

OFFICE OF CITIZEN COMPLAINTS - OMBUDSMAN

Amy Calderwood, Ombudsman - Director

MEMORANDUM

DATE:

November 29, 2006

TO:

Honorable Metropolitan King County Councilmembers

Honorable Ron Sims, King County Executive

FROM:

Amy Calderwood, Ombudsman-Director#C

VIa: Jon Stier, Senior Deputy Ombudsman

CC:

Dorothy Teeter, Interim Director, Department of Public Health

Reed Holtgeerts, Director, Department of Adult & Juvenile Detention

Bette Pine, Manager, Jail Health Services

SUBJECT: Report on Jail Health Medication Errors and State Inspection Results

I. INTRODUCTION

We write to inform you about recurring deficiencies within King County Jail Health Services (JHS) pharmacy and medication administration services. We are concerned that identified deficiencies put patient health and safety at risk, and increase King County's potential legal liability.1

We are informing you of these problems now because JHS recently received a report detailing results of an October inspection by the Washington State Board of Pharmacy (hereafter, "the Board").² The Board made critical findings, made recommendations for improvements, acknowledged progress in some areas, and

Services since 2004.

¹ Counties may be held liable for medical negligence. <u>E.g., Shea v. City of Spokane</u>, 17 Wn. App. 236, 241-44, 562 P.2d 264 (1977), affd, 90 Wn.2d 43, 578 P.2d 42 (1978). Moreover, the Eighth Amendment to the U.S. Constitution affords inmates the right to be free of "deliberate indifference to their serious healthcare needs." Estelle v. Gamble, 429 U.S. 97, 104, 97 S.Ct. 285 (1976). Generally, officials violate this standard, "when they deny, delay, or intentionally interfere with medical treatment." See <u>Hunt v. Dental Dept.</u>, 865 F.2d 198, 201 (9th Cir. 1989), <u>quoted in</u>, <u>Sullivan v. County of Pierce</u>, 216 F.3d 1084, 2000 WL 432368 *2 (9th Cir. 2000) (unpublished). In addition, the Civil Rights of Institutionalized Persons Act allows inmates and the U.S. Attorney General to institute civil actions against persons allegedly responsible for denying inmates their civil and constitutional rights. 42 U.S.C. § 1997 et seq.

The Ombudsman's Office has been in contact with Board personnel regarding Jail Health

Office of Citizen Complaints—Ombudsman Report on Jail Health Medication Errors and State Inspection Results November 29, 2006 Page 2 of 17

assessed the lowest passing score to JHS. This latest inspection follows a failing score JHS received from a March 2006 Board inspection, and Seattle-King County Department of Public Health (DPH) assurances to the Board and the Ombudsman's Office that previously identified deficiencies would be addressed.

JHS staff members and managers confront enormous and daunting challenges in providing health care in an extremely challenging correctional environment. It is our hope that this report will assist policymakers in ensuring that inmates in King County custody receive adequate care.

II. SUMMARY

This report discusses inmate medication complaints to the Ombudsman's Office. relevant JHS staff complaints, and inspection reports produced by the Board. In summary, the Ombudsman's Office regularly receives jail inmate allegations of medication errors. Medication-related allegations substantiated by the Ombudsman's Office tend to be consistent with patterns or unsubstantiated allegations. JHS nursing and pharmacy employees report poor morale, poor working conditions, and poor relationships and communication with management. JHS employees allege that those challenges, combined with chronic understaffing, result in frequent medication errors, with potentially serious patient outcomes. In its inspection reports, the Board has noted many recurring deficiencies that are consistent with inmate and employee complaints. In response, we recommend that the Council and Executive take steps necessary to ensure that the Board's recommendations are fully implemented and that JHS safely and effectively administers prescription medications to patients in jail custody. The Ombudsman's Office will continue to monitor and follow up on the performance of JHS, and is available to advise policymakers further if so requested.

III. INVESTIGATIVE AUTHORITY

The Office of Citizen Complaints—Ombudsman (hereafter, "the Ombudsman's Office") was created by the voters of King County in the County Home Rule Charter of 1968, and operates as an independent office within the legislative branch of King County government. The Ombudsman's Office is authorized, by King County Code (KCC) section 2.52, to investigate complaints regarding the administrative conduct of King County agencies. In addition, the Ombudsman's Office investigates alleged violations of the King County Employee Code of Ethics (KCC 3.04), and reports of improper governmental action under the Whistleblower Protection Code (KCC 3.42). The purpose of these activities is to promote public confidence in King County government by responding to citizen complaints in an impartial, efficient and timely manner, and to contribute to the

Office of Citizen Complaints—Ombudsman Report on Jail Health Medication Errors and State Inspection Results November 29, 2006 Page 3 of 17

improved operation of county government by making recommendations based upon the results of complaint investigations.

