

**State of Connecticut
Department of Public Health
Division of Health Systems Regulation**

In Re: Yale – New Haven Hospital, Inc. of New Haven
20 York Street
New Haven, CT, 06504

CONSENT AGREEMENT

WHEREAS, Yale – New Haven Hospital, Inc. of New Haven hereinafter the (“Licensee”), has been issued License No. 0044 to operate a General Hospital hereinafter the (“Facility”) under Connecticut General Statutes Section 19a-490, by the Department of Public Health hereinafter the (“Department”); and

WHEREAS, the Department’s Division of Health Systems Regulation conducted unannounced inspections at the Facility on April 22, 23, 24, 25, May 14, July 29, 30, 31, August 12 and September 4, 2003 for the purposes of conducting multiple investigations and a validation survey; and

WHEREAS, during the course of the aforementioned inspections violations of the Regulations of Connecticut State Agencies were identified in violation letters dated June 4, 2003 (amended on July 2, 2003 - Exhibit A), and October 31, 2003 (Exhibit B); and

WHEREAS, an office conference regarding the June 4, 2003 violation letter was held between the Department and the Licensee on July 1, 2003; and

WHEREAS, it is expressly understood that the execution of this Agreement, any provision of this Agreement, any contribution paid by Licensee in accordance with this Agreement, and any statements or discussions leading to the execution of this Agreement, shall not be construed to constitute any admission or adjudication of any violation of the Regulations of Connecticut State Agencies, the Connecticut General Statutes, the U.S. Code or the Code of Federal Regulations by the Licensee, its agents, servants, employees or any other person or entity; and

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

NOW THEREFORE, the Division of Health Systems Regulation of the Department of Public Health of the State of Connecticut, acting herein by and through Marianne Horn, its Director, and the Licensee, acting herein by Joseph Zaccagnino, its President, hereby stipulate and agree as follows:

1. The Licensee shall within thirty (30) days of the execution of the Consent Agreement, develop or review or revise, as necessary, all policies and procedures relating to Emergency Department (ED) triage, assessment and monitoring, inclusive of, but not limited to guidelines for the triage, physical examination, assessment and monitoring of patients with cardiopulmonary symptoms and wounds, documentation of said assessments and subsequent interventions, restraint-assessments and completion and communication of laboratory testing results.
2. The Licensee's medical board shall review and approve the revised policies and procedures stipulated in paragraph one (1) above, within sixty (60) days of this execution of this Consent Agreement.
3. The Licensee shall immediately upon execution of this document review staffing patterns for the Emergency Department with particular emphasis on the numbers, qualifications of staff and mechanisms to supplement staffing to periods of high demand.
4. The Licensee shall within sixty (60) days of the execution of this Consent Agreement, develop and implement a program to assess staff compliance with the Emergency and Surgical Department policies, procedures, and standards of practices. The program shall include but not limited to a mechanism whereby remediation of staff occurs for failure to adhere to facility policy and procedures.
5. The Licensee shall within ninety (90) days of this Consent Agreement, ensure that it has in place an inservice program for newly employed ED staff totalling not less than (3)

- hours. Said program shall include, but not be limited to Emergency Department policies, procedures, practices, emergent interventions for cardiopulmonary emergency conditions, diseases or disorders including diagnoses, treatment and monitoring. Presenters shall be clinical professionals. A record of new employee attendance at all didactic sessions shall be maintained for Department review.
6. The Licensee represents that its Performance Improvement (Quality Assurance) Program, combined with other Hospital programs shall, within thirty (30) days of the execution of this Agreement, be reviewed and revised as necessary, to include the following components:
- a. The adoption or revision of policies, as applicable, addressing state and federal laws and regulations;
 - b. Assessment of incidents which have occurred in the Emergency Department and Surgical Department including operating rooms to identify all situations which have a potential for risk or harm, inclusive of, but not limited to accurate sponge counts following surgical procedures and ensuring that site verification is performed on all patients preoperatively;
 - c. Remediation of staff who fail to comply with facility policies/procedures;
 - d. Review of medication errors to determine cause and ensure staff are following policies/procedures;
 - e. Educational programs for licensed and unlicensed personnel, which reflect topics pertinent to those identified by the Performance Improvement Committee; and
 - f. Monitoring and evaluation of the medical care rendered of twenty (20) patients with acute conditions monthly for a period of twelve (12) months.
7. The Licensee shall contract at its own expense with a registered nurse acceptable to the Department to serve as an Independent Nurse Consultant (INC) for a minimum of three (3) months. The Department shall review the necessity of continuing the Independent Nurse Consultant at the end of the three (3) months time frame. The INC shall be at the facility thirty (30) hours a week. The Independent Nurse Consultant shall have

fiduciary responsibility to the Department. The responsibilities of the INC shall include monitoring of care and services provided to patients on all three (3) shifts and or remediation of staff when potential care issues are identified. The Independent Nurse Consultant shall have the responsibility for:

- i. Assessing, monitoring and evaluating the delivery of direct patient care with particular emphasis and focus on the delivery of nursing services by registered and licensed practical nurses;
 - ii. Recommending to the Licensee and the Department an increase in the Independent Nurse Consultant's monitoring hours if unable to fulfill the responsibilities within the stipulated thirty (30) hours per week;
 - iii. Review of all patient care policies and procedures relative to monitoring and assessing patients; and
 - iv. Assessing, monitoring and evaluating the coordination of patient care and services delivered by the various health care professional providing services within the Facility.
8. Any records maintained in accordance with any state or federal law or regulation or as required by this Consent Agreement shall be made available to the Independent Nurse Consultant and the Department, upon their request.
 9. The Department shall retain the authority to extend the period the Independent Nurse Consultant functions are required, should the Department determine that the Licensee is not able to maintain substantial compliance with federal and state laws and regulations.
 10. The Independent Nurse Consultant and the Licensee or a designee of the Governing Authority shall meet with the Department every four (4) weeks for the first three (3) months after the effective date of this Consent Agreement and if necessary, thereafter submit reports on a biweekly basis to the Department to address the facility's initiative to comply with applicable federal and state statutes and regulations and the assessments of the care and services provided to patients.

