

**STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
FACILITY LICENSING AND INVESTIGATIONS SECTION**

In Re: Hospital of Saint Raphael of New Haven, Inc.
d/b/a Hospital of Saint Raphael
1450 Chapel Street
New Haven, CT 06511

CONSENT ORDER

WHEREAS, Hospital of Saint Raphael, of New Haven, CT., (hereinafter the "Licensee"), has been issued License No. 0056 to operate a General Hospital known as Hospital of Saint Raphael (hereinafter the "Facility"), by the Department of Public Health (hereinafter the "Department"); and

WHEREAS, the Facility Licensing and Investigations Section of the Department conducted inspections on November 15, 16, and 18, 2005, with additional information received through December 13, 2005 in order to determine the Licensee's compliance with the provisions of the Regulations of Connecticut State Agencies; and

WHEREAS, as a result of the Department's inspections, a violation letter dated January 13, 2006 (copy attached-Exhibit A) was issued by the Department to the Licensee; and

WHEREAS, an office conference was held on January 27, 2006 at the Department; and

WHEREAS, the execution of this Consent Order, any provision of this Consent Order, any payment made by Licensee in accordance with this Consent Order, and any statements or discussions leading to the execution of this Consent Order, shall not constitute or be construed to constitute any admission or adjudication of any wrongdoing, regulatory noncompliance or violation of the Regulations of the Connecticut State Agencies, the Connecticut General Statutes, the United States Code or the Code of Federal Regulations by the Licensee, its agents, servants, employees or any other person or entity.

WHEREAS, the Licensee is willing to enter into this Consent Order and agrees to the conditions set forth herein without admitting any wrongdoing.

NOW THEREFORE, the Facility Licensing and Investigations Section of the Department of Public Health of the State of Connecticut, acting herein by and through Joan Leavitt, its Section Chief, and the Licensee, acting herein and by David Benfer, its President and Chief Executive Officer, hereby stipulate and agree as follows:

1. Within twenty-one (21) business days of the execution of this Consent Order, the Licensee shall complete a review of the computerized physician order entry system (CPOE). The review shall focus on evaluation of the following:
 - a. Drug advisory alerts for all disciplines which includes focusing on the dose, frequency and route of medications;
 - b. Ordering format and structure relative to reducing duplicative medication orders;
 - c. Integration of medication orders between all service areas within the facility including but not limited to the Emergency Department, inpatient units and outpatient clinics;
 - d. Reliability and ease of access to patient medication histories;
 - e. Decision support features and safety mechanisms to prevent errors; and
 - f. Actions taken to address deficiencies prior to the execution of this Consent Order may be considered to comply with the terms of this Consent Order.
2. Within thirty (30) days of the execution of this Consent Order, the Licensee shall review and revise, as applicable, all policies/procedures relative to applicable disciplines regarding medication administration and computerized order entry for medications.
3. Within sixty (60) days after the effective date of this Consent Order, all direct patient care staff who are licensed to prescribe, dispense and/or administer medications shall be inserviced regarding CPOE policies and procedures utilized in their specific professional disciplines and assignments. Said inservices shall also be provided to all newly employed staff or upon introduction of new technology or system updates. Documentation of said programs shall be made

available to the Department upon their request and shall be maintained for a period of three (3) years.

4. Within sixty days (60) days of the execution of this Consent Order the Licensee's quality assurance committee shall review the recommendations made by the computer software contractor relative to modifications of the CPOE system. The committee shall review implementation and adherence of staff regarding CPOE systems and oversee remediation and education of staff as appropriate. In addition, the committee shall develop a system to measure, track and analyze medication errors related to the CPOE system. Documentation of said activities shall be maintained by the Facility for a minimum of three (3) years and shall be available to the Department for review upon request.
5. Within sixty (60) days of the execution of this Consent Order, the Medical Staff Committee shall review and revise bylaws governing oversight of interns/residents specifically related to assessments of patients upon admission and treatment of patients during off shifts.
6. Within sixty (60) days of the execution of this Consent Order, the Licensee shall arrange for inservice education regarding the treatment of hypokalemia for all medical and surgical interns and resident physicians. Any interns and resident physicians who are unable to attend the inservice programs presented by the Licensee shall be given access to the program content in an alternate manner via written material, audiotape, videotape or computer aided instruction.
7. Within forty-five (45) days of the execution of this Consent Order, the Licensee shall review and revise, as applicable, all policies and procedures related to emergency responses within the hospital. The Licensee shall adopt policies/procedures for emergency responses appropriate to the needs of the hospital. Inservice education regarding such policies and procedures shall be provided to all direct care staff involved in emergency response teams.
8. Ongoing training of applicable direct care staff in emergency protocols shall be assessed, monitored and simulated on a semi-annual basis through mock emergency events.