IV. OVERVIEW OF INMATE MEDICATION COMPLAINTS TO THE OMBUDSMAN'S OFFICE

Since January 1, 2004, the Ombudsman's Office has logged at least 192 complaints³ from inmates and JHS employees alleging medication errors. Typically, medication-related inmate complaints to the Ombudsman's Office fall into the following categories:

- Failure to verify (and provide) outside prescriptions within a reasonable time after booking;
- Failure to provide uninterrupted supply of refill prescriptions for critical and non-critical medications;
- · Wrong medication delivered or administered;
- Failure to provide timely psychiatric evaluation and/or medication:
- Failure to respond to medication-related kites⁴ and grievances.

The Ombudsman's Office helps resolve many inmate medical complaints informally, often facilitating communication between inmates and JHS in timesensitive cases. However, the Ombudsman's Office cannot follow up effectively in many cases, because of limited Ombudsman resources, medical privacy laws requiring signed patient releases before medical providers may disclose any medical information, and the fact that many inmates are only briefly in custody and do not provide non-jail contact information.

³ This floure likely understates the true number of jail medication-related allegations received by the Ombudsman's Office, because medication issues are sometimes anciliary to inmates main allegations, woreover, compaints received by the Ombudsman's Office likely constitute only a subset or actual complaints by inmates, who are encouraged to use the medical "kite" (see note 4, infra) and grievance system as their primary avenue of complaint resolution. A recent study asserted that, nationally, medication error reporting greatly underestimates the true numbers. "Preventing Medication Errors—Report Brief", Institute of Medicine of the National Academies, July 2006.

July 2006.

A "kite" is a paper form that allows inmates to request services or communicate needs to appropriate jail and medical staff members.

In a recent case (Ombudsman Case No. 2006-01769), for example, on November 16, 2006, an inmate alleged that, due to nausea and vomiting, he had lost 45 pounds after entering jail custody on August 25 weighing 183 pounds. The inmate said he is six feet tall. He alleged that he had been prescribed, but had not yet received, a drug for nausea after jail staff transported him to Harborview Medical Center on November 16. The Ombudsman's Office sent the allegation by email to the Manager of JHS, and to JHS line staff by telephone. On November 17, the inmate called the Ombudsman's Office and stated that he still had not received his medication and had lost eight more pounds. On November 20, the JHS nursing director called the Ombudsman's Office and said she followed up on the complaint. Later, the inmate called the Ombudsman's Office and said he had received his medication on the evening of November 17.

Office of Citizen Complaints—Ombudsman Report on Jail Health Medication Errors and State Inspection Results November 29, 2006 Page 4 of 17

Despite those constraints, the Ombudsman's Office does formally investigate medication error allegations that go unresolved or are egregious. In such cases, the Ombudsman's Office transmits written complaints to the DPH director; collects and analyzes evidence, laws and policies; produces formal findings; and makes recommendations to DPH where possible. The Ombudsman's Office summarizes completed investigations in tri-annual reports distributed to the County Council, the Executive, and senior departmental managers. The tri-annual reports show that inmate complaints frequently do not lend themselves to substantiation by a preponderance of the evidence.

Nevertheless, the Ombudsman's Office makes critical findings in some cases and detects patterns from others. Within the past nine months, for instance:

- In a case closed on October 11, 2006,⁸ the Ombudsman's Office found that JHS administered a non-fatal overdose of insulin to a diabetic inmate. The patient's chart was apparently confused with that of another inmate. The inmate fell and injured his neck sometime after the overdose, though we did not establish a causal link between the overdose and the fall. The patient was transported to Harborview Medical Center for the overdose. The Ombudsman's Office's closing memorandum to DPH noted continuing concerns regarding JHS's medication error prevention efforts.
- In a case closed on September 28, 2006, ⁹ the Ombudsman's Office found that JHS failed to administer an uninterrupted supply of medications to an inmate suffering from a potentially life-threatening disease. Treatment protocol required uninterrupted dosing to prevent development of resistance to the medications. The Ombudsman's Office repeatedly assisted the inmate by calling JHS to report the alleged errors, and by demanding explanations from JHS. Eventually, the inmate began receiving an uninterrupted medication supply. Our final report described problems with DPH's Quality Improvement Program (QIP). As we wrote, "should the QIP continue to function inadequately, the ability of DPH staff and managers to detect and correct individual errors and patterns of errors will be hampered, thereby increasing risks to future patients' health and safety." We also expressed concern that a poorly functioning QIP increased King County's potential liability.

⁶ The Ombudsman's tri-annual reports are required by KCC 2.52.150.

⁷ A preponderance of the evidence means that, considering all available evidence, an allegation is more likely true than not true. Many jail medication complaints amount to an inmate's word against that of accused staff members, and thus do not meet the preponderance standard.

⁸ Ombudsman Case No. 2006-00483.

⁹ Ombudsman Case No. 2004-00790.