11. The Licensee shall designate a multidisciplinary team of applicable professionals to evaluate new equipment. Said team shall develop policies procedures relative to new equipment and staff education prior to deployment onto patient care units.
12. The Licensee shall ensure that all patients admitted to the hospital shall be admitted to a hospital bed.
13. The Licensee, through the Chief of Staff and Vice President for Patient Care Services, upon the execution of this Consent Agreement, shall:
 - a. Designate an RN Off Shift Administrator on all shifts who have responsibility for supervision of nursing and ancillary patient care on all clinical units including the assessment of patients care planning and the care provided by staff. The Off Shift Administrator shall evaluate staff competence, maintain a record of any patient related issue(s) or problem(s) identified on his or her shift and subsequent action taken to resolve the problem(s). Said documents shall be available to the Department and shall be retained for a period of three (3) years.
 - b. RN Off Shift Administrator shall be provided with:
 - i. A job description which clearly identifies their day-to-day duties and responsibilities:
 - ii. Training programs which clearly delineate each Off Shift Administrator responsibilities and duties in relation to the hospital's policies and procedures for patient and staff observations, interventions, staff remediation, changes in patient condition, and clinical record documentation:
 - iii. Supervision (including reasonable on-site supervision as described below) and monitoring by a representative of the hospital administrative staff, (e.g. Vice President for Patient Care Services) to ensure the Off Shift Administrator are functioning in accordance with this Consent Agreement and state and federal requirements. Said administrative supervision and oversight shall be provided on all three (3) shifts on an irregular schedule of visits; the scheduling and frequency of these visits shall be at the discretion of the responsible

administrator. Records of such administrative visits and supervision shall be retained for the Department's review.

14. The RN Off Shift Administrator shall be responsible for ensuring that care is provided to patients by all caregivers in accordance with individual assessments, comprehensive care plans, dialogue with unit staff, observation of patient care and medical record review.
15. Within forty-five (45) days of the execution of this Consent Agreement, the Licensee shall review and revise, as applicable, policies and procedures relative to:
 - a. Patient specific interventions to be implemented prior to the utilization of mechanical and physical restraints and documentation of said interventions;
 - b. The specific types of restraints the institution shall utilize, including but not limited to, application, positioning of the patient, medical contraindications for utilization, assessment for least restrictive restraint, components of a patient assessment during the period a patient is in restraints and documentation of said assessment;
 - c. Specific delineation of professional staff who may order restraints;
 - d. Specification of professional staff who must be present to supervise and observe the application of restraints.
16. The Facility shall designate one individual who shall assume the overall responsibility for full implementation of this Consent Agreement. The Department shall be notified as to the identity of this person within seven (7) days of the effective date of this Consent Agreement. A report regarding facility compliance with this Agreement shall be forwarded to the Department on a monthly basis for the first six (6) months and every three (3) months thereafter, by the individual identified by the Facility.
17. The Licensee agrees to pay the Department sixty thousand dollars (\$60,000.00), which shall be payable by certified check to the Treasurer of the State of Connecticut and shall be posted to the Department within two (2) weeks of the effective date of this Agreement. Said check shall be directed to Judy McDonald, Supervising Nurse Consultant at the address previously identified in this document.

18. Reports and meetings required by this document shall be sent to:

Judy McDonald, R.N.
Supervising Nurse Consultant
Department of Public Health
Division of Health Systems Regulation
410 Capitol Avenue, MS #12HSR
P.O. Box 340308
Hartford, CT 06134-0308

19. All parties agree that this Consent Agreement is an order of the Department with all of the rights and obligations pertaining thereto and attendant thereon. Nothing herein shall be construed as limiting the Department's available legal remedies against the Licensee for violations of this Agreement or of any statutory or regulatory requirements, which may be sought in lieu of or in addition to the methods of relief listed above, or any other administrative and judicial relief provided by law. This Consent Agreement may be admitted by the Department as evidence in any proceeding between the Department and the Licensee in which compliance with its terms is at issue. The Licensee retains all of its rights under applicable law.
20. 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.
21. The terms of this Consent Agreement shall remain in effect for a period of two (2) years from the effective date of this document.

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

YALE - NEW HAVEN HOSPITAL, INC. OF
NEW HAVEN

3-1-04
Date

By: [Signature]
Joseph Zaccagnino, President

State of Connecticut)
County of New Haven

ss March 2004

Personally appeared the above named Joseph Zaccagnino and made oath to the truth of the statements contained herein.

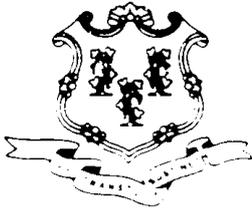
My Commission Expires: 10/31/05

[Signature]
Notary Public
Justice of the Peace
Town Clerk
Commissioner of the Superior Court

STATE OF CONNECTICUT,
DEPARTMENT OF PUBLIC HEALTH

March 7 2004
Date

By: [Signature]
Marianne Horn, R.N., J.D., Director
Division of Health Systems Regulation



STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

July 2, 2003

Joseph A. Zaccagnino, President and CEO
Yale – New Haven Hospital
20 York Street
New Haven, CT 06504

Dear Mr. Zaccagnino:

This is an amended edition of the violation letter originally sent on June 4, 2003.

Unannounced visits were made to Yale – New Haven Hospital on April 22, 23, 24, 25, 2003 and May 14, 2003 by representatives of the Division of Health Systems Regulation for the purpose of conducting multiple investigations with additional information received through May 15, 2003.

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 June 18, 2003 at 10:00 AM in the Division of Health Systems Regulation Conference Room, Department of Public Health, 410 Capitol Avenue, Hartford, Connecticut.

Please prepare a written Plan of Correction for the above mentioned violations to be presented at this conference.

Each violation must be addressed with a prospective Plan of Correction which includes the following components:

1. Measures to prevent the recurrence of the identified violation, (e.g., policy/procedure, inservice program, repairs, etc.).
2. Date corrective measure will be effected.
3. Identify the staff member, by title, who has been designated the responsibility for monitoring the individual plan of correction submitted for each violation.