9. The Licensee shall comply with applicable Federal and State laws and regulations.
10. The Licensee shall within seven (7) days of the execution of this Consent Order, designate an individual who shall assume overall responsibility for full implementation and monitoring of the components of this Consent Order. Said individual assigned this responsibility shall submit monthly summary reports, which address the components of this document to the Department.
11. Any information, monetary payment, documents or reports required by this Consent Order shall be directed to:

Elizabeth S. Andstrom, RN, MS
Supervising Nurse Consultant
Department of Public Health
Facility Licensing and Investigations Section
410 Capitol Avenue, MS #12 HSR, PO Box #340308
Hartford, CT 06134-0308

12. The individual designated as responsible for the implementation and monitoring of this Consent Order shall meet with the Department and the designated Department's representative every four (4) weeks for the first six (6) months and every two (2) months thereafter for the duration of this Consent Order.
13. Hospital of Saint Raphael of New Haven, CT., the Licensee, agrees to make a monetary payment to the Department in the amount of eighteen thousand dollars (\$18,000.00) which is payable by bank check made payable to the Treasurer, State of Connecticut within two (2) weeks of the effective date of this Consent Order. Said check shall be directed to Elizabeth Andstrom, Supervising Nurse Consultant at the address previously identified in this document.
14. The terms of this Modified Consent Order shall remain in effect for a period of two (2) years from the effective date of this document.
15. The Licensee hereby acknowledges and agrees that this Consent Order is an order of the Department of Public Health with all the rights and obligations pertaining thereto and attendant hereon and that in accordance with Connecticut General Statutes Section 19a-494(7) and 4-177(c). Nothing herein shall be construed as limiting the Department's available legal remedies against the

Licensee for violations of this Consent Order, which may be sought in lieu of or in addition to the imposition of civil penalties or any other administrative and judicial relief provided by law. This Consent Order may be admitted by the Department as evidence in any proceedings between the Department and the Licensee in which compliance with its terms is at issue.

16. The Licensee, by execution hereof, knowingly and voluntarily waives any right it may have to a hearing with respect to the alleged violations contained in the letter to the Hospital of Saint Raphael dated January 13, 2006.
17. The Licensee understands that this Consent Order and the terms set forth herein are not subject to reconsideration, collateral attack or judicial review under any form or in any forum including any right to review under the Uniform Administrative Procedure Act, Chapter 368a of the Statutes, Regulations that exists at the time the agreement is executed or may become available in the future, provided that this stipulation shall not deprive the Licensee of any other rights that it may have under the laws of the State of Connecticut or of the United States.
18. The execution of this document has no bearing on any criminal liability without the written consent of the Director of the MFCU or the Bureau Chief of the DCJ's Statewide Prosecution Bureau.
19. The Licensee has had the opportunity to consult with an attorney prior to executing this document.

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IN WITNESS WHEREOF, the parties hereto have caused this Consent Order to be executed by their respective officers and officials, which Consent Order is to be effective as of the later of the two dates noted below.

HOSPITAL OF SAINT RAPHAEL, OF NEW HAVEN, INC. - LICENSEE

4/12/06
Date

By: David W. Benfer
David Benfer, President and Chief Executive Officer

STATE OF Connecticut

County of New Haven ss New Haven 4/12/2006

Personally appeared the above named David W. Benfer and made oath to the truth of the statements contained herein.

