are various medications that must be approved by the interdisciplinary practitioners committee within the facility. These may be medications used to treat respiratory distress, heart problems, allergic reactions, or other medical emergencies. In some instances a very limited amount of a controlled substance was also kept in the emergency drug boxes.

The Administrative Code, R338.486(4)(i), requires the facilities to maintain medications in areas located within a medical institution, other than the pharmacy area, so that medications can be obtained and administered at times when the pharmacist is not available or the pharmacy is closed. This same section of the

Administrative Code also states, "...A pharmacist shall audit the storage locations as often as needed to guarantee control, but not less than once every 30 days."

Our review of the required monthly audits of the night drug cabinets, emergency drug boxes, and medication rooms disclosed the following:

- a. Four of the seven facilities did not maintain documentation to substantiate that all monthly audits of the night drug cabinet were performed.
- b. Of 3 emergency drug boxes examined at one facility there were 2 instances where 4 of 23 items in the box were not on the approved list of contents, and one instance where 6 of 23 items in the box were not on the approved list.
- c. Documentation was missing for 348 (59%) out of a total of 588 required pharmacist medication room audits involving five of the seven facilities.
- d. At one facility, the night drug cabinet included 13 out of 129 medications that had expired and 5 others that were to expire in the next month. This would tend to indicate that regular, monthly, and comprehensive audits had not been performed.

Regular monitoring through these required audits is an important tool to help ensure that medication supplies are being adequately safeguarded and maintained in appropriate and necessary quantities. By not performing these audits on a regular basis, the pharmacy has no accurate method to determine the quantity and type of medications on hand and available at any particular time. The pharmacies could be ordering medications that they don't need, unnecessarily wasting medication by allowing them to exceed their expiration date, and even perhaps causing residents to go without needed medications because the pharmacy may not have been aware that the needed medication was depleted or expired.

Recommendation

We recommend that all of the DCH facilities, under the direction of the licensed pharmacist, improve their monitoring activities over the storage areas located throughout the facilities by ensuring that audits/inspections are conducted not less than every 30 days.

16. Pharmacy Purchasing

The DCH facilities have not implemented adequate and effective internal controls over their pharmacy purchasing activities.

Our review disclosed the following weaknesses:

- a. The DCH facilities have not established an appropriate segregation of duties over the ordering, receiving and maintenance of the medications and medication records.

Sound internal controls include procedures adopted to provide reasonable assurance that resources are safeguarded against waste, loss, and misuse and include such procedures as preventing a single employee to document and approve all aspects of a transaction.

At least three facilities did not maintain appropriate segregation of duties within the pharmacy. One of the facilities does not have sufficient employees within the pharmacy department to allow for a proper segregation of duties. At the other two facilities a pharmacist or technician would place the order, receive the ordered pharmaceuticals, maintain the controlled substances perpetual inventory records, perform the physical inventories, and reconcile the physical inventory results to the controlled substances perpetual inventory records. At a minimum, the person placing the orders should not be accounting for the receipt/delivery of the order and the person maintaining the perpetual inventory records should not be performing the actual inventory counts and reconciliation.

Without a proper separation of duties, medications and other pharmacy resources could be subject to waste, loss, and misuse.

- b. Invoices were not being initialed and dated by pharmacy staff to recognize and document the receipt of pharmaceuticals.

Four of the facilities have internal policies that require an initial/signature and date to be recorded on the vendor invoice to signify receipt of the pharmaceuticals. The remaining three facilities have made it their practice to initial and date the vendor invoices, but have not adopted formal policies and procedures. The Administrative Code, R338.3153 (3), also indicates “A licensee shall initial the invoice and indicate the date that the controlled substances are received.” The original invoices are forwarded to the facilities accounting department for payment. These invoices are the only documents that accounting can use to verify that the medication was actually received. Medications received at the facilities are delivered directly to the pharmacies and therefore, receiving documents are not available as would be in the normal DCH purchasing process.