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

Respectfully,

Judy McDonald, RN
Supervising Nurse Consultant
Division of Health Systems Regulation

JEM/zbi

cc: Director of Nurses

vlyalenhosp.doc

#2002-1064, #2002-1061, #2002-1106, #2002-1255, #2002-1135, #2002-1296, #2003-0099, #2003-016
#2003-0444, #2003-0401, #2003-0399, #2003-0398, #2003-0375, #2003-0298, #2003-0296, #2003-016
#2003-0258, #2003-0130, #2003-0121, #2003-0103, #2003-0378, #2003-0379, #2003-0400, #2003-012
#2003-0257, #2003-0068, #2003-0297



Phone

Telephone Device for the Deaf 860-509-7191

410 Capitol Avenue - MS #

P.O. Box 340308 Hartford CT 06134

DATES OF VISIT: April 22, 23, 24, 25, 2003 and May 14, 2003

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

1. The facility failed to ensure one patient (Patient #8) was appropriately evaluated for hemorrhaging in a timely manner. The findings are based on a review of the medical record, review of facility policy, and interviews.
 - a. Patient #8 was admitted to the facility on 10/12/02 for syncope, ventricular tachycardia, and left bundle branch block. A left femoral pseudoaneurysm developed after an electrophysiology study. On 10/18/02 attempts to treat the problem with an ultrasound compression performed at 3:00 PM and thrombin injection performed at 5:10 PM were unsuccessful. A review of nursing progress notes between 5-7 PM on 10/18/02 and 7:00 PM on 10/19/02 identified the patient had severe groin pain, low blood pressure readings, a paced rhythm of 80, a dropping hematocrit and hemoglobin, received blood and plasma, was cool, clammy, diaphoretic, and nauseous. The hematoma increased in size. Decreased urine output was identified and the patient became anxious, agitated, confused at times, respiratory rate increased to 30 to 40, and no oxygen saturations were obtainable. There were multiple references to contacting MDs #12, #13, and #14 who were made fully aware of the patient's condition, evaluated and treated the patient during the night. The medical record lacked progress notes of assessments by MDs #12 and #13 between 8:30 PM on 10/18/02 and 7:30 AM on 10/19/02. Patient #8 was taken to surgery on 10/19/02 at 7:30 AM and underwent a repair of the left superficial femoral artery and vein, and evacuation of a thigh hematoma due to a ruptured left femoral artery pseudoaneurysm. The patient was identified pre and postoperatively as hemodynamically unstable, on presser support, severely acidotic, anemic, thrombocytopenic, experiencing diffuse coagulopathic bleeding, hypothermic, and oliguria. Due to the patient's lack of response to numerous resuscitative interventions, pressors, and blood administration, the patient was made a comfort measure only by the family and expired on 10/19/02 at 10:47 p.m. An autopsy identified the patient died from soft tissue hemorrhage complicated by hypotension and acidosis. During an interview, MD #4, Director of Clinical Quality Assurance and MDs #5 and #6, the patients' attending physicians, all stated MDs #12, #13, and #14, resident physicians, should have communicated with the attending physicians during the night about the patient's change in condition and the patient should have been taken to the OR earlier. During interviews, MD #12, first year ER Resident, and MD #13, second year Medical Resident, stated they should have called the Fellow or Attending Physicians for assistance and had not because they had communicated with MD #14, Surgical Resident whom they assumed would call an Attending if needed and they followed the usual chain of command for physician notification.

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2. For fourteen (14) of fifty-one (51) medical records reviewed, the facility failed to ensure that nursing care was provided according to standards of practice and/or facility practice, the findings are based on reviews of the clinical records, review of policies and procedures and staff interviews and include the following:
 - a. Patient #48 was admitted to the facility on 4/14/03 with a diagnosis inclusive of subarachnoid hemorrhage. Review of an anesthesiology record dated 4/15/03 identified a naso-gastric/oral gastric tube in-situ. Review of the adult critical care flow sheets from 4/16/03 through 4/17/03 identified that the patient had received continuous enteral feedings via a naso-gastric tube. Review of the clinical management protocol for naso-gastric feedings identified that patency should be monitored every two to four hours. Placement should be assessed by instilling a small amount of air via the gastric port while auscultating over the left upper quadrant. Review of the clinical record failed to identify that patency and placement had been assessed in accordance with policy and procedure.
 - b. Patient #36 was admitted with diagnoses inclusive of sepsis, end stage renal disease, diabetes, gastrointestinal bleeding, and hemophilia. A physician's order dated 11/18/02 identified a fingerstick glucose be obtained three times a day. Review of the daily patient care record dated 11/26/02 identified that a fingerstick glucose obtained at 9:00 PM revealed a result of 71. Orange juice was given to the patient. A follow up glucose fingerstick obtained at 11:00 PM revealed a result of 58. Review of the clinical record identified a resuscitation flow sheet dated 11/27/02 at 6:50 AM which identified that the patient was unresponsive with a faint heart rhythm, shallow respirations, and an absent blood pressure and oxygen saturation. Resuscitative efforts were initiated. A glucose fingerstick of "8" at 7:11 AM was recorded. Subsequent to resuscitation, the patient was transferred to the Medical Intensive Care Unit (MICU). A physician's progress note dated 11/27/02 identified that the patient was found unresponsive probably due to a low glucose. Review of the clinical management protocol for diabetes mellitus identified that the physician should be notified of a fingerstick or serum glucose of less than 70 unless otherwise ordered. An interview with RN #20 on 4/25/03 at 11:00AM revealed that subsequent to a result of 58 an action should have been initiated which would have included notifying the patient's physician, re-assessing the glucose fingerstick, and monitoring the patient for signs and symptoms of hypoglycemia.
 - c. Patient #24 was triaged in the ED on 11/9/02 at 10:15AM with complaints of pain in both calves with pain assessed as a 6 on a scale of 0-10. Review of the ED triage assessment identified that the patient was sent in to rule out a deep vein thrombosis.