Office of Citizen Complaints—Ombudsman Report on Jail Health Medication Errors and State Inspection Results November 29, 2006 Page 5 of 17

In a case closed March 2, 2006, 10 three inmates alleged that a nurse failed to deliver medications to their units. The inmates said that during the evening medication pass, one inmate asked the nurse why she did not deliver medications in the afternoon. The inmates said the nurse looked in a book and replied, "No, it looks like I was here. You should just be happy with what you get." Separately, another inmate complained that the same nurse failed to deliver needed medication. Again separately, two nurses alleged that the same nurse frequently fails to deliver medications and falsely marks on patient charts that medications are refused. While the Ombudsman's Office could not substantiate these allegations, we alerted DPH to the pattern of allegations against this nurse, and recommended that she be monitored closely to ensure she is fulfilling her medication pass duties. DPH responded that it had instructed "charge nurses" to be more aware of workload issues. DPH also said it changed its medication distribution protocol so that nurses distributing medications are visible to more witnesses in inmate areas than before, thereby decreasing the risk of such incidents.11

These and other cases¹² are generally consistent with patterns of unsubstantiated inmate medication-related complaints. Standing alone, this indicates to us the likelihood of systemic deficiencies.

V. OVERVIEW OF JHS STAFF COMPLAINTS

A. Nursing Staff Allegations

Since 2004, the Ombudsman's Office has spoken numerous times with JHS employees about medication errors and other medical-related problems in the County jails. ¹³ In 2005, two nurses alleged that patient care, and working

¹⁰ Ombudsman Case No. 2005-01186.

¹¹ In a November 16, 2006, interview with the Ombudsman's Office, a nurse not involved in the initial allegations stated that the accused nurse still routinely fails to deliver inmate medications, and falsely marks on medication administration forms that medications have been delivered.
¹² The Ombudsman's Office has also made critical findings in less-egregious cases than those

cited above. For example, in a case closed on June 17, 2005 (Ombudsman Case No. 2005-00120), a JHS nursing supervisor admitted that an inmate received the wrong dosage of his depression medication at least once, attributing the error to a history of different physicians prescribing different dosages of the medications. In a case closed on August 29, 2003 (Ombudsman Case No. 2003-00322), the Ombudsman's Office found that JHS administered the wrong medication to an inmate whose first and last names were identical to that of another inmate but whose middle names and birth dates differed. In response, DPH told the Ombudsman's Office that discovery of the error increased awareness among nurses, and detailed new safeguards that DPH said would prevent future similar errors.

13 The complaining employees' names are withheld pursuant to the confidentiality provision of the

The complaining employees' names are withheld pursuant to the confidentiality provision of the Whistleblower Protection Code, KCC 3.42.040, and exemptions from disclosure contained in the state Public Records Act, RCW 42.56.001 et seq.

Office of Citizen Complaints—Ombudsman Report on Jail Health Medication Errors and State Inspection Results November 29, 2006 Page 6 of 17

conditions for nurses, has deteriorated in recent years. These nurses alleged that while their work is rewarding, it is also overwhelming due to short staffing and heavy workloads. The nurses said these conditions result in patients missing medications, or medications being delivered late. They said that patient care also suffers because "agency" (non-County-employee) nurses are not oriented to protocols, and gave an example of a diabetic inmate who went without insulin overnight because the agency nurse did not follow up properly.

The nurses alleged that incident reporting, a key part of DPH's Quality Improvement Program, was not being handled effectively. They said management had changed the incident report forms to preclude employees from seeing the results of incidents they report.

The nurses reported low morale, said performance evaluations had not been conducted in many years for some nurses, and stated that JHS could not retain enough employee nurses due to the working conditions. At the same time, the nurses alleged that the JHS personnel structure is "top-heavy" with managers. Finally, the nurses reported what they believed to be a culture of reprisal, wherein employees fear retaliation by managers if they speak out for better patient care.

In July 2005, the Ombudsman's Office obtained an email message sent by another nurse to JHS managers, and cc'd to career service nurses. The email accused management of intentionally understaffing a night shift at the King County Correctional Facility (KCCF). The nurse wrote that, "[t]he regularly staffed RN [registered nurse] slated to work nights in psych is no longer posted there," and warned that, "we appear, in this facility, to be willingly leaving this unit (which has 138 patients on this particular evening) unmanned by an RN for 8 hours a day." The nurse alleged that several of the inmates did not receive prescribed medications that night. In the email, the nurse told managers that,

JHS has a legal and ethical obligation to appropriately train employees, staff this facility and provide safe adequate health care to the tens of thousands of individuals who are legally remanded to this facility each year. None of these obligations are currently being met under the current levels of training, staffing and healthcare delivery that is currently in place. You, as administration, are placing inmates at risk and our licenses at risk with current practices as they stand.