AmeriSource Bergen delivers medications directly to the pharmacy along with a packing slip/invoice. These documents serve as the record of delivery and bill for the facility. We examined 431 invoices at the seven DCH facilities. In this examination we found 90 invoices, ranging from 4 to 43 per facility that did not include the initial of pharmacy staff and/or the date received.

Initialing and dating the invoice serves to document that the medications were received and billed appropriately. As pointed out in the previous section, the person receiving and approving the invoice should not be the same person that placed the order. Ideally, the invoices should be sent from the vendor directly to the accounting department and the pharmacy would send a copy of the packing slip with the date and initials of the person that received and approved the shipment. The invoice should then only be paid after being matched against the packing slip.

- c. Five of the DCH facilities had not implemented procedures to ensure that pharmaceuticals were not being purchased using the State of Michigan issued procurement card.

The Procurement Card Program Cardholder Manual indicates that “the procurement card may not be used for any of the following categories:...Health, Legal, and medical services.” In addition DCH issued further clarification of this restriction in Attachment A, DCH Human Resources and Administrative Services, Administrative Services Division, Credit Card Purchasing Information, Revised January 2002. Health and medical supplies were listed as specific examples of items that cannot be purchased by credit card.

There are times when medication required for patients cannot be obtained from the pharmacy or from other storage areas within the facility. This generally occurs when a patient is admitted after the pharmacy closed. The patient may be prescribed medication that is not available in the night cabinet or the emergency medication boxes. Since the medication is needed immediately, AmeriSource Bergen cannot be used to obtain the needed medication.

All seven of the facilities obtained pharmaceuticals not found in the night cabinet or other hospital storage locations from a source outside of the pharmacy during our audit period. Five of the facilities used the State of Michigan issued procurement card for the purchase of those pharmaceuticals. The remaining two facilities maintained charge accounts with local 24-hour pharmacies for such purchases. The use of a procurement card to purchase medical supplies is a violation of DMB and DCH policy and procedures.

Recommendations

We recommend that the pharmacy staff initial and date all invoices to document that the pharmaceuticals were received.

We also recommend that DCH ensure that facilities segregate duties among pharmacy staff in order to safeguard resources against waste, loss, and misuse.

We further recommend that DCH implement procedures to ensure that facilities do not use the procurement card to purchase pharmaceutical supplies.

17. Inconsistent/Incomplete Pharmacy Policies/Procedures

DCH does not have standard, statewide policies and procedures to ensure that the facilities are uniformly operating the pharmacies in accordance with the Administrative Code and other applicable policies and procedures.

Although each pharmacy may operate in a slightly different capacity, due to differences in the populations that they serve, the pharmacy department operations are very similar in nature. Each pharmacy purchases medications from the same vendor (based upon a statewide contract negotiated by DMB); performs various types of inspections; maintains medication storage rooms, emergency drug boxes and night cabinets located in various units or areas throughout the facility; disposes of/returns expired and/or wasted medications; etc. Yet each pharmacy develops its own policies and procedures, forms to be used, processes followed, etc. for the purchase, inventory, distribution, and administration of medications. These policies are not always complete or consistent. For example, one facility, while having adopted many policies and procedures, did not have any policies relating to the following areas: inventories, formularies, authorized prescribers, emergency drug boxes, ordering/purchasing medications and the preparation of medication orders. Another facility had a procedure in which controlled substances were removed from a locked cabinet, in which an inventory was maintained, and placed into the shelving area among the non-controlled substances where an inventory was not maintained. A third facility used an inventory card to track medication that was expired, returned, dispensed to/from the units. This procedure required detailed recording of transactions in a small area of space, making it extremely difficult to read and track transactions that were processed. Each of the seven facilities had developed their own controlled substance administration records. Two facilities had policies that did not require the maintenance of inventory records for specified controlled substances contrary to the provisions of the Administrative Code.

Another facility had a practice of storing all of their controlled substances on an open shelf.