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had no complaints of respiratory distress or chest pain, and was designated a triage classification of level II. Vital signs obtained at 10:20AM revealed a blood pressure of 162/87, a pulse of 107, oxygen saturation of 92% on room air, and pain rated at a level of 5 on a scale of 0-10. An ED progress note dated 11/9/02, 10:40 AM identified that the Registered Nurse (RN) assessment was completed with the patient reporting that he was coughing yellow brown sputum and complaining of chest pain at a level of 5 on a scale of 0-10. Vital signs obtained at 10:40 AM revealed a blood pressure of 102/86, a pulse of 104 and an oxygen saturation of 91% on 2 liters of oxygen. Review of the ED record identified that the patient was not re-assessed until 1330 when vital signs included B/P of 100/70, pulse of 110, respirations of 18, and an oxygen saturation of 95% on two liters of oxygen, however, lacked a pain assessment (two hours and forty five minutes after previous vitals). At 13:55 the patient was found on the floor and assessed with pulseless electrical activity. Resuscitative efforts were initiated without success and the patient was pronounced at 14:47. Review of the autopsy report dated 11/10/02 identified that the cause of death was multiple, massive pulmonary emboli. Review of the pain management principles specific to the ED identified that the pain assessment at triage will include information about the onset, location, cause, duration, intensity, response to interventions, and aggravating factors. The patient will be assessed before administering any analgesia or performing any pain relief measure and then within one hour of administration of medicine or pain control intervention until the pain score is less than 4 or the patient is satisfied with the pain relief. Although the patient was complaining of pain, review of the ED record failed to identify that the pain had been assessed and that the patient was without the benefit of any pain control interventions in accordance with the policy and procedure.

- d. Patient #38's discharge summary identified that the patient was a 51-year-old female with a history of mitral valve repair in 4/02. The patient was admitted to the hospital on 11/19/02 and underwent a cardiac catheterization which revealed an ejection fraction of about 30-35 percent. An echocardiogram revealed non-dilated cardiomyopathy and the patient was treated with intravenous Dobutamine. The patient was going to be worked up for a heart transplant and was scheduled to be discharged home on 11/27/02 and continue the intravenous Dobutamine on an outpatient basis. The nursing transplant note dated 11/27/02 identified that Chartwell Homecare Infusion Services would deliver the Dobutamine and infusion pump. Progress notes indicated that the homecare nurse placed the patient on the homecare pump at 11 am on 11/27/02. On 11/27/02, (no time identified) the

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physician identified that the patient developed hypotension to 60's systolic and that the portable pump had been found clamped. The patient was transferred back to a hospital pump and reported feeling better and the patient's blood pressure increased to the 70's. The patient's blood pressure ranged from the 90's to the 70's during her hospital stay. Review of the daily patient care record reflected that the Dobutamine infusion set was recorded hourly during the period of 8:00 AM through 11:00 AM on 11/27/02 but documentation of the rate was lacking from 12 noon through 2:30 PM. During interview RN #7 identified that there was no specific protocol for the administration of Dobutamine and acknowledged that she was unfamiliar with the homecare infusion pump, but noticed at approximately 1:00 PM on 11/27/02 that one of the clamps on the tubing was open and one was clamped and that this was noticed around the time that the patient became unstable. RN #7 acknowledged that the portable pump never alarmed to indicate that the tubing was clamped. This nurse stated that the patient was on continuous telemetry monitoring and that the patient received the Dobutamine continuously at a rate of 10 cc/s an hour. Upon interview the Risk Manager identified that the Dobutamine was in fact administered to the patient during the hours of 11:00 AM through 1:00 PM on 11/27/02 because the manufacturer tested the pump and the machine log identified that the pump was working and that the patient received the medication as prescribed.

- e. Patient #27 was admitted to the facility on 12/31/02 with diagnoses that included Right Lower Lobe Pneumonia and status post Right Below the Knee Amputation. The nursing assessment dated 12/31/02 indicated that the patient was at risk for falls. The patient's Interdisciplinary Plan of Care dated 1/2/03 indicated that the patient had sustained a fall. Review of the history and progress notes dated 1/4/03 at 7:45 AM indicated that the patient had been found on the floor, nose bleeding and an abrasion to the patient's forehead. Review of the Imaging Department report dated 1/4/03 at 8:57 AM indicated that the patient had sustained a left frontal sinus fracture. After the first fall on 1/4/03, there was no documentation to reflect that staff implemented monitoring of this patient related to falls and/or assessed the patient's complete neurological status to include checking the pupils following a fall with a head injury. Further review of the day nursing history and progress notes dated 1/4/03 indicated that after the patient had returned from the Imaging Department, the patient had been found on the floor with the patient's forehead against the foot peddle of the linen cart. Review of the clinical record with Unit Manager #2, indicated that the facility was unable to provide documentation that the patient's pupils had been checked and monitored after both falls on 1/4/03.

