DEPARTMENT OF HEALTH
WASHINGTON STATE BOARD OF PHARMACY
P.O. Box 47863
Olympia, Washington 98504-7863
(360) 236-4825

Inspection Report

Seattle-King Co. Jail
Regional Justice Center
Pharmacy Inspection – March 3, 2006

Score: 80, Class B
(Pharmacies must attain inspection scores of
90 points or better per WAC 246-869-190.)

Point deductions:

- Five points were deducted for lack of adequate drug control in the OmniCell system.
- Two points (warning) were deducted for lack of pharmacy and medication room security.
- Four points (with two points being warning) deducted for pharmacy computer system security and system not in compliance with Washington Regulations.
- Two points were deducted for lack of adequate narcotic control.
- One point was deducted for Nursing dispensing without a valid Prescriber order.
- Two points were deducted for ITR area citations.
- Five points were deducted for lack of an ongoing QA improvement program.
- Three points was deducted for lack of a ADR program.

Pharmacies must attain inspection scores of 90 points or better per WAC 246-869-190.

Please note:

Point loss values may be increased or doubled if identical infractions are observed on subsequent inspections. Responsible personnel may also be cited, individually, when violations of controlled substance law or regulation are found.

Stan Jeppesen, Pharm.D.
Pharmacist Investigator

Comments, Observations, and Recommendations

Inventory control:
Pharmacy has continued to utilize the OmniCell machine for nursing access to medications during hours when the Pharmacy is closed. Drug stock is stored in the OmniCell dispensing machine. Pharmacy states that they are shutting off the device (OmniCell) during Pharmacy open hours.

Pharmacy is completing only a limited reconciliation of drug stock utilized from the OmniCell machine, and a number of inventory discrepancies occur.

Daily discrepancies in inventory are NOT reconciled. Pharmacy staff reviews the daily OmniCell transaction report each day to determine the number of withdrawals of medication, following the generation of new orders written during after-hours periods while the pharmacy was closed. Theoretically, only new orders should have been withdrawn from the OmniCell machine during the after-hours periods, however daily it is noticed that withdraws are being made for other reasons, which would include shortages in dispensed medication stock for patients.

Board of Pharmacy concerns with medication management include:

- Shortages in dispensed medications to include "borrowing" for other patients from patient single dose (SD) supplies. **Missing medications from the patient supply stock has been a long standing issue for the last six years, and has been brought to the attention of Jail Health staff on several occasions, but no resolution appears to have occurred in regarding this issue.**
- Withdrawals for patients without orders, to include Tylenol#3 (narcotic) was noticed.
- That the pharmacy staff does not have time to follow-up on patient medication withdrawals that do NOT or may not have new orders for the withdrawn medications.
- That the number of daily discrepancies appears from a review of records to average 5 or more per day.
- That when medications are lost in the system, no accounting of the lost medications occurs.
- That returned patient medications are not reconciled or "credited" in the system.
- That the staff did not appear to have knowledge of the OmniCell protocol approved by the on Board January 26, 2006. Staff informed this investigator that the OmniCell system had a 16 day deletion period, in that patients would be deleted from the system after 16 days, if the patient's record was not accessed in that period of time. Director Dean Webb was able to demonstrate that the time had actually been recently changed to 12 hours.
- Concerns with the Omnicell system are:
    - That communications with the Staff had not occurred regarding significant operational changes. That the staff did not know what the OmniCell protocol specified, or if the staff were complying with the protocol

requirements. A copy of the protocol was made available to the staff during the inspection.
   - That the patient names can be continued indefinitely in the system, when access is made to the patient name within twelve (12) hours of the last system access. That discharged patients may have medication withdrawals long after actual discharge, with no apparent discovery of "diversion" by the pharmacy staff. This item is in conflict with the specifications approved under the Board approved protocol.
   - That all patient entries are made by the nursing staff, and pharmacy has no pragmatic mechanism to reconcile patient entries to assure that withdrawals are being made for legitimate inmates.
     - OmniCell withdrawals have been noted for patients NOT recorded as present in the Jail.
- That the Pharmacy staff reports that many shortages are noted in the dispensed single dose (SD) medications that have been dispensed to the patients. The Single dose mediations are stored under the control of Nursing for administration to patients.
- A spot check of approximately 50 OmniCell bins found approximately 5 discrepancies on bin counts, to include the controlled substance clonazepam 0.5mg where the discrepancy indicated the bin was short 10 tablets. On questioning pharmacy staff, it was learned that the OmniCell resets the count to the last "counted" number, when back counted by the person accessing the bin.
- Staff do not have a system or mechanism to resolve and/or reconcile these count discrepancies, to include nursing miscounts. The current system appears to allow for a significant number of medications to be taken from this system, without any follow-up and reconciliation by pharmacy staff. **No mechanism exists to determine precisely the quantity of medications that were withdrawn to include narcotics**, benzodiazepines, and the other legend drugs. Most bins are open to the Nursing staff to access and withdrawal multiple medications with one system access, and thus no recording of the actual medications withdrawn.
- Pre-pouring of medications is not allowed. One (1) packet was found prepared for patient administration with two pills opened without the original unit dose packaging dispensed by pharmacy, and placed in an envelope for patient administration. This practice has been discussed with administration in the past, and strongly discouraged. **I know of no legitimate reason that this practice should be allowed to continue.**