It would be beneficial for both the facility and pharmacy employees if DCH would standardize their policies/procedures/forms. Extensive cross training in pharmacy operations would not be necessary if an employee were to transfer to a new facility. Standardized policy/procedures/forms would make oversight and monitoring of pharmacy operations at DCH facilities easier. Without complete and consistent policies, DCH cannot be assured that the pharmacy departments are being operated uniformly, effectively, and efficiently.

Recommendation

We recommend that DCH establish consistent policies and procedures applicable to pharmacy operations at all DCH facilities.

GLOSSARY OF ACRONYMS AND TERMS

Adderal	An amphetamine typically prescribed for the treatment of attention deficit hyperactivity disorder or for the treatment of narcolepsy.
Administrative Code	Michigan Administrative Code, Board of Pharmacy, General Rules and Controlled Substances.
Ambien	A sedative-hypnotic controlled substance used for the short-term treatment of insomnia.
CMS	Centers for Medicare and Medicaid Services
Controlled Substance	Medication having a potential for abuse, such as narcotics, stimulants, and sedatives requiring special handling and security measures. Controlled substances are those drugs listed in the Controlled Substance Act of 1970 that is administered by the Drug Enforcement Administration (DEA) of the Justice Department. Controlled drugs are categorized into five schedules.
DCH	Department of Community Health
DOC	Department of Corrections
DMB	Department of Management and Budget
Diazepam	Diazepam is used to relieve anxiety, nervousness, and tension associated with anxiety disorders. It is also used to treat certain types of seizure disorders and muscle spasms.
Dispensing	To prepare for administration of medication.
Doses	A specified quantity of a therapeutic agent, such as a drug or medicine, prescribed to be taken at one time or at stated intervals.

GLOSSARY OF ACRONYMS AND TERMS

Emergency Drug Box	A container holding emergency medication for patients in the treatment unit.
Estazolam	Used for short-term treatment of insomnia.
Formulary	A listing of pharmaceutical substances approved for use within the facility by the hospital/center Pharmacy and Therapeutics Committee.
Informed Consent	The process by which a fully informed patient can participate in choices about health care. It originates from the legal and ethical right the patient has to direct what happens to their body and from the ethical duty of the physician to involve the patient in his/her health care.
Internal Controls	All measures and practices that are used to mitigate exposures to risks that could potentially prevent an organization from achieving its objectives.
JCAHO	Joint Commission On Accreditation Of Healthcare Organizations is a voluntary, nongovernmental organization based in Oakbrook Terrace, Ill. that establishes standards for the operation of hospitals and nursing homes.
Lorazepam	A controlled substance used to relieve anxiety, nervousness, and tension associated with anxiety disorders. It is also used to treat certain types of seizure disorders and to relieve insomnia (induce sleep).
Medical Institution	An institution created for the practice of medicine.
Medication Error	Any preventable event that has caused inappropriate or unintended medication use.

GLOSSARY OF ACRONYMS AND TERMS

Medication Order	A directing of the selection, preparation, and administration of medications that is prescribed only by a licensed physician or dentist.
Medication Room Inspections	The examination of the cleanliness, refrigeration temperature, storage of medication, expiration dates of medication, inventory of controlled substances, etc. within a room in which medication is stored.
Medication Room	A room in which medication to be administered to patients is stored. These rooms are located within the treatment units.
Michigan Mental Health Code	An act to codify, revise, consolidate, and classify the laws relating to mental health; to prescribe the powers and duties of certain state and local agencies and officials and certain private agencies and individuals; to regulate certain agencies and facilities providing mental health services; to provide for certain charges and fees; to establish civil admission procedures for individuals with mental illness or developmental disability; to establish guardianship procedures for individuals with developmental disability; to establish procedures regarding individuals with mental illness or developmental disability who are in the criminal justice system; to provide for penalties and remedies; and to repeal acts and parts of acts.
Night Drug Cabinet	Intended for the proper and safe storage of needed drugs when the pharmacy is closed, available for emergency use by authorized facility personnel only.
Perpetual Inventory	A daily written record of inventory that is continuously in agreement with stock on hand.
Physical Inventory	Establishing a complete physical count of all inventory stock.