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- f. The facility failed to perform an assessment when the patient complained that something was wrong with her leg and/or document a pain assessment. Patient #37 presented to the facility on 1/21/03 with diagnoses that included Esotropia and Fibromyalgia for a Strabismus to both eyes. The Intraoperative Nursing Record dated 1/21/03 indicated that the patient was at risk for injury related to positioning, extraneous objects, chemical, physical or electrical hazards with interventions to use appropriate positioning devices. Review of the Intraoperative Nursing Record dated 1/21/03 from 10:09 AM to 12:35 PM (a total of two hours and twenty-six minutes) indicated that a pillow had been placed under the patient's knees during the surgery. Review of the Postoperative Phone Call note dated 1/22/03 at 9:30 AM indicated that Patient #37 had complained of the left foot dragging and numbness of the left arm and foot. Further review of the Postoperative Phone Call note dated 1/22/03 indicated that during the surgical procedure, the patient had been placed on the patient's back with a wedge under both knees to relieve back tension. Physician #2 on 4/24/03 stated that a pillow had been placed under the patient's knees at the time of the surgery. Interview with Patient #37 on 4/29/03 identified that the Patient #37 had ambulated before being discharged home on 1/21/03, and had complained that something was wrong with the leg, however, there was no documentation to reflect that an assessment of the patient's leg had been performed. Subsequently, Patient #37 developed a foot drop, required physical therapy and a brace. In addition, a review of the Post Anesthesia Care Unit notes dated 1/21/03 indicated that Patient #37 had been given Tylenol 650 milligrams (mg) at 1:25 PM and Tylenol #3 at 2:00 PM. Review of the facility's policy on Acute Pain indicated that the nursing management of the adult patient experiencing acute pain include, obtaining information on onset, location, character, causes alleviating or aggravating factors, frequency, duration, intensity and response to the interventions. Further review of the facility's policy on Acute Pain, indicated that when administering analgesics or implementing another intervention intended to ameliorate pain, the patient's level of pain needs to be assessed before the analgesic intervention, then within one hour reassess effectiveness of the intervention. Although the Post Anesthesia Care Unit note reflected that the patient had been medicated with Tylenol 650mg and Tylenol #3 after the surgery, there was no documentation to indicate what the medication had been given for and or its effectiveness.
- g. Patient #16's diagnoses included dementia and a history of cerebral vascular accidents. Nurses' notes dated 2/27/03 at 2:30 AM, identified that Patient #16 was punched in the face by Patient #30. Nurses' notes identified that the patient called

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out stating that she had been "struck in the face." The physician's progress note dated 2/27/03 at 3:00 AM identified that the patient had a laceration to the bridge of the nose and a bandage was applied. Review of the clinical record failed to identify documentation that the patient's eye was assessed until 8:40 a.m. when the patient had decreased vision in the right eye with moderate swelling. RN #14 stated that on 2/27/03 at 8:40 AM, she notified the physician that Patient #16's right eye was swollen and discolored and that she could not open the eye. RN #14 also stated that during report that morning, there had been no specific information reported by the previous shift regarding Patient #16's right eye. RN #15 stated that after the physician examined Patient #16 at 3:00 a.m. on 2/27/03, she medicated Patient #16 with Tylenol and then noted that she was sleeping with her eyes closed. RN #15 also stated that although she went into Patient #16's room on 2/27/03, there is no documentation regarding an assessment of Patient #16's right eye. RN #15 further stated that if there had been anything out of the ordinary, she would have documented it. Subsequently, the patient was sent to the emergency department for an orbital CT scan and an eye exam. Patient #16 was referred to the Eye Center for follow-up where it was determined that she sustained a layered hyphema, a right choroidal hemorrhage, and a right vitreous hemorrhage.

- h. Patient #19 was transferred to the facility from another acute care facility on 11/27/02 with diagnoses that included right-sided rib fractures sustained in a fall on 11/26/02. Review of the medical record identified that the patient sustained multiple injuries to the right side of the body including a laceration to the right parietal occipital area. Review of the Emergency Department (ED) record dated 11/27/02 identified a body outline with the number "5" and a line drawn to the patient's right occipital parietal area. Patient #19 was admitted to the Surgical Intensive Care Unit (SICU). Review of the daily assessment records dated 11/27/02 through 12/11/02 reported the right parietal occipital area as "intact." Review of the daily assessment dated 12/11/02 identified a "stage II" area at the patient's occipital region and "sutures" at the right occipital site but provided no further information including size and or number of sutures. No further assessments of the areas were made including the day of discharge from the acute care facility to the skilled nursing facility on 12/20/02. During a review of the medical record with the Manager of the SICU on 04/25/03, the record lacked evidence of complete and accurate assessment of the patient's right parietal occipital wound and further that after the identification of the sutures, the problem was not addressed on the plan of care. Patient #19 was discharged to a skilled nursing facility on 12/20/02 with the sutures still in place. Review of the facility's wound care policies identified that the

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specific criteria for assessing wound size and status included wound bed color, drainage, tunneling and periwound skin assessments. The policy further included the need to measure the length, width and dept of wounds in centimeters. The policy identified that wound assessments using these criteria are to be documented at least every twenty-four hours and that nursing interventions would be added to the nursing plan of care.

- i. Patient #18 had diagnoses that included severe Peripheral Vascular Disease (PVD) with a non-healing ulcer of the left leg. Patient #18 was admitted for aggressive debridement of the leg ulcers with eventual revascularization procedure of the left leg. Review of the physician's order sheets dated 05/31/00 identified orders that included the regularly scheduled Oxycontin and Tylenol with 30 mg. of Codeine every three to four hours as needed for breakthrough pain. Review of the progress notes dated 06/08/00 identified that Patient #18 complained of "extreme severe pain" with movement and dressing changes and that a Patient Controlled Analgesic (PCA) pump that contained Morphine was set up for the patient in accordance with the physician's orders. Morphine Sulfate (MS) Contin 30 mg. two times daily, and additional MS 2 mg. intravenously (IV) prior to dressing changes was added to Patient #18's medication regime for pain management. Review of the psychiatric consult dated 06/12/00 identified that the family and the staff reported some confusion and that Patient #18 reported that he'd experienced some visual hallucinations. The psychiatric consult identified that the "delirium could be related to opiate dosing." Review of the medical record identified a pulmonary consult dated 07/10/00 that identified that Patient #18 had experienced "increased confusion and mental status changes over the last several days" with desaturation (lowering oxygen levels) that were reported "in the 80's" (Normal 92-100) and required subsequent oxygenation by way of a Bi-Pap machine. Upon interview with MD #3 on 04/23/03, he said that Patient #18 had complained of severe pain and that he ordered the medication based on attempts to relieve the patient's pain so that he could be compliant with the aggressive treatment regime. MD #3 said that Patient #18 did receive oversedation but not because the amount of narcotics he received was out of standard doses, but rather because it was more than the patient could tolerate. Review of the medical record with Clinical Director #4 on 04/24/03 identified that while the medications were given in accordance with physician's orders, the record failed to identify that pain assessments and/or sedation assessments were consistently documented.
- j. Patient #22's diagnoses included a cervical neck fracture. Review of a nursing note dated 12/06/02 identified that Patient #22 was at risk for skin breakdown as