(5 points deducted)

System and Physical Security:

The pharmacy door to the medication room was found open. When pharmacy staff was requested to produce a list of staff who had access to the medication room, I was informed by pharmacy staff that they could not provide this information. The nursing supervisor was also requested to provide a system generated list of who had access to the medication room, and was unable to provide a list. I was informed by the Nursing

supervisor that only RN and LPN staff had access, but when pharmacy staff was questioned, I was informed that social workers and therapy staff also had access.

Pharmacy staff was requested to provide an OmniCell generated list of staff who had access to the OmniCell machine. This list revealed several persons who had not been employed in the system for several months to over a year. When staff was questioned as to how deletions of staff for OmniCell access is maintained, I was informed that no process was apparently in place, and infact no request had ever been received to delete a persons access from the OmniCell system. **A review of OmniCell reports found that medication withdrawals had been attributed to staff that had not worked at the time of the withdrawal.** Explanation was attributed to the fact that the OmniCell medication drawers are at times are NOT closed, allowing subsequent staff to withdraw medications without logging in, and attributing the withdrawals to someone else. The OmniCell system has no self-closure mechanism to close drawers when left open.

It was also observed that one of the two patient medication carts was left unlocked. A bag of miscellaneous medications was also found on the top of the medication room cabinet, which appeared to be a stash of extra medications. **I suspect this stash is clearly against your internal policies, certainly state law.**

Pharmacy staff was unable to provide or inform me who had electronic access to the Pharmacy. The Nursing manager informed me that all staff must have an electronic badge to gain access to the various areas they are allowed, and that these badges are removed when employment ends, but pharmacy staff later informed that they were aware of former staff retaining their badges.

Interim Pharmacist are provided with key access to the pharmacy by the Nursing Supervisor. No record of this access has been maintained, and Nursing controlling the key, obviously allows Nursing access. I would suggest that a better system is needed to allow and track interim Pharmacist access.

My largest concern with pharmacy security, is that Pharmacy personnel do not have any input or control into the Pharmacy security and access system, and can not regulate or control the personnel having access to the medication room and pharmacy areas. This negates the intent of the pharmacy regulations, and the authority of the Responsible Manager.

(-2 points deducted).

Pharmacy Computer System FSI:

- Staff appear to review the FSI exception report daily for Prescriber order discrepancies. For the date 1/31/06, it was noted that 9 discrepancies were noted for refill changes and four (4) discrepancies for changes in the prescription SIG.
  - Past Investigator concerns have been raised regarding the ability of non-pharmacist staff to make critical changes in a prescription record. Staff demonstrated how the pharmacy system utilizes patient prescription cards

that can be used to double check the electronic entry, but the opportunity still exists for significant errors to slip by the pharmacist. The current system configuration does not conform to Board regulations. Discussions with the staff regarding these errors indicated that the system's master file controlling the SIG mnemonic definitions can be changed by individuals at other sites. This results in across the board changes to all records at all pharmacy sites. One serious example of this situation was found in a large box of medication errors waiting to be addressed by the staff.

  - The FSI master file issue was followed up by the Investigator to discover that several non-pharmacist persons had Pharmacist access credentials to the FSI master file system. That non-pharmacist persons had changed the mnemonic master file definitions on several occasions and without notice to the responsible manager at this site. Since these system changes result **in across the board changes**, without any ability to track or audit **the changes, this Investigator finds providing this access to non-pharmacist and non-pharmacy staff unacceptable and unsafe for patient care.**
  - Non-Pharmacist staff can also make changes to other patient medication record fields, to include the manufacture of the medication dispensed. This results in a change to all historical dispensing transactions for that prescription, thus not accurately reflecting what was actually dispensed.

- The FSI system does not have an interface with the correctional computer system. This lack of an interface results in numerous errors for pharmacy, with little apparent ability of pharmacy to pragmatically reconcile and adjust to inmate relocations. The lack of an interface contributes to the following problems:
  - **Numerous lost patient medications that can not be tracked** or **reconciled (five a day is probably a conservative number).**
  - The distribution of duplicate patient medications.
  - The inappropriate OmniCell medications withdrawals following patient transfers.