Office of Citizen Complaints—Ombudsman Report on Jail Health Medication Errors and State Inspection Results November 29, 2006 Page 7 of 17

In a conversation the following month, a JHS nurse told the Ombudsman's Office that for the evening of August 8, 2005, no treatment nurse was on duty at KCCF, and consequently 71 medical treatments were not done. The nurse stated that many of the treatments were for inmates with serious medical needs such as very high blood pressure, seeping wounds, blood sugar checks, tuberculosis test readings, alcohol withdrawal vital sign checks, pregnant inmate blood pressure readings, and obtaining urine for analysis to rule out an infection or kidney stones.

The nurse believed this situation occurred because of chronic understaffing problems that are so severe that nurses cannot take leave for illness or other reasons without endangering patients. The nurse believed that this situation creates the potential for extremely serious patient outcomes.

The Ombudsman's Office transmitted these allegations to the director of DPH, warning that if true, they could constitute a "substantial or specific danger to the public health or safety." DPH responded that an agency nurse had been assigned to treatments for the shift in question, but had not reported to work as scheduled. DPH stated that a supervisor became aware of the situation when the shift was half over, immediately prioritized treatments in order of importance, determined which ones could wait until the next day, and did the priority treatments. In response to the incident, DPH told the Ombudsman's Office that it instituted a sign-in system for agency nurses, and planned to institute a similar system for career service nurses. In a follow-up email message, the complaining nurse stated a lack of awareness of any new sign-in procedures following the incident.

In order to gauge whether staff members believe patient care at JHS is improving, on November 16, 2006, the Ombudsman's Office interviewed a nurse who has complained about JHS management practices in the past. The nurse said managers used to react punitively when nurses spoke out for patient welfare, but that now managers routinely ignore such communications. The nurse said that the incident reporting system is "a big mess," and that recently she could not find a blank incident report form. The nurse alleged that senior management hires people who they know to be ineffective, simply to fill slots on paper. For example, the nurse alleged, JHS recently hired a "nurse trainer," a position that should facilitate continuing education, ensure nurses are up to date regarding their certification, conduct nurse orientations, and be a resource for nurses; but this new hire is doing "nothing."

¹⁴ KCC 3.42.020(C) (Whistleblower Protection Code definition of "improper governmental action").

Office of Citizen Complaints—Ombudsman Report on Jail Health Medication Errors and State Inspection Results November 29, 2006 Page 8 of 17

As an example of what the nurse believes to be dangerous understaffing. 15 the nurse stated that on November 7, 2006, KCCF night medical staffing consisted of one RN in the infirmary, one RN in ITR, ¹⁸ and two licensed nurse practicioners. (According to KCCF records, the facility housed 1,352 inmates that night, a ratio of 1:388 if the nurse's allegation is accurate.) The nurse said KCCF is currently supposed to be staffed by 2 RNs in the infirmary, one RN in ITR, two LPNs [licensed nurse practicioners], and a floating RN charge nurse, a staffing level she believes is itself inadequate when fully met.

In the November 16 interview with the Ombudsman's Office, the nurse recounted a very recent medication error in which a jail infirmary patient developed symptoms of unexplained dehydration. Nurses urged the patient to drink more fluids. The patient had been prescribed an antibiotic for an infection. However, someone eventually read the medication package and discovered that in fact the patient had been receiving a diuretic, not an antibiotic. 17

The complaining nurse could not explain why this error occurred, but speculated it was due to staff member apathy or exhaustion. 18 She said that while she and most of her colleagues are committed to practicing public health nursing in the correctional context, they feel discouraged and do not believe positive changes will occur in the foreseeable future.

B. Pharmacy Staff Allegations

The Ombudsman's Office has spoken numerous times with JHS pharmacy employees over the past year. A Regional Justice Center (RJC) pharmacist, designated as the RJC "responsible manager" alleges that JHS managers refuse to authorize adequate pharmacy staffing despite her repeated requests. The RJC pharmacist alleges that, as a result, staff members are more prone to errors than they should be, and that many prescriptions are filled late.

¹⁵ According to the National Commission on Correctional Health Care, "it is not possible to specify exact provider-to-patient ratios," although adequate staffing plans "include having an adequate number of physicians, midlevel practicioners, and support staff to provide necessary care . . . NCCHC, Standards for Health Services in Jails, Standard No. J-C-08 (2003). A study conducted for JHS in 2001 states that only one state, North Carolina, has established nurse-to-inmate staffing ratios, but that "[m]any private sector firms try to establish a ratio of 1 nurse to 30-35 inmates" and "Multnomah County indicated that they used a ratio of 1 nurse to 250 inmates but adjusted the staffing according to type of care and population such as infirmary, segregation etc." Moore and Associates, "Health Care Staffing Analysis: Seattle-King County Jail Health Services," (March 3, 2001).

18 "ITR" means, "Intake, Transfer and Release."

¹⁷ The Ombudsman's Office has no record of an inmate complaint about this alleged incident. Notably, the nurse would likely have been prohibited from disclosing the patient's name to the Ombudsman's Office, pursuant to medical privacy laws.