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- evidenced by the observation of a "erthematous (red) area at the sacral area" and "pressure noted from (cervical) collar area." Review of the medical record dated 12/09/02 through 12/16/02 identified that although Patient #22 continued to wear the cervical collar, the record lacked further documentation of assessments of the skin beneath the collar. A nursing note dated 12/26/02 identified that Patient #22 had developed a three by five centimeter skin breakdown at the back of his head. Review of the flow sheet dated 12/27/02 failed to identify any open areas at the back of Patient #22's head. Review of facility documentation and the flow sheet dated 12/28/02 identified that Patient #22 had developed a Stage IV area to the back of the head.
- k. Patient #23's diagnoses included Coronary Artery Disease (CAD), Peripheral Vascular Disease (PVD), and Insulin Dependent Diabetes Mellitus (IDDM). Review of the nursing summary and flow records dated 10/24/02 identified that Patient #23 was at low risk for pressure areas and that the patient's skin was intact. On 11/02/02, the flow sheet identified that Patient #23 had a "skin tear" of an undetermined, undocumented size on the coccyx area. On 11/08/02, the nursing note identified that a Duoderm (an occlusive dressing) was applied to the area. Review of a nursing note dated 11/14/02 identified that the area was at a Stage II and was six centimeters (cm.) long and four cm. wide. Review of the flow record dated 12/30/02 identified that a green, quarter sized area at the tip of the coccyx was observed as well as Stage II breakdown of both buttocks. The documentation identified that on 01/03/03, Patient #23 had a Stage IV open area at the tip of the coccyx and Stage II areas on both buttocks. Review of the medical record identified that the record lacked consistent and accurate documentation of the patient's wound assessments. Review of the facility's wound care policies identified that the specific criteria for assessing wound size and status included wound bed color, drainage, tunneling and periwound skin assessments. The policy further included the need to measure the length, width and dept of wounds in centimeters. The policy identified that wound assessments using these criteria are to be documented at least every twenty-four hours and that nursing interventions would be added to the nursing plan of care.
- l. An observation on 04 22 03 of Patient #42's room identified a posted sign that a signified the need for contact precautions. The precautions required that staff don a gown and gloves prior to entering the room if they were to come in direct contact with the infected site. Although the patient care summary identified the type of precautions as "contact", review of the care plan failed to identify the responsible organism and or site of the infectious process. Review of the infectious process

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- printout with the unit manger identified that Patient #42 had enterobacteria in his sputum and urine.
- m. Patient #43 had diagnoses that included End Stage Renal Disease (ESRD) and Insulin Dependent Diabetes Mellitus (IDDM). Patient #43 routinely received scheduled hemodialysis treatments. Observation on 04/22/03 at 11:45 AM identified that Patient #43 was sitting up in bed and eating breakfast that included cereal and juice. Upon interview with the patient, he said that he had just returned from his dialysis treatment and was hungry. Patient #43 said that he leaves the unit for his dialysis treatments "early" and that he had not received breakfast before he left for the treatment. Patient #43 said that he had "told them a lot of times" about his breakfast but that nothing had been done. Upon interview with Unit Manager # 8, she said that Patient #43 had been offered a boxed breakfast before leaving for dialysis but had refused. Review of the medical record identified that Patient #43 had a fingerstick reported as 88 at 6:00 AM, that the patient received his routinely scheduled two units of NPH insulin, and that he left for dialysis at 6:00 AM, "before breakfast." The documentation failed to support that Patient #43 was offered breakfast and refused. Review of Patient #43's plan of care failed to identify the patient's individual needs for an early breakfast on the days he was scheduled for dialysis. Further observation on 04/22/03 of Patient #43's room identified a posted sign that a signified the need for contact precautions. The precautions required that staff don a gown and gloves prior to entering the room if they were to come in direct contact with the infected site. Although the patient care summary identified a source organism of Vancomycin Resistant Enterococcus (VRE) and MRSA, the plan of care failed to identify the type of precautions and/or the site of the infectious process.
- n. An observation on 04/22/03 of Patient #44's room identified a posted sign that a signified the need for contact precautions. The precautions required that staff don a gown and gloves prior to entering the room if they were to come in direct contact with the infected site. Review of the care plan with the unit manager failed to identify the need for contact precautions, the responsible organism and or site of the infectious process. Review of the infectious process printout with the unit manger identified that Patient #44 had Methicillin Resistant Staphylococcus Aureus (MRSA) in his sputum and enterobacteria in his urine. Patient #44 had diagnoses that included an odontoid fracture sustained in a fall prior to hospitalization with surgical fusion on 03/24/03. Review of the care plan identified that Patient #44 was to wear a hard cervical collar at all times. During an interview with the unit manager on 04/22/03, she said that the collar would be removed each day during

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daily care and that the skin under the collar would be checked. The unit manager said that the documentation of the process would be "by exception", documented only if there were an issue with the skin checks under the cervical collar. While the care plan reviewed with the unit manager and Clinical Director #4 on 04/22/03 identified that Patient #44 was at risk for pressure ulcers, the interventions included assessment of the patient's sacral skin every shift. The plan of care failed to identify that any checks of the skin under the cervical collar were included as of the treatment plan. Review of the facility policy on the management of a patient with a cervical collar identified that after a collar is applied, the patient's skin integrity will be evaluated every eight hours. Patient #44 had additional diagnoses that included questionable cirrhosis of the liver with abdominal ascites. Review of the progress note dated 04/22/03 identified that Patient #44 had a gastric tube placed on 04/11/03 for feeding purposes with documentation of significant leaking of fluid around the gastric tube site requiring a colostomy bag be placed over the incision site to collect the drainage. Review of the plan of care failed to identify the placement of the gastric tube, the problem with the leaking fluid, and/or the need for the collection bag at the site.