Following discussions with the new Responsible Manager **(Anh-Thu Nguyen)** regarding the Investigators concerns, master files were checked to find that several persons, who had left the employment, still had access authorization for the computer master files. It was also found that several non-pharmacy personnel also had unrestricted Pharmacist level access to the computer system, and had on several occasions changed master files that resulted in the change of patient data records across all system sites. Subsequently when these person's access was restricted, access was again provided to the same non-pharmacy personnel, and the Responsible Manager's access was restricted. **This issue confirms the inability of the Responsible Manage to restrict confidential data, information and access. WAC 246-869-070 requires that the Responsible Manager shall have complete control and responsibility for all pharmacy functions, and this does not appear** to be in place **for the King County pharmacy facilities**. This also provides additional concerns to this Investigator regarding the safety of patient data files that can be relied on as being accurate, **and creates an unsafe patient environment**. This investigator has serious concerns that pharmacy management needs provide unrestricted Pharmacist

access to non-pharmacy personnel. **Again, I suspect that King County corrections administration has not provided the necessary resources to pharmacy and Jail Health Services to do the work that should rest strictly with pharmacy licensed personnel.** The expectation is that this security deficit will correctly immediately, with control of these files exclusively under the Responsible Manager and Pharmacist personnel.

The Pharmacy management staff have informed me in the past that they have contacted the computer vendor regarding the deficits cited in this report regarding the system. Although these issues may be difficult to move forward, the Board expects that these issues have to be resolved, and response has not been adequate in this regard.

The computer system (FSI) utilization as currently designed does not appear to comply with Washington State regulations.

(-4 points deducted)

It is recommend that your facility consider other technology to increase automation since it could provide the facility with substantial cost savings while augmenting your medication control.

Pharmacy is responsible for the appropriate control of the drug stock, and Pharmacy should be able to track where and to whom stock is dispensed. Board approved protocols require that stock counts be performed, and that inventory can be tracked to the patient.

Medical Records:

The facility has apparently made significant improvement in the collection of disease state and allergy information for patients. Prescribers are noting this significant information on the written orders. Substantial improvement in automation is possible, but planned automated improvements appear to be in the distant future. Hopefully the future automated systems will mitigate this issue and the rework and transcription errors that originate from the current system. Patient charts were not reviewed during this inspection, but will be at a later time.

Narcotic control:

A floor stock manual narcotic control system is utilized for dispensing of single dose (SD) narcotics to patients. This system still requires pharmacy audits and review. It was noted that for report sheets covering the period of 11/2/2005 to 2/17/2006, 30 sheets were noted to not have written dates on the sheets. It was noted that a number of these sheet could not be reconciled. Interview of pharmacy staff indicated that sufficient audits were not completed to verify that sheets were complete or to follow up on incomplete sheets. It was noted that for patient dispensed narcotics, there was no reconciliation with narcotics withdrawn for the same patents from the OmniCell system. **This is a substantial opportunity for narcotic diversion.**

(-2 points deducted)

The facility has apparently implemented procedures to eliminate all verbal orders for C-II prescriptions. Thank you.

Valid Prescriber orders:

One order was found written by a Nurse, without any apparent authorization from a Prescriber. -1 point deducted.

ITR (Intake-Transfer-Release) Area:
Patient admit orders (from ITR) are being generated by Nurses, performing "verification" of patient orders from physicians or other local area pharmacies. Orders are often being written for one year refills, when no apparent last fill date was obtained or noting when the patient was last seen by the Prescriber, or for how many refills were left on an order, and without any apparent Patient medication history assessment being obtained. Pharmacy Staff report that transcription errors are common with respect to drug names, drug order instructions, and the prescribed dosages. Patients are often in the facility 10 to 14 days (and at times much longer) before they are seen by a Jail Health Services Prescriber. Pharmacy is often subsequently requested to interchange prescription products for patients without a Prescribers order and a patient assessment that the interchange would be appropriate for the patient. These issues present significant opportunity for medications errors that may be of a significant concern for patient welfare.
Inspection of the ITR area indicated that the stock of medications had been reduced which I appreciate. Unfortunately, of the four (4) medications stocked in the cabinet, medication logs for two medications were short and unaccounted for, and current logs indicted dispensing to two (2) patients without recording the patient names to which medication had been dispensed. The ITR inspection also found two bottles of insulin that had exceeded their 30 day expiration dating, one (1) open and undated vial, and temperature logs that had not been maintained.

Concern with patient intake area continues, since an order dispensing an Albuterol inhaler to a patient was found without a physician order.