GLOSSARY OF ACRONYMS AND TERMS

Psychotherapeutics	For our purposes, psychotherapeutics include antipsychotics (tranquilizers), antidepressants, antimaniacs, benzodiazepines, and sedatives.
Treatment Unit	A wing or floor within a DCH facility in which patients are housed. Also call a nursing unit, housing unit, or unit.
Vicodin	A controlled substance used to relieve moderate to severe pain.

**Department of Community Health
Audit of Pharmacy Operations
Corrective Action Plan
As of March 2006**

Finding Number: One

Finding: Non-Controlled Substance Inventories

Recommendation: We recommend that DCH immediately develop and implement an inventory control program that requires at a minimum, an annual physical inventory of all the pharmaceuticals purchased and maintained by the facilities.

Comments: DCH agrees with this finding.

Corrective Action: The Bureau will establish a work group to determine the needs of the hospitals/centers. An area for exploration is a system that utilizes bar codes or some other method to enable the pharmacies to scan pharmaceutical data into the system.

Anticipated Completion Date: October 1, 2006

Responsible Individual: Hospital/Center Directors

**Department of Community Health
Audit of Pharmacy Operations
Corrective Action Plan
As of March 2006**

Finding Number: Two

Finding: Controlled Substance Perpetual Inventory Records

Recommendation: We recommend that DCH ensure that all facilities maintain perpetual inventory records for all controlled substances as required by the Administrative Code.

Comments: DCH agrees with this finding and recommendation.

Corrective Action: The two facilities were immediately notified to correct this deficiency. This process would be further enhanced by the purchase of a system wide inventory control program.

Anticipated Completion Date: Completed

Responsible Individual: Hospital/Center Directors

**Department of Community Health
Audit of Pharmacy Operations
Corrective Action Plan
As of March 2006**

Finding Number: Three

Finding: Documenting Changes to Inventory Records

Recommendation: We recommend that DCH facilities reconcile the physical inventory counts to the perpetual inventory records whenever a physical inventory is conducted and explain any discrepancies fully.

Comments: DCH agrees with this finding.

Corrective Action: In the event discrepancies occur at the time of a physical inventory, the hospitals and centers have been instructed to fully document and explain any variances.

Anticipated Completion Date: Completed

Responsible Individual: Hospital/Center Directors

**Department of Community Health
Audit of Pharmacy Operations
Corrective Action Plan
As of March 2006**

Finding Number: Four

Finding: Controlled Substances Physical Inventories

Recommendation: We recommend that DCH establish and implement policies and procedures to ensure inventories are conducted in accordance with their internal policies/procedures, the Administrative Code, and the Public Health Code.

Comments: DCH agrees with this finding.

Corrective Action: The Bureau will oversee the development and implementation of standardized policies and procedures to ensure consistency in all facilities relative to controlled substances physical inventories.

Anticipated Completion Date: October 1, 2006

Responsible Individual: DCH Hospital Bureau and Hospital/Center Directors.

**Department of Community Health
Audit of Pharmacy Operations
Corrective Action Plan
As of March 2006**

Finding Number: Five

Finding: Excess Medication Inventory (JCAHO Medication Testing)

Recommendation: We recommend that DCH establish policies/procedures to ensure that only medications necessary for the immediate care needs of the patients be held/maintained in the treatment units.

Comments: DCH agrees with this finding.

Corrective Action: The Bureau will oversee the development and implementation of standardized policies and procedures to ensure consistency in all of the facilities for maintaining medication inventory in the treatment units.

Anticipated Completion Date: October 1, 2006

Responsible Individual: DCH Hospital Bureau and Hospital/Center Directors.