- o. Patient #44 had a sign posted outside his door that identified that the patient was on contact precautions. On 04/22/03 at 11:18 AM, RN #9 was observed in the patient's room without the benefit of a gown. At 11:25 AM, RN #9 was observed removing her gloves but without a gown as she exited Patient #44's room. Upon interview with RN #9, she said that she had just administered medications to the patient through his gastric tube. RN #9 said that she had not donned a gown prior to entering Patient #44's room. Review of the infectious process printout with the unit manger identified that Patient #44 had Methicillin Resistant Staphylococcus Aureus (MRSA) in his sputum and enterobacteria in his urine. Review of the facility's policy on contact precautions identified that all persons entering the room of a patient on contact precautions will don a gown and gloves prior to entering the room.

- 3. Facility staff failed to develop individualized and comprehensive treatment plans for three (3) of fifty-one (51) patients reviewed. The findings are based on medical record reviews, interviews with facility personnel, a review of facility policies and procedures, and include the following:
 - a. Patient #2 was admitted to the facility's adult psychiatric unit on 3/26/03 for treatment of schizophrenia. On 3/27/03 he was identified as refusing to take his medications, exhibiting pestering and menacing behaviors with female staff, being

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intrusive, and making inappropriate sexual comments. The patient was placed in the intensive observation unit, with structured group and community times, and remained there through 3/30/03 due to his sexually inappropriate behaviors including approaching females for sex. The master treatment plan dated 3/27/03 identified a patient objective to refrain from propositioning female staff and patients, but lacked specific approaches for the identified problem. Nurses' notes dated for the 3/30/03 evening shift, identified an RN assessed Patient #2, his behaviors were appropriate, and he exhibited no inappropriate sexual behaviors. At that time, the patient was moved out of the observation area and into the general population. Notes further identified that on 3/31/03, Patient #2 was awake between 2:30 and 3:30 AM and was last seen walking down the corridor. Directly following this observation, Patient #1, a seventeen year old, approached staff and stated a man fitting the description of Patient #2 had just touched her on the stomach and groin through the bed linens while she slept. The touch caused her to wake up and when she did, the man left her room without saying anything. Patient #2 denied touching Patient #1 but was moved back into the intensive observation room. The master treatment plan was then updated to include separating Patient #2 from the female population.

- b. Patient #9 was admitted to the adolescent psychiatric unit on 12/20/02 for treatment of out of control behaviors. Throughout the admission the patient exhibited hypersexual behaviors such as disrobing in public. Although the master treatment plan identified the patient was placed on restriction during the period of 12/26/02 and 1/3/03, she was allowed to leave her room to attend group therapy and meals. The master treatment plan did identify the patient was placed on room restriction, but the plan did not include written criteria, per the facility policy, that included a treatment goal, daily schedule, and criteria for discontinuing the room restriction.
- c. Patient #26, a 17-year-old, was admitted to the adult psychiatric unit on 3/21/03 for treatment of bipolar disorder and polysubstance abuse. The master treatment plan identified aggressive behaviors but did not identify what the behaviors were, who they were directed towards, measures to decrease the aggressiveness, or how to protect the patient from peers he may have angered. On the evening of 4-2-03 Patient #26 was hit in the face by Patient #41 resulting in a headache, a red mark below the left eye, and the patient later complained of seeing "floaters." A CT scan revealed no injuries. Patient #26 was placed on constant supervision following the incident for his own protection due to instigating arguments with other patients.

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- 4. Based on review of the medical record, review of facility policies, and interviews, the facility failed to provide a prescribed anticoagulant medication in accordance with the physician orders for one patient, (Patient #17), who required the medication for a cardioversion procedure. The findings included:
 - a. Patient #17 was admitted to the facility with diagnoses that included Atrial Fibrillation (A-Fib). Review of the medical record identified that Patient #17 was scheduled for cardioversion on 10/26/02. Review of the physician's order sheet dated 10/25/02 identified an order for Heparin, 2000 unit bolus to be administered intravenously (IV) at 9:04 AM and to then begin the administration of 800 units of Heparin per hour IV until discontinued by the physician. Additional orders included blood work to monitor the effects of the anticoagulant. Review of the nursing note dated 10/26/02 at 9:20 AM, RN #11 documented that she turned off the Heparin as Patient #17 was "on call for cardioversion." Upon interview with RN #11 on 05/02/03, she said that while she was aware of the physician's order for the Heparin, RN #11 said that because it was the usual practice on that unit to shut off Heparin prior to cardiac catheterizations and/or surgical procedures, that she had shut off the Heparin based on her experience. During an interview with MD #15 on 04/28/03, he said that while he could not confirm that Patient #17 had an adverse effect related to the discontinuation of the Heparin, that the anticoagulant should not have been discontinued during the cardioversion due to the patient's increased risk of clot formation.

- 5. Based on medical record review, the facility failed to ensure that for one (1) of fifty-one (51) patient records that the records were complete and or accurate.
 - a. Patient #20 presented at the Adolescent Clinic on 12/02/02 with complaints of a sore throat where a throat culture was obtained. Although a hard copy laboratory report dated 12/5/02 identified that Patient #20 had Group A Strep, there was no documentation to reflect that these positive results were reported to the physician. Patient #20 was subsequently evaluated at the Emergency Department (ED) on 12/16/02 for complaints of right-sided throat pain, fever, and neck pain and was prescribed antibiotic therapy. Patient #20 was seen again at the clinic on 12/19/03 by MD #16 who acknowledged the 12/16/02 ED visit and the current antibiotic regime in his note. Patient #20 was again evaluated in the ED on 12/21/02 for complaints of left ankle pain, and on 01/11/03, for complaints of multiple areas of pain including ankle, neck, shoulders, wrists and headache. Review of the ED record dated 01/11/03 identified that Patient #20's throat culture identified "Group A Strep 3+ on throat culture three weeks ago." that the patient was advised to

