KING COUNTY
OFFICE OF CITIZEN COMPLAINTS - OMBUDSMAN

Amy Calderwood, Ombudsman - Director

MEMORANDUM

September 28, 2006

TO: Dorothy Teeter, Interim Director, Department of Public Health

FR: Amy Calderwood, Ombudsman-Director
Via: Jon Stier, Senior Deputy Ombudsman JS.

CC: Bette Pine, Manager, Correctional Health and Rehabilitative Services

RE: [redacted] (Ombudsman Case No. 2004-00790)

This office has completed its investigation in the above-referenced case. As the enclosed final report explains, we found that Mr. [redacted] missed doses of his [redacted] medications on March 15, April 4 and 5, and in the days before June 17, 2004. Related to these findings, our report expresses ongoing concerns about DPH's Quality Improvement Program as it impacts patient health and safety, and the risk of King County liability.

While we do not require that DPH provide this office with a response to the final report, we would accept any response received and include it in the case file.

Thank you for your attention to this matter.

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KING COUNTY OFFICE OF CITIZEN COMPLAINTS—OMBUDSMAN
FINDINGS AND OMBUDSMAN CONCERNS
Complaint No. 2004-00790
Complainant: [redacted]
Respondent: King County Department of Public Health, Jail Health Services
September 28, 2006

I. ALLEGATION

[redacted] alleged that Jail Health Services (JHS) failed to provide an uninterrupted supply of his [redacted] medications as required by medical protocols.

II. BACKGROUND

Mr. [redacted] an inmate at the King County Correctional Facility in Seattle, has been diagnosed with [redacted] and has been seen at the Madison Clinic at Harborview Medical Center by Dr. Alison Heald, MD, who prescribed [redacted] therapy consisting of three [redacted] medications, [redacted] and [redacted]. In a letter addressed to this office, dated June 24, 2004, Dr. Heald wrote,

> The key to successful treatment of [redacted] is compliance with taking the [redacted] medications. If a patient does not take his [redacted] medications regularly (every dose, every day), the [redacted] can become resistant to the medications, and they stop working. Furthermore, if resistance develops to one medication, it often means that resistance has developed to all medications in that class. It is imperative a patient with [redacted] not miss ANY doses of his medications.

III. OMBUDSMAN INVESTIGATION

This investigation was conducted pursuant to authority granted by KCC 2.52.

In a letter to this office, dated June 18, 2004, Mr. [redacted] detailed his allegations that he missed doses of one or more [redacted] medications on March 15, April 3-5, and June 15-16, 2004. On July 21, 2004, this office formally transmitted Mr. [redacted]'s allegations to DPH, requesting, in part, that DPH "provide the date, medication missed, and reason, for each of Mr. [redacted]'s missed doses up to the present date." In a response dated August 25, 2004, and consistent with this office's review of Mr. [redacted]'s medical records, DPH admitted that Mr. [redacted] missed medication doses on April 4 and 5. DPH also stated that it did not have records indicating that Mr. [redacted] missed doses on other days.

On October 26, 2004, this office responded to DPH's August 25 memorandum, noting, in part, that Mr. [redacted]s medical records contained a medical grievance concerning the March 15 missed dose, and a JHS response to that grievance that did not dispute Mr. [redacted]s allegation. This office requested that DPH state whether Mr. [redacted] missed that dose and that DPH provide documentation. In a response dated November 18, 2004, DPH acknowledged that Mr. [redacted] missed his March 15 dose of [redacted] but DPH did not explain the error.

On August 10, 2004, Mr. [redacted] alleged that his [redacted] refill was delivered late (June 17), resulting in his missing two doses of that medication, and that a jail health staff member delivered to him an extra, unneeded, bottle of [redacted] The JHS response to Mr. [redacted]'s grievance appeal, dated August 1, 2004, states, "[p]harmacy has been made aware of the above medication being delivered in error. They will double check your medications to ensure this type of error does not occur again." In its November 18, 2004, response to this issue, DPH did not deny that Mr. [redacted] missed the June [redacted] doses.

As part of the investigation, this office:

- interviewed Mr. [redacted] and several DPH staff members;
- relayed Mr. [redacted]s allegations of emergent medication errors made during the course of the investigation to JHS staff members by telephone;
- corresponded and spoke regularly with Mr. [redacted]
- obtained authorization for access to, obtained copies of, and reviewed Mr. [redacted]s medical records from JHS and Harborview Medical Center;
- obtained and reviewed relevant JHS policies, procedures and practices regarding medication error reporting and the JHS quality improvement program;
- discussed the JHS quality improvement program with officials of the Washington State Department of Health;
- interviewed personnel with the Washington State Board of Pharmacy; and,
- conducted other relevant, independent, factual and legal research and analysis.

On August 11, 2006, this office transmitted its preliminary findings and concerns to the director of DPH, and offered DPH the opportunity to provide a response by September 11, 2006. This office has not received a response as of this date.

IV. OMBUDSMAN FINDINGS

This office makes findings based on a preponderance of the evidence standard of proof. A preponderance means that, in light of all the available evidence, we are persuaded that the allegation is more likely true than not true.

In light of DPH's admission in its August 25, 2004, response (consistent with Mr. [redacted]'s medical records reviewed by this office), and in DPH's August 1, 2004,

response to Mr. [redacted]'s grievance appeal, this office finds that Mr. [redacted] missed doses of his [redacted] medications on March 15, April 4 and 5, and in the days before June 17, 2004.