**Department of Community Health
Audit of Pharmacy Operations
Corrective Action Plan
As of March 2006**

Finding Number: Six

Finding: Distribution to the Treatment Units

Recommendations: We recommend that appropriate signatures be obtained at the time of medication transfer, unit shift change, and disposal of wasted medications to ensure the accuracy of controlled substances on hand.

We also recommend that DCH review the policies and procedures at facilities with little waste and determine whether those procedures could be applied at the facilities experiencing a large amount of waste.

Comments: DCH agrees with this finding.

Corrective Action: The Bureau will oversee the development and implementation of standardized policies and procedures for consistency in all facilities relative to obtaining appropriate signatures at the time of medication transfers, unit shift changes, and disposal of wasted medications to ensure the accuracy of controlled substances on hand.

The policies and procedures in place at the facilities with little waste will be reviewed for possible application at the other facilities.

**Department of Community Health
Audit of Pharmacy Operations
Corrective Action Plan
As of March 2006**

Anticipated Completion Date: All facilities are now ensuring that appropriate signatures are obtained and maintained.

October 1, 2006: Development and/or revision and implementation of policies and procedures for consistency throughout the facilities.

Responsible Individual: DCH Hospital Bureau and Hospital/Center Directors.

**Department of Community Health
Audit of Pharmacy Operations
Corrective Action Plan
As of March 2006**

Finding Number: Seven

Finding: Returns and Disposals of Medication

Recommendation: We recommend that DCH facilities maintain documentation of disposals and reconcile that documentation to the returnable/non-returnable manifests received from Guaranteed Returns.

Comments: DCH agrees with this finding.

Corrective Action: Subsequent to the audit, the facilities noted in the report implemented methods to maintain and reconcile disposal data received from Guaranteed Returns.

The Bureau will oversee the development and implementation of a standardized procedure and/or spreadsheet to document disposals and reconciliation of that documentation to the returnable/non-returnable manifests received from Guaranteed Returns.

Anticipated Completion Date: All facilities have taken steps to implement methods to maintain and reconcile disposal data.

October 1, 2006: Development and/or revision of standardized policies and procedures to ensure consistency throughout the facilities.

Responsible Individual: DCH Hospital Bureau and Hospital/Center Directors.

**Department of Community Health
Audit of Pharmacy Operations
Corrective Action Plan
As of March 2006**

Finding Number:	Eight
Finding:	Authorized Prescribers
Recommendation:	We recommend that DCH ensure that each facility maintain an appropriate authorized prescriber list in accordance with the Administrative Code.
Comments:	DCH agrees with this finding.
Corrective Action:	The two facilities noted in the report took immediate steps to implement an authorized prescriber list.
Anticipated Completion Date:	Completed
Responsible Individual:	Hospital/Center Directors

**Department of Community Health
Audit of Pharmacy Operations
Corrective Action Plan
As of March 2006**

Finding Number: Nine

Finding: Lack of Informed Consent

Recommendation: We recommend that documentation of the communication of adverse side effects and/or the informed consent be retained in the patients' record as required by Mental Health Code and facility policy.

Comments: DCH agrees with this finding.

Corrective Action: The forms currently being utilized by each facility in their Informed Consent process will be reviewed and modified to reflect the different levels of the consent process. All facilities will ensure that proper documentation is maintained in the patients' records as required by section 330.1719 of the Mental Health Code and facility policy.

Anticipated Completion Date: Completed

Responsible Individual: Hospital/Center Directors

**Department of Community Health
Audit of Pharmacy Operations
Corrective Action Plan
As of March 2006**

Finding Number: Ten

Finding: Unauthorized Distributions of Flu Vaccinations to Employees

Recommendations: We recommend that the DCH determine whether it needs specific authority to provide flu vaccinations to its employees.

We also recommend, if DCH has the authority and wishes to continue this program, that it develop a policy regarding the administration of flu vaccinations for all DCH facility employees.

Comments: DCH agrees with this finding.