¹⁸ The Ombudsman's Office has no record of an inmate complaint about this alleged incident. ¹⁹ A pharmacy "responsible manager" is required to "ensure that the pharmacy complies with all the laws, rules and regulations pertaining to the practice of pharmacy". WAC 246-869-070.

Office of Citizen Complaints—Ombudsman Report on Jail Health Medication Errors and State Inspection Results November 29, 2006 Page 9 of 17

Regarding staffing cuts, on August 9, 2006, the RJC pharmacist wrote to her supervisor that, "I do not see how we could safely complete[] our workload with the new staffing level." The RJC pharmacist later alleged that pharmacy staffing had been reduced by 40 hours per week, effective October 2, 2006, and that workloads had increased to 250 to 350 prescriptions per day. The RJC pharmacist alleged that on September 26, 2006, for example, she filled 295 or 297 prescriptions.²⁰

On August 8, 2006, a KCCF pharmacist wrote to managers that new procedures intended to produce printed medication administration records (to reduce the incidence of missing medication sheets) were taking too much time. The KCCF pharmacist wrote,

Today, we have another two inmates missing their Amitriptyline.[21] I found the stickers where we sent the medications and it was not returned. I am not replacing these medications. I am also not replacing any muscle relaxant that goes missing. I believe if the provider wants the inmate to have it; a new order needs to be rewritten. This is the only proper way to document all the missing muscle relaxant and Amitriptyline. It will be available to providers and nurses who look in the chart. Sorry, but this is completely out of hand. It has generated an overwhelming amount of work for the pharmacy; that we are not able to absorb.

The KCCF pharmacist wrote to managers on August 15, 2006, that, "I am short staff[ed] on the weekends. On Saturday, it is only one technician and myself."

The RJC pharmacist alleges that patient care suffers due to lack of adequate pharmacy staffing, and stated that she does not have adequate time to perform required administrative tasks with the heavy prescription-filling workload. This pharmacist also believes that a culture of reprisal exists at JHS, wherein employees fear retaliation by managers if they speak out for better patient care.

²⁰ To date, the Ombudsman's Office has discovered no state or national standards dictating how many prescriptions a pharmacist may fill per day. However, the North Carolina Pharmacy Board has stated that pharmacists and facilities in that state will be cited in disciplinary proceedings when a medication error occurs at a location where more than 150 prescriptions per pharmacist per day were filled. North Carolina Board of Pharmacy, "Board Statement: Pharmacist Workload" (March 26, 1997).

²¹ Amitriptyline is a tricyclic antidepressant that reportedly can be abused as a recreational drug. "Amitriptyline Abuse and Misuse," Am. J. Forensic Med. Pathol. v. 26, pp. 86-88 (2005), abstract accessed online at, http://cat.inist.fr/?aModele=afficheN&cpsidt=16573386; Abuse of Amitriptaline, JAMA, Vol 240, No. 13 (1978), abstract accessed online at, http://jama.ama-assn.org/cgi/content/abstract/240/13/1372.

Office of Citizen Complaints—Ombudsman Report on Jail Health Medication Errors and State Inspection Results November 29, 2006 Page 10 of 17

Our investigation to date indicates that pharmacy technicians may be unable to regularly accomplish tasks that the Board requires. Examples of such tasks include: reconciling discrepancies from medication carts; checking off and shelving new inventory; checking refrigerator temperature; checking for and pulling expired medications from inventory; reconciling returned medications; and filling refills two days ahead of time. Up to 20 prescriptions allegedly go unfilled per day, and refills due on Fridays allegedly may not be done until Mondays for maintenance medications (e.g., high blood pressure and diabetes medications).

VI. OVERVIEW OF JHS PHARMACY BOARD INSPECTIONS

A. 2004 and 2005 Inspections

The KCCF pharmacy failed a Board inspection in October 2004. Point deductions included:

- inadequate drug (including narcotic) control history;
- · non-complying pharmacy computer system;
- · inadequate personnel utilization and training; and
- · lack of ongoing quality assurance program.

In his report, the Board investigator wrote, "[i]t still does not appear the pharmacy has an active QA/CQI [quality assurance/continuous quality improvement] program. . . . No CQI projects of any significance were noted on this visit, and in the past visit of 2/5/2003. Inadequate staff resources is still noted as the primary reason."

The KCCF pharmacy received the lowest passing inspection score in December 2004, but the Board noted many continuing deficiencies, including "lack of an ongoing QA program," writing that while JHS had done substantial quality assurance *planning*, these plans had not been implemented. Another Board inspection, in March 2005, cited many of the same deficiencies noted in the 2004 inspections, and the 2006 inspections.