We note that Mr. [redacted] has not alleged any instances of missed doses since September, 2005. We presume that he has received all prescribed doses since that time.[1]

V. OMBUDSMAN CONCERNS: QUALITY IMPROVEMENT PROGRAM

A. Patient Health & Safety

According to section 7.6.8 of the JHS Health Services Policy and Procedures Manual (2001), actual and potential medication errors are to be reported on an "incident report form." Sections 7.6.8 and 7.7.1 of the Manual states that the JHS Medication Committee is to report incident report form outcomes in its quarterly minutes.

In 2004, this office received an updated version of the JHS Health Services Policy and Procedures Manual. The new and superceding sections relating to Jail Health Pharmacy do not contain provisions concerning medication error monitoring and quality control. However, in a memorandum from JHS management to all JHS clinical staff, dated June 1, 2006, JHS instituted new procedures requiring that staff members complete incident reports when adverse drug reactions result in adverse health outcomes for patients. DPH also recently constituted a Pharmacy Quality Improvement Committee. We expect that these recent developments will be formalized in the JHS Policy and Procedures Manual to help ensure full staff compliance.

As part of the investigation into Mr. [redacted]'s complaint, this office requested access to incident report forms and JHS Medication Committee quarterly minutes concerning medication errors related to Mr. [redacted] Following protracted delays in responding substantively to this request,[2] DPH informed this office that no responsive incident report forms or quarterly minutes exist.

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[1] Mr. [redacted] was committed to the custody of the Washington Department of Corrections on [redacted] 2006.

[2] In its November 11, 2004, response to this office's request, DPH stated that the records are "confidential and not subject to disclosure pursuant to RCW 43.70.150 [sic] and WAC 246-50-020." In fact, at that time, the statute authorizing quality improvement programs, RCW 43.70.510, only prohibited disclosure under the Public Records Act and in the course of civil litigation. However, this office sought the records as part of an Ombudsman investigation in which this office invoked its power to "examine the records and documents of all administrative agencies." KCC 2.52.090. This office had full authority to access any existing records. The law was not subject to any serious interpretation to the contrary, and DPH's arguments served only to obstruct and delay this investigation. We note that the Legislature amended the confidentiality provisions of RCW 43.70.510 during the course of this investigation. Laws of 2005, Ch. 291.

We are concerned that jail health staff members apparently did not make incident reports regarding Mr. [redacted]'s repeated medication errors, despite Mr. [redacted]s complaints to JHS. Although Mr. [redacted] has not alleged adverse health outcomes resulting from JHS's medication errors, [redacted] therapy protocol requires that such errors must be avoided, and the errors here certainly increased the risk to Mr. [redacted]

Furthermore, staff members' failure to use DPH's Quality Improvement Program (QIP) casts doubt on the integrity of that program as it functioned in the time frame of this investigation. More pointedly, 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.

B. Increased Risk of King County Liability

State law currently 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(3), (4) & (5). These protections apply when a QIP either complies with enacted state standards located in RCW 70.41.200, or when a facility obtains approval from the Washington Department of Health (WDOH) to operate an alternative program that is equivalent to RCW 70.41.200. RCW 43.70.510(1)(b). The confidentiality protections do not apply if a facility fails to comply with its alternative program as approved by WDOH.[3]

In 1996, DPH sought and obtained approval from WDOH for an alternative QIP program. DPH updated some elements of the plan in 2001. The approved program sets forth QIC responsibilities, program documentation requirements including QIC and sub-committee minutes, continual information collection and maintenance protocols, incident and accident reporting protocols, quality improvement education, provider review, and complaint resolution. Appendices to the plan provide procedures to implement the above-noted responsibilities.

While ascertaining the full extent of DPH compliance with its approved QIP falls outside the scope of this investigation, in this case, DPH did not keep quarterly minutes of Medication Committee meetings as required by its plan. It is also clear that the incident reporting system was not functioning while Mr. [redacted]s medication errors were occurring. While we are encouraged by DPH's April 2006 inauguration of a Pharmacy QIC, we note that this was apparently reactive to a March 2006 state Board of Pharmacy inspection rather than a proactive

[3] RCW 43.70.510(1)(b). This is the interpretation of the Washington Department of Health (WDOH) and the Attorney General's office. Telephone conversation with Patti Rathbun, Policy Development Coordinator, WDOH, July 14, 2005.

measure. We also note that the effectiveness of this new QIP cannot yet be evaluated.

We remain concerned about DPH adherence to the terms of its state-approved QIP relating to medication administration in the County jails, as well as QIP terms relating to non-medication-related jail medical matters. While our primary concern is patient health and safety, we are also concerned that lack of adherence removes DPH personnel and records from the confidentiality protections afforded to properly functioning QIP programs by RCW 43.70.510. Without these protections, patients who allege medical errors may be entitled to access sensitive records, and to subpoena the testimony of County employees who may have engaged in relevant QIP functions. The availability of such evidence could assist plaintiffs in securing settlements from, or judgments against, King County.

VI. CONCLUSION

In light of our finding that JHS committed medication errors as discussed above, we conclude that Mr. [redacted]s allegations are supported, and have closed this case file with that designation. This office will continue to monitor DPH efforts to reduce the risk of jail medication errors, including DPH's compliance with its QIP.