GLORIA ASTARITA
NOTARY PUBLIC
MY COMMISSION EXPIRES OCT. 31, 2008

My Commission Expires:
(If Notary Public)

Gloria Astarita
Notary Public
Justice of the Peace
Town Clerk
Commissioner of the Superior Court

STATE OF CONNECTICUT,
DEPARTMENT OF PUBLIC HEALTH

4/13/06
Date

By: Joan Leavitt
Joan Leavitt, R.N., M.S., Section Chief
Facility Licensing and Investigations Section



STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

EXHIBIT A
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January 13, 2006

David Benfer, President and CEO
Hospital of Saint Raphael
1450 Chapel Street
New Haven, CT 06511

Dear Mr. Benfer:

Unannounced visits were made to Hospital of Saint Raphael on November 15, 16 and 18, 2005 by a representative of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting an investigation with additional information received through December 13, 2005.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visits.

An office conference has been scheduled for January 27, 2006 at 10:00 AM in the Facility Licensing and Investigations Section of the Department of Public Health, 410 Capitol Avenue, Second Floor, Hartford, Connecticut.

The purpose of the meeting is to discuss the issues identified. Should you wish legal representation, please feel free to have an attorney accompany you to this meeting.

It will not be necessary for you to bring a plan of correction to this meeting as Department staff will be discuss alternative remedies to address the non-compliance issues identified during the course of the investigation.

If there are any questions, please do not hesitate to contact this office.

Respectfully,

Elizabeth S. Andstrom, R.N., M.S.
Supervising Nurse Consultant
Facility Licensing and Investigations Section

ESA:zbj

c: Director of Nurses
vlhsr2.doc
CT #4726



Phone:

Telephone Device for the Deaf: (860) 509-7191

410 Capitol Avenue - MS # _____

P.O. Box 340308 Hartford, CT 06134

Affirmative Action / An Equal Opportunity Employer

DATES OF VISITS: November 15, 16 and 18, 2005

THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT
STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES
WERE IDENTIFIED

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (d) Medical records (3) and/or (e) Nursing service (1) and/or (g) Pharmacy (1) and/or (i) General (7).

1. Based on clinical record review, review of hospital information and interviews, the hospital failed to provide the correct medication dose via the correct route to the patient. The findings include:
 - a. Patient #1, a 21 year old with a history of cerebral palsy and seizure disorder was admitted into the hospital's Emergency Department (ED) on 11/1/05 at 6:49 PM. Review of the record identified that the patient was non-verbal and the patient's family indicated the patient had developed a chin rash four days prior to admission, as well as increased agitation for the past three weeks. Review of the ED record revealed the patient's serum potassium level was 2.9 (normal 3.3 -5.1) at 12:47 AM on 11/2/05. Review of ED Physician Orders dated 11/2/05 at 2:00 AM indicated MD #6, a second year medical resident, directed potassium chloride (KCL) 10 milliequivalents (mEq) intravenously (IV) x 3 and KCL 40 mEq via percutaneous endoscopic gastrostomy (PEG) x 2 be administered. While in the ED, the patient received potassium chloride (KCL) 10 mEq intravenously (IV) at 2:30 AM and 40 mEq KCL at 2:35 AM via the PEG tube. Review of the record indicated Patient #1 was admitted and transferred to the nursing unit at 4:30 AM with the diagnoses of folliculitis and urinary tract infection. Review of computerized inpatient Physician Orders dated 11/2/05 at 2:00 AM indicated MD #6 directed KCL 10 mEq IV x 3 and KCL 80 mEq by mouth (po) x 3 be administered. Review of the record identified that on 11/2/05, after admission to the nursing unit, the patient received IV KCL 10 mEq at 5:39 AM and KCL 240 mEq via the PEG tube at 7:28 AM. Nurses' Notes dated 11/2/05 identified that the patient's vital signs deteriorated, the patient became unresponsive and cardiopulmonary resuscitation (CPR) was initiated at 7:43 AM. Resuscitation efforts were unsuccessful and subsequently, MD #3, a second year medical resident, pronounced Patient #1 dead at 8:15 AM. Review of hospital documentation, the clinical record and interview with MD #6 identified that she ordered KCL (IV and enteral routes) twice for Patient #1. MD #6 indicated that she intended to reenter the same KCL orders that she had ordered in the ED into the computerized system for two reasons: 1) because the ED physician orders were hand written and not integrated with the hospital's computerized physician order entry (CPOE) system and 2) because the patient may not receive the total amount of KCL in the ED. MD #6 identified that she created the medication order not utilizing the typical order screen of the CPOE