B. March 2006 Inspection

On March 3, 2006, the Board produced an 11-page inspection report for the Regional Justice Center (RJC) pharmacy. The report notes that pharmacies

Office of Citizen Complaints—Ombudsman Report on Jail Health Medication Errors and State Inspection Results November 29, 2006 Page 11 of 17

must attain inspection scores of 90 points or better.²² The JHS score for this inspection was 80. The Board deducted points for the following reasons:

- 1. Lack of adequate drug control in the OmniCell system;[23]
- 2. Lack of pharmacy and medication room security;
- 3. Pharmacy computer system security and noncompliance with state regulations;
- 4. Lack of adequate narcotic control:
- 5. Nursing dispensing without valid prescriber order;
- 6. ITR [intake, transfer, and release] area citations:
- 7. Lack of ongoing QA improvement program.

The Board report provides many specifics related to the above-cited problems,²⁴ and notes that many are "recurring deficiencies," some going back as far as six years. In a follow-up letter to JHS, dated June 20, 2006, the Board investigator wrote,

It is suggested that administration verify that the Responsible Pharmacy Managers have control over all aspects of pharmacy staffing and work load with authority to make adjustments as their

²² <u>Citing</u> WAC 246-869-190. A pharmacy scoring 80 to 89 "shall have sixty days to raise its inspection score rating to 90 or better. If upon reinspection after sixty days, the pharmacy fails to receive a rating of 90 or better, then the pharmacy will be subject to disciplinary action." The purpose of a pharmacy inspection is "to determine compliance with the laws regulating the practice of pharmacy." <u>Id.</u>

practice of pharmacy." Id.

23 The Omnicell is an information technology network system and physical cabinet that dispenses and houses pharmaceuticals. The purpose of this system is to allow nurses to withdraw medications when the pharmacy is closed, thereby saving resources by allowing for reduced pharmacy hours. If properly operated, administered, and integrated with other computer systems, the Omnicell could help provide accurate tracking of medications, from receipt by the pharmacy to utilization by patients. Telephone conversation with Stan Jeppesen, Investigator, Washington State Board of Pharmacy (November 21, 2006); see Omnicell marketing information online at, http://www.omnicell.com.

24 In a July 19, 2006, memorandum to DPH, the Ombudsman's Office listed the following

specifics, and requested a response detailing JHS actions to cure them: unreconciled daily inventory discrepancies; medication withdrawals for patients without orders, including narcotics; no accounting of lost medications; returned medications not reconciled; staff unawareness of changes to Omnicell system; discharged patients may have medication withdrawals long after discharge; withdrawals of medications for patients not recorded as being in jail custody; no list of employees with access to medication room; medication carts left unlocked; medication withdrawals attributed to staff who had not worked at withdrawal time; dispensing to patients without recording their names; pharmacy staff and Responsible Manager have no input or control over pharmacy security; large box of unaddressed medication errors; no computer interface with correctional computer system, resulting in inability to track patient relocations; responsible Manager unable to control confidential data, information, and access; patients not seen by prescriber for 10 to 14 days, or longer; no notable QA/QCI follow-up to staff reports of medication errors and discrepancies; many medication incidents not reported within the past year; Medication Administration Committee discontinued in June 2005; no "adverse drug reporting system."

Office of Citizen Complaints—Ombudsman Report on Jail Health Medication Errors and State Inspection Results November 29, 2006 Page 12 of 17

professional discretion may dictate, to provide for pharmaceutical services.

Staffing issues continue[] to be a recurring problem from my observations during the past inspections. The routine dispensing function occupies the majority of the pharmacy staff time; both due to the volume of prescription orders and the manual system employed by the pharmacy. Pharmacy staffing does not have adequate resources to monitor and reconcile medication activities. Contact with former JHS staff revealed that production pressures and expectations have directly resulted in several staff leaving. Staff who have left JHS employment have expressed concerns for patient safety with respect to the errors committed due to production demands.

Regarding JHS quality assurance capabilities, the Board investigator wrote, "tracking and documentation of all errors and discrepancies needs and should occur. . . . medication errors are significant, and a comprehensive plan needs to be developed to address the various causes involved."

In response to the Board's March report and June letter, JHS sent a detailed work plan to the Board in August, and provided a copy to the Ombudsman's Office. The work plan details actions that JHS stated it had taken or was in the process of taking to address identified deficiencies. The work plan includes 18 attachments, including draft JHS policies and procedures, and memoranda to staff members instituting new measures.

C. October 2006 Inspection

In a 15-page report dated October 18, 2006, the Board assessed the lowest passing score of 90 to the RJC pharmacy. The report provides comments, observations, and recommendations concerning matters that were the focus of the inspection. Each of these items from the report is summarized below.

1. Continued Omnicell²⁵ discrepancies and tracking problems

The RJC pharmacy continues to perform only limited reconciliations of Omnicell drug stocks used by nursing staff. "Inventory discrepancies continue to occur frequently." The majority of discrepancies are not reconciled by nursing staff. While the number of discrepancies appears to be lower than in the past, pharmacy staff report inadequate resources to follow up on discrepancies. Approximately one fourth of Omnicell withdrawals are for medications that were already provided to inmates. Many missing medications may be attributed to

²⁵ See supra note 23 for a description of the Omnicell system.