Corrective Action: The Bureau confirmed with the Office of State Employer (OSE) that no action had been taken by either the OSE or the Department's Human Resources with regard to discussions held on October 22, 1996, relative to employee vaccinations. The practice of providing vaccinations at no cost to the employee had continued since that time.

The Bureau further determined that Bargaining Unit contract language specifically indicated that flu shots would be provided to employees upon request, but the cost would be borne by the employee, if not covered by a third party.

**Department of Community Health
Audit of Pharmacy Operations
Corrective Action Plan
As of March 2006**

Beginning in FY05, the four facilities ended their practice of providing flu vaccinations to employees at no cost

Anticipated Completion Date: Completed

Responsible Individual: DCH Hospital Bureau

**Department of Community Health
Audit of Pharmacy Operations
Corrective Action Plan
As of March 2006**

Finding Number: Eleven

Finding: Reporting and Investigating Medication Errors

Recommendation: We recommend that DCH ensure that medication error/incident reports are properly completed and utilized in the assessment of patient care within the facilities.

Comments: DCH agrees with this finding.

Corrective Action: The Bureau immediately notified all facilities to reiterate current policy to staff and to complete educational training as necessary. In addition, the work group will assess the forms and procedures currently being utilized by each facility for the review and documentation of medication errors and incident reports involving medications and modify as necessary.

Anticipated Completion Date: June 30, 2006
October 1, 2006: Development and/or revision and implementation of policies and procedures for consistency throughout the facilities.

Responsible Individual: Hospital/Center Directors

**Department of Community Health
Audit of Pharmacy Operations
Corrective Action Plan
As of March 2006**

Finding Number: Twelve

Finding: Employment of Individuals with Felony Convictions

Recommendation: We recommend that DCH develop formal policies and procedures regarding the hiring of convicted felons, which at a minimum should consider requiring criminal background checks for any prospective employee that will have access to pharmaceuticals.

Comments: DCH agrees with this finding.

Corrective Action: The DCH-operated hospitals and centers have had an informal process in place for several years to conduct background checks on potential employees. The use of the Michigan State Police ICHAT (Internet Criminal History Access Tool) system, and the LEIN (Law Enforcement Information Network) system have been and continue to be the current methods by which the facilities process background checks. The Bureau will oversee development and implementation of formal standardized policies and procedures for conducting criminal background checks for potential new employees, contractual staff, and students for use in all the facilities.

**Department of Community Health
Audit of Pharmacy Operations
Corrective Action Plan
As of March 2006**

The facility that permitted an individual with a felony conviction involving controlled substances to work in its pharmacy was the Huron Valley Center. As revealed by the audit findings, this facility was subject to the policies and procedures of the Michigan Department of Corrections (MDOC). Upon being informed of this, the DCH Hospital Bureau intervened and the individual was immediately removed from working in the facility.

The pharmacy at this facility has since been taken over by the Michigan Department of Corrections. On November 18, 2004, the patient/prisoners being served at the Huron Valley Center inpatient program were physically relocated to another site operated by the MDOC. It was also at this time that the pharmacy staff and all pharmacy responsibilities became the sole responsibility of the MDOC.

Anticipated Completion Date: October 1, 2006

Responsible Individual: DCH Hospital Bureau and Hospital/Center Directors.

**Department of Community Health
Audit of Pharmacy Operations
Corrective Action Plan
As of March 2006**

Finding Number: Thirteen

Finding: Lack of Required Pharmacy Supervision

Recommendation: We recommend that DCH ensure that only persons that hold the proper license supervise and direct the operations of the pharmacies at the facilities.

Comments: DCH agrees with this finding.

Corrective Action: The Bureau immediately instructed the facility noted in the audit to correct the deficiency. In addition, the bureau will oversee development of standardized policies and procedures to ensure that only persons that hold a proper license, as determined by the Michigan Department of Labor Economic Growth (DLEG), supervise and direct the operations of the facility pharmacies.

Anticipated Completion Date: October 1, 2006: Development of polices and procedures.