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system. However, MD #6 could not recall how she entered and/or recreated the KCL 80 mEq po x 3 medication order in the computer. MD #6 did not recall viewing and accepting the KCL order noted in the provider order entry computer screen that identified 80 mEq packet po x 3 in the order information category. MD #6 indicated that she was trained for 1-2 days on the CPOE system by the hospital information system personnel prior to internship and had been utilizing the CPOE system for 1½ years. MD #6 identified that she had ordered the IV route, as well as the enteral route because she was not sure the PEG tube was functioning. Although interview with MD #1, Chairperson of Medicine, revealed IV KCL was indicated for symptomatic and unstable hypokalemia, MD #6 noted that the patient was not experiencing symptoms of the hypokalemia nor was the patient unstable from the hypokalemia. Review of the physician KCL order directed the route of administration was po (not via PEG tube as in the ED). Interview with MD #6 identified that the patient was not able to swallow and the nurse would "automatically" administer the medication via the PEG tube. Interview with the Director of Pharmacy indicated that the rate of absorption would be different between routes. Although MD #6 indicated a repeat serum potassium was usually performed 4 to 5 hours after the first lab result, review of the record and interview with MD #6 revealed a repeat serum potassium level was not ordered. Review of hospital documentation and the Lines of Responsibility/Residency Supervision Policy indicated that the resident must interact with the attending physician at the time of the patient's admission and after patient evaluation for the General Medicine Service. Further record review and interview revealed the attending physician was not notified by the resident, MD #6, as per hospital policy. Interview with the Director of Pharmacy identified that the ED was not utilizing the hospital CPOE system and therefore, pharmacy personnel were unable to view the medications that were administered to ED patients. The Pharmacy Director noted the hospital did not have a policy concerning drug advisory alerts and the overriding process. Furthermore, the Pharmacy Director identified that the pharmacists receive and view the drug dosing advisories on the CPOE system and physicians do not receive and view the drug dosing advisories. Review of hospital information and interview with the Director of Pharmacy and Pharmacist #1 identified that not all medications have a dose range advisory. Although a dose range advisory alert was identified for the KCL order, Pharmacist #1 indicated that she overrode the dose range advisory for the KCL 80 mEq x 3 po order using her professional judgment. Pharmacist #1 explained that the KCL order on the pharmacist review computer screen did not specifically identify x 3 doses as was

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identified on the provider review screen. Although the order indicated 80 mEq on the same date and at the same time three times under the "when" category, Pharmacist #1 believed it was a one-time dose. Pharmacist #1 identified the advisory alert had specified the maximum individual dosage for KCL was 40 mEq po, however, Pharmacist #1 believed the patient would not have tolerated 80 mEq po and the daily dose of 80 mEq was within the normal range of 20-100mEq as noted on the review screen. Pharmacist #1 also revealed that upon reviewing the KCL order, the route of medication administration was identified as po, not via the PEG tube and that she was unaware the patient had a PEG tube. Interviews with Pharmacist #1 and RN #1 identified that a pharmacist must review medication orders prior to medication administration.