Office of Citizen Complaints—Ombudsman Report on Jail Health Medication Errors and State Inspection Results November 29, 2006 Page 13 of 17

patient transfers, and difficulties in tracking inmate movements. Fewer medication withdrawals are occurring without orders. Tracking medications to patients remains a problem. The report recommends that reconciliations completed by nursing be attached to the daily Omnicell report, and that the inmate transfer process be used to improve medication tracking systems.

2. <u>Communication problems regarding Omnicell access</u>

While lists of staff members with access to the Omnicell are now reconciled, pharmacy staff had no knowledge of a new process in which they would be notified of changes in nurse staffing. The report states, "Incomplete communications and expectations appear to have contributed to problems in this area." New nurses may be trained for ten to 16 days before seeking Omnicell access from the pharmacy, "which did seem a very excessive period to Pharmacy Staff." The current list of employees with Omnicell access appeared appropriate, and no medication withdrawals were attributed to employees who had not worked at the time of withdrawal.

3. <u>Communication problems regarding pharmacy and medication room access</u>

The RJC pharmacy responsible manager is not directly involved in allowing permissions to access the pharmacy, and the responsible manager does not communicate directly with the jail security chief to provide individual access permissions. The report recommends that the system be changed to allow the responsible manager and security chief to collaborate on electronic access permissions. JHS implemented a new job-class pharmacy access procedure, but the report noted that seven people without authorized access had accessed the medication room. Several "procedural deficits" still exist in this area.

4. <u>Inadequate servicing of nurse medication carts</u>

"The system for servicing of the nursing medication carts is inadequate." Patient medications and medication administration records (MARs) are not reconciled to appropriate nursing carts and record books when inmates are moved or transferred. "Nursing is often unable to find patient medications when the time is appropriate." JHS implemented new procedures in October 2006 to assist with these problems, but, "Pharmacy staff did not appear to have had any input into the development of these procedures that affect pharmacy operations." Review of MAR records showed patient medications marked as unavailable. "Several patients did not receive their designated medication for several days and pharmacy was not notified of a problem for resolution of the issue." The pharmacy cannot discover these problems on its own because the pharmacy cannot service medication carts.

Office of Citizen Complaints—Ombudsman Report on Jail Health Medication Errors and State Inspection Results November 29, 2006 Page 14 of 17

5. <u>Inadequate computer system security</u>

The computer system may still be updated in idiosyncratic ways by staff members or managers at other sites (e.g., other County jail pharmacy or public health clinics), and the RJC responsible manager is therefore not in control of the system on-site. This appears to result in discrepancies (e.g., end of day reports not reflecting work entered; changes to codes that impact dosing instructions) and lost orders. "This Investigator is not aware of any other healthcare facilities where this type of inadequate system security would be tolerated on a live system." No system training beyond on-the-job learning has been provided to staff. While the report commends JHS for attempting to enhance the interface between JHS's system and the jail's, the responsible managers may not have resources to devote to the necessary tasks. Though the Chief of Pharmacy recently assumed control over system master file changes, "The FSI computer system as currently configured does not appear to comply with Washington State regulations".

6. <u>Flawed process for implementing medication administration record (MAR) system</u>

Computerized MARs are an improvement over the past, however, "there are serious concerns over how this implementation has been conducted." Many categories of errors and discrepancies appear on printed MARs destined for distribution to nurses. Such errors "could result in an adverse or allergic reaction." RJC staff stated that patient records had been substantially corrected, resulting in fewer MAR errors at the end of September. But, "a significant number of errors were still observed." The new MAR system was apparently brought on line and used for patient servicing before testing of the system was completed, and "without fixing the identified problems first". As "patient welfare and safety needs to come first," this raises professional concerns regarding future implementation of a planned new "Pearl" system. Pharmacy staff "do not feel involved" in the planning for this.

7. <u>Improved Narcotic control, but inadequate tracking</u>

For September 2006, six witnessed narcotic report sheet counts were not documented by nursing, "which is a significant improvement from the earlier review." However, pharmacy staff lacks resources to conduct the required audits, reviews, and reconciliations with patient orders and Omnicell withdrawals. "[F]or patient dispensed narcotics, there was no reconciliation with narcotics withdrawn for the same patients from the Omnicell system. . . . narcotics were signed out, but no MAR documentation noted." There is a "substantial opportunity for narcotic diversion."

Office of Citizen Complaints—Ombudsman Report on Jail Health Medication Errors and State Inspection Results November 29, 2006 Page 15 of 17

8. <u>Improved ITR medication distribution</u>

Accountability of ITR medications appears to be "substantially improved" compared with previous inspection results.