Responsible Individual: DCH Bureau and Hospital/Center Directors

**Department of Community Health
Audit of Pharmacy Operations
Corrective Action Plan
As of March 2006**

Finding Number: Fourteen

Finding: Storage of Controlled Substances

Recommendation: We recommend that DCH ensure that facility pharmacies implement procedures to ensure that all of their controlled substances are stored in a secure location in accordance with the Administrative Code.

Comments: DCH agrees with the findings.

Corrective Action: The two facilities immediately ensured that all controlled substances are stored in a secure location. Subsequent to the auditor's fieldwork the two facilities immediately took steps to secure all controlled substances.

The Bureau will oversee the development of standardized policies and procedures to ensure consistency in all facilities so that all controlled substances are stored in a security location in accordance with Administrative Rule R338.3143.

Anticipated Completion Date: October 1, 2006: Development and implementation of standardized policies and procedures.

Responsible Individual: DCH Hospital Bureau and Hospital/Center Directors.

**Department of Community Health
Audit of Pharmacy Operations
Corrective Action Plan
As of March 2006**

Finding Number: Fifteen

Finding: Audits of Medication Storage Areas

Recommendation: We recommend that all of the DCH facilities, under the direction of the licensed pharmacist, improve their monitoring activities over the storage areas located throughout the facilities by ensuring that audits/inspections are conducted not less than every 30 days.

Comments: DCH agrees with the finding.

Corrective Action: The Bureau will oversee in the development and implementation of a standardized policy and procedure to ensure compliance with Administrative Rule R338.486(4)(i) that audits of medication storage areas are conducted not less than once every 30 days.

Anticipated Completion Date: October 1, 2006

Responsible Individual: DCH Hospital Bureau and Hospital/Center Directors.

**Department of Community Health
Audit of Pharmacy Operations
Corrective Action Plan
As of March 2006**

Finding Number:	Sixteen
Finding:	Pharmacy Purchasing
Recommendations:	<p>We recommend that the pharmacy staff initial and date all invoices to document that the pharmaceuticals were received.</p> <p>We also recommend that DCH ensure that facilities segregate duties among pharmacy staff in order to safeguard resources against waste, loss, and misuse.</p> <p>We further recommend that DCH implement procedures to ensure that facilities do not use the procurement card to purchase pharmaceutical supplies.</p>
Comments:	DCH agrees with the findings.
Corrective Action:	<p>The Bureau immediately instructed the facilities noted to correct the deficiencies reported in the audit. In addition, the Bureau will oversee the development and implementation of a standardized policy and procedure that will:</p> <ol style="list-style-type: none">(1) Require the staff initial the invoice and indicate the date the pharmaceuticals are received.(2) Ensure segregation of duties among pharmacy staff to safeguard resources against waste, loss, and misuse.

**Department of Community Health
Audit of Pharmacy Operations
Corrective Action Plan
As of March 2006**

(3) Establishment of a charge account with a 24-hour pharmacy for the purchase of pharmaceutical supplies, and ensure that the use of procurement cards are not used for these purchases.

Anticipated Completion Date: October 1, 2006: Development and/or revision of standardized policies and procedures to ensure consistency throughout the facilities.

Responsible Individual: DCH Hospital Bureau and Hospital/Center Directors.

**Department of Community Health
Audit of Pharmacy Operations
Corrective Action Plan
As of March 2006**

Finding Number: Seventeen

Finding: Inconsistent/Incomplete Pharmacy Policies/Procedures

Recommendation: We recommend that DCH establish consistent policies and procedures applicable to pharmacy operations at all DCH facilities.

Comments: DCH agrees with this finding.

Corrective Action: The DCH Hospital Bureau and Hospital/Center Directors, together with the work group to be established consisting primarily of DCH facility Pharmacy Directors, or their designees, will be responsible for the development of standardized policies and procedures applicable to pharmacy operations at all DCH-operated facilities.

Anticipated Completion Date: October 1, 2006

Responsible Individual: DCH Hospital Bureau and Hospital/Center Directors.