(-2 points deducted)

Quality Assurance/Adverse Drug Events/Drug Utilization Evaluation:

It still does not appear the pharmacy has implemented an adequate QA/CQI program. The Pharmacy staff has attempted to record medication errors and discrepancies, but no notable follow-up appears to have occurred regarding long-standing issue.

It was noted that in a report of 190 incident reports of the last quarter of 2005. The following breakdown was noted:

- 78 – were for filled prescriptions with medications pulled (from OmniCell) by Nursing.
- 49 for missing medications.
- 4 for wrong medications pulled (from OmniCell) by Nursing
- 6 for wrong medication strength pulled.
- 3 for medications pulled after the order was discontinued.
- 1 medication pulled without an order.
- 31 other miscellaneous discrepancies.

For medication related incidents the following was noted:
  - 1 - Single dose to Keep on Person
  - 3 - Wrong medication dispensed
  - 2 - wrong medication dose dispensed.

For MAR related incidents:
  - 1 -MAR made with no order
  - 1- Medication discontinued, but MAR not pulled
  - 4- Single dose (SD) to KOP (keep on person)
  - 1- No MAR written when should have been
  - 4 - MAR written incorrectly.
  - 1 - Written Keep On Person MAR produced.

The investigators review of daily OmniCell discrepancy reports noted the following:
- That eighteen (18) medication count discrepancies were noted for 2/15/2006 that staff did not have an opportunity to follow-up on or reconcile. Many others occasions were also noted in the pharmacy files where staff was not able to follow-up on OmniCell discrepancies.
- That over 100 med count discrepancies were noted for February 2006 at the Seattle site.
- That 78 medication procedure incidents were noted at the RJC for January 2006
- That 65 medication procedure incidents were noted at the RJC for February 2006.

The investigator noted for internally reported medication incidents:
- 302 were noted for the combined first, second and third quarters of 2005.
- 269 were reported for the first quarter of 2005. These numbers imply to this investigator that a substantial decrease occurred for the last two quarters of 2005, resulting in only 33 discrepancies. Pharmacy staff were unable to explain the differential in reported numbers. The lack of reporting of incidents appears most probable.
- Summary:
  - First quarter : - 269
  - First, 2nd and 3rd quarters combined: - 302
  - Calculated 2nd and 3rd quarters: - 33

Interview of staff, indicated that a substantial number of medication incidents have not been reported in the recent past. Staff did not have adequate time to process the medication incidents. It was noted that essentially all medication incident reports appeared to have been generated by Pharmacy, with few if any generated by Nursing. This Investigator questions whether Nursing has adequately oriented and/or instructed its staff in completing incidents reports.

A box was found in the pharmacy with what appeared to be several hundred incident reports for January and February 2006, that had been started, but had not been completed and forwarded on to administration for review.

A review of a few submitted incident reports revealed:

- Patient incidents of double dosing by Nursing.
- Patient administration of methadone to an unknown patient.
- The miss-dosing of a methadone patient.
- The double dosing of a two(2) methadone patients.
- Patient chart medication sheet with two different patient names on the sheet.
- Wrong doses pulled multiple times and administrated to patients.
- MAR (medication administration records) not reflecting clinic doses given.
- The dispensing of an albuterol inhaler by an RN without the written order of a Prescriber.
- The missing of 27 tablets of methadone 5mg tablets on 1/3/2006. This incident [illegible] un-resolved.
- The miss-prescribing of Paxil 50 for the wrong patient, with orders sent to pharmacy.
- Multiple incidents of lost, but dispensed medications to patients.
- Incidents of extra doses of medications administered to patients, and MAR doses not signed off.
- Incidents of medications administered to patients following the discontinuation of the orders.

This Investigator was informed by Dr. Sander, Medical Director, that the Medication Administration Committee had been discontinued in June 2005, and had not been re-implemented to address medication error problems. Thus no effective mechanism to address these issues appears to be in place at this time.

(5 points deducted for lack of QA Improvement implementation. Warnings have been given in the past).

<u>ADR reporting</u>:

No ADR (adverse drug reporting) system is in place at this time. In the past the Jail Health Services has stated they have devoted substantial planning efforts toward creating an ADR reporting system. I expected to see reportable results on this inspection.

(3-point deducted)

Pharmacy in general:

Staff appear from a review of internal reports, to be processing between 230 and 250 prescriptions daily and at time much higher, while staffed with one Pharmacist and two Technicians.
I want to commend the management staff for the work they completed prior to this inspection and their efforts to meet patient and institutional demands. **Unfortunately, the staff is considerably short of the resources needed to respond adequately to the issues cited in this report.**

Respectfully,
Stan Jeppesen, Pharm.D.
Pharmacist Investigator