9. QA program beginning, but needs follow-up

JHS has formed a new pharmacy quality improvement committee (QIC) and developed a pharmacy quality improvement plan (QIP). Staff members are commended for the quality of data collected and the process for collecting it. Several focused QA projects have been completed. However, there is concern that these new systems and data should now be used to improve existing processes, or they are of little use. Also of concern is that the QA projects have been limited to relatively low volume weekends, and therefore may not fully measure JHS QA challenges. The report notes that DPH published a comprehensive QIP in 1996, which is "still relevant for JHS and could be used for QI program guidance.²⁶

Lack of adverse drug reporting program

"No ADR (adverse drug reaction) reporting system appears to be in place at this time. No ADR data has been collected, and no data was available for review." The report notes that JHS indicated that training for ADR reporting was scheduled for October 2006, and that implementation of a future computer system should facilitate an ADR system.

11. Medical records improvements, but more QA needed

JHS has maintained improvements to its collection of disease and allergy information for patients. More QA monitoring, including data for weekdays, is warranted, however, as is "[i]nformation sharing with JHS staff" regarding these issues.

²⁸ The Ombudsman's Office warned DPH, in a September 28, 2006, memorandum, that its failure to follow its own quality improvement plan (QIP) increases DPH's potential legal liability. This is because state law exempts from liability and prohibits testimony of persons who provide information as part of a state-approved QIP, and likewise protects from review or disclosure any information and documents created and maintained by a facility's quality improvement committee (QIC). RCW 43.70.510. We discovered, in Ombudsman Case No. 2004-00790 (see supra p. 4), that JHS was not following the terms of its state-approved QIP, and therefore waived the confidentiality protections. In that case, we also criticized DPH for obstructing the Ombudsman's investigation regarding its QIP. While JHS has now formed a pharmacy QIC after the Board failed the RJC pharmacy in March 2006, it is unclear at this time whether the QIC is functioning adequately. Moreover, we remain concerned that DPH's non-pharmacy-related QIP may not be functioning adequately, or in conformance with the 1996 plan.

Office of Citizen Complaints—Ombudsman Report on Jail Health Medication Errors and State Inspection Results November 29, 2006 Page 16 of 17

12. Responsible manager lacks significant control

The pharmacy responsible manager does not appear to have significant control over pharmacy operations, as is required by WAC 246-869-070. Indicia of control include: master file access and control; ability to adjust pharmacy staffing; input into pharmacy staffing model; pharmacy access control; medication room access control; control/participation in procedural changes and monitoring of patient medications; control of implementation of new systems; and ability to impact institutional policy in a significant way. "The Responsible Manager does not appear [to] generate or formulate policy, but appears to receive policy directives and subsequently reacts to directed policy."

13. Flawed organizational reporting structure

The report notes that the pharmacy reports to nursing administration. However,

Each profession should have the autonomy to exercise their professional obligations and responsibilities without the impediment of supervisory oversight of another profession that can mitigate health care professionals from exercising their professional responsibilities on behalf of the patient. This model requires that each profession can approach the other professions on equal terms . . . while working collaboratively

The Board report concludes by noting that "everyone is trying very hard." But it states that "JHS does not appear to have the resources necessary" to respond to the issues identified in the report, to ensure that the expectations of the responsible managers are achieved, or to adequately support QA and ADR systems.

Finally, we note that DPH has informed the Ombudsman's Office that it has serious concerns with information included in the Board report, and said it contains "numerous misrepresentations." DPH stated that it intends to submit a response to the Ombudsman's Office concerning the Board report, but we have not received it as of this date. In a November 21, 2006, telephone conversation, the Board investigator told the Ombudsman's Office that DPH had submitted five or six pages of objections to his draft report, and that he had incorporated points for which there was support into the final draft.

Office of Citizen Complaints—Ombudsman Report on Jail Health Medication Errors and State Inspection Results November 29, 2006 Page 17 of 17

VII. CONCLUSION

Based on the Ombudsman's Office's experience investigating inmate medication complaints, concerns raised by JHS staff members, and the detailed inspection reports produced by the Board of Pharmacy, we reiterate our concern for patient health and safety, and for King County's increased potential liability. While we recognize the extraordinary challenges inherent in providing basic health care in a correctional context, we are concerned that JHS may not be consistently providing inmates with an adequate pharmacy and medication administration system.

Consistent with the Ombudsman's Office charter, the primary purpose of this report is to inform policymakers about systemic deficiencies. The Ombudsman's Office is not a policy-setting body. In individual cases, we have offered DPH recommendations that we believe would improve administration of the jail health program, but we are not in a position to direct changes. Nevertheless, we recommend that the Council and Executive take steps necessary to ensure that the Board's recommendations are fully implemented and that JHS safely and effectively administers prescription medications to patients in jail custody.

The Ombudsman's Office will continue to monitor the performance of JHS. We will follow up on specified deficiencies through our regular case work, and our contacts with JHS employees, managers, and the Board. In the meantime, we are ready to advise the Council and Executive further if requested to do so.