Interview with RN #1 identified that she called pharmacy to review the medication order so that she could administer the medication. RN #1 also revealed that after seeing the KCL 80 mEq x 3 oral dose and the KCL IV dose, she called MD #6 and asked "You have 2 bags of IV potassium and the oral dose, is this what you want?" and MD #6 replied "Yes". Although interview with RN #1 identified and that she and RN #2, the charge nurse, had reviewed the medication administration record (MAR) and physician order together, interview with RN #2 revealed that she did not review the MAR or physician order with RN #1. RN #2 indicated RN #1 informed her verbally of the KCL 80 mEq x 3 po order and that they had retrieved three of the twelve KCL packets from the Pyxis medication system together. RN #2 revealed she had thought the KCL dose was high and had instructed RN #1 to question the physician about the dose. RN #2 identified that the drug resource available for medication information, micromedex, was not utilized for drug dosage information. RN #1 revealed that, although she had been instructed on the use of the drug advisory alert on the computer system, the advisory that appeared for the KCL order was not utilized. Interview with the Vice President of Patient Services identified that it was not mandatory to review drug advisory alerts. Interviews with RN #1 and RN #2 identified both were present in the patient's room when RN #1 queried MD #6 concerning the KCL medication order. RN #1 identified that prior to KCL administration via the PEG tube, she asked MD #6 "is it okay to give all at once?" and received a positive response. RN #1 identified that she had mixed 6 packets (KCL 20 mEq/packet) per glass of water and administered 2 glasses of the medication mixture via the PEG tube. Patient #1 had received a total of KCL 300 mEq within 5 hours. The Physician Desk Reference (2005, page 482) identified that doses of 40-100 mEq per day or more are used for the treatment of potassium depletion and that dosage should be divided if more than 20 mEq per day is given

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such that no more than 20 mEq is given in a single dose. Review of the clinical record and interviews with hospital personnel identified that the hospital failed to provide the correct medication dose via the correct route to the patient.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical staff (2)(B) and/or (d) Medical records (3) and/or (e) Nursing service (1) and/or (i) General (7).

2. Based on clinical record review and interviews, the hospital failed to provide advanced cardiac life support according to the hospital's policy during cardiopulmonary resuscitation of one patient. The findings include:
 - a. Patient #1, a 21 year old with a history of cerebral palsy and seizure disorder was admitted into the hospital's Emergency Department (ED) on 11/1/05 at 6:49 PM. Review of the clinical record identified that on 11/2/05 Patient #1 had received potassium chloride (KCL) 50 mEq while in the ED and KCL 250 mEq after admission into the hospital. Admission Physician Orders dated 11/2/05 identified that the patient's vital signs deteriorated, the patient became unresponsive and cardiopulmonary resuscitation (CPR) was initiated at 7:43 AM. The hospital's Resuscitation/Code 254/Post-Resuscitation Management Protocol identified that the code was managed according to the American Heart Association Guidelines for Advanced Cardiac Life Support. Interview with MD #2, Chief of Anesthesia, indicated that he intubated Patient #1 during the resuscitation. Although MD #2 asked who was in charge, the code team leader was not clearly identified. MD #2 also revealed he did not stay for the entire resuscitation and did not believe that there was "a lot of activity going on." Review of the Resuscitation Protocol directed that the Code Leader was the Medical Intensive Care Senior resident and the Resident in charge was to be identified during the active resuscitation period. Interview with MD #3, the Code Leader revealed tat he did not clearly identify himself as team leader for approximately ten minutes. Interview with MD #3 identified the initial rhythm was ventricular fibrillation (VF), that the patient was "not shocked right away," the initial joules (J) utilized for defibrillation were 200, 300 and 360 and arterial blood gases were not performed. Review of the Code 254 Flow Sheet (resuscitation flow sheet) identified the initial rhythm was pulseless electrical activity (PEA), however, no electrocardiogram (EKG) cardiac rhythm strips were mounted to the Code 254 Flow Sheet as per Guidelines For The use of the Arrest Resuscitation (Code 254) Record Form. Nursing Staff indicated that the initial rhythm was pulseness ventricular tachycardia (VT) and the initial defibrillation was at 360 J. Further review of the clinical record and

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interviews with hospital staff failed to provide evidence that the American Heart Association Guidelines for Advanced Cardiac Life Support (2002) were followed during the resuscitation as per hospital policy.