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follow up with her physician, and was subsequently admitted to the hospital on 01/13/03 with a diagnoses of Rheumatic Fever. Upon interview with MD #19 on 04/24/03, he said that a physician or others who would have initially checked the culture results would have seen them on the screen as negative. MD #19 said that there was a problem with the way that lab personnel were entering the results that caused the results of the quick strep test (of 12/2/02 which was negative) to be reported as "final" and thus did not allow the true final culture results to be posted. Although the lab staff entered the preliminary report into the computer system, the logician system recorded the preliminary report as a final report incorrectly. Upon interview with the Chief Resident of the Primary Care Center (PCC) on 5/16/03 at 3:10PM, he stated that while he was responsible for checking all laboratory values on the logician system that the PCC had no system in place for checking the hard copies of laboratory values sent by the lab. Upon interview with MD #21 on 05/06/03, he said that Patient #20 had developed Mitral Stenosis, Mitral Regurgitation, and Aortic Insufficiency relative to Rheumatic Fever. MD #21 said that Patient #20's symptoms are classic of Rheumatic Fever and that Rheumatic Fever is only caused by untreated strep. MD #21 said that he could not be exactly sure of the onset of the disease process but that the symptoms of Rheumatic Fever would take at least a month to show up after the initial strep infection. MD #21 said that Patient #20 would continue to receive Penicillin each month.

6. The facility failed to release Patient #25's medical records within thirty days of the request. The findings are based on medical record review and staff interviews and include the following:
 - a. Patient #25 was hospitalized during the period of 12/06/00 through 12/24/00 and underwent debridement of open wounds in the left lower extremity. Written correspondence dated 10/21/2002, from the patient's attorney identified that a request had been made to forward all leg "films" of Patient #25, taken on 12/7/00 to this attorney. Correspondence reflected that only the written reports were sent and not the actual films, as requested. Subsequently on 4/8/03, another request for these same films were made by the patient's attorney. Interview with the medical record and radiology record staff person identified that they could not recall the original request but had received a request dated 4/8/03 for these films and upon receipt of payment would send the necessary documentation to this attorney.

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7. For five (5) of five (5) records reviewed the facility failed to ensure that documentation contained sufficient information. The findings are based on review of clinical records, review of policy and procedure, and staff interview and include the following:
 - a. Patient #48 was admitted to the facility on 4/14/03 with a diagnosis inclusive of subarachnoid hemorrhage. An adult critical care flow sheet body diagram dated 4/14/03 identified the presence of an endotracheal tube, absent of any naso and/or oral gastric tubes. Review of an anesthesiology record dated 4/15/03 identified a naso-gastric/oral gastric tube in-situ. An adult critical care flow sheet body diagram dated 4/15/03 identified the presence of an oral gastric tube. Review of the clinical record with the NICU Manager on 4/23/03 identified that the clinical record lacked documentation of the insertion of the oral gastric tube.
 - b. Patient #47 was admitted to the Coronary Care Unit (CCU) on 4/23/03 with a diagnosis inclusive of an acute myocardial infarction. Review of the transferring facility documentation and the receiving facility's admission assessment dated 4/23/03, failed to identify the presence of an oral gastric tube. An adult critical care flow sheet dated 4/23/03 identified the presence of an oral gastric tube with placement assessed. Review of the clinical record with the CCU Unit Manager on 4/25/03 identified that the clinical record lacked documentation of the insertion of the oral gastric tube. Review of the policy and procedure for naso gastric tube insertion identified that the documentation should include type and size of the tube, time of placement, and any adverse patient responses.
 - c. Patient #46 was a 70-year-old male admitted to the MICU (medical intensive care unit) on 4/8/03 with a diagnosis of congestive heart failure and subsequently developed respiratory failure requiring intubation on 4/10/03. Patient #46's medical record lacked an admission skin assessment and no skin assessments for 4/9/03 could be found. The nursing progress noted dated 4/10/03 identified that the skin on the coccyx had a non-open pressure area and that a 3 M spray was applied. Progress notes dated 4/12/03 identified that the patient had developed a stage two pressure ulcer on the coccyx and no size of this area was documented. There was no documentation of initiation of care planning based on this skin impairment until five days later on 4/15/03. Interview with the MICU Manager and review of the patient's record indicated that staff do perform skin assessments on admission but that she could not locate the initial Braden scale from admission. The Manager further stated that although there was no specific physician's order for skin treatment that staff nurse's utilized 3 M spray and or xeroform as a nursing measure. The facility's policy was to begin skin assessments on the day of admission and if a wound is present to document the location, stage, size and

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- presence of necrotic tissue, undermining, exudates and presence of granulation tissue.
- d. Patient #45 was admitted to the hospital on 4/22/03 following a respiratory/hypoxic arrest. The respiratory assessment dated 4/22/03 identified that the patient was ventilated and receiving supplemental oxygen. Review of the physician's orders lacked documentation of an order directing the administration of oxygen to Patient #45.
- e. Review of the medical record identified that Patient #21 was admitted to the hospital on 12/11/02 with diagnoses that included esophageal squamous cell carcinoma. The critical care flow dated 12/23/02 identified that Patient #21 had problem areas on the coccyx and both heels, however, descriptions including sizes of the areas were lacking. While the medical record identified that a transparent dressing was applied to the coccyx area at that time, the record failed to identify any intervention to address the patient's heels. No further description of the Patient #21's skin and/or pressure areas was documented in the record until 12/27/02 when the patient was described as having a Stage II buttocks pressure area that was treated with Xerofoam and Bacitracin. The record continued to lack evidence of any intervention to address the patient's heels. Review of facility documentation identified that Patient #21 had developed a non-stageable pressure area on the coccyx that measured fifteen by ten centimeters and blackened areas of undetermined size on both heels. Review of the medical record with the Clinical Nurse Specialist identified that the record lacked consistent documentation of the patient's wound assessments. Review of the facility's wound care policies identified that the specific criteria for assessing wound size and status included wound bed color, drainage, tunnelling and peri wound skin assessments. The policy further included the need to measure the length, width and depth of wounds in centimeters. The policy identified that wound assessments using these criteria are to be documented at least every twenty-four hours and that nursing interventions would be added to the nursing plan of care.
8. Based on a review of the medical record of Patient #8 and interviews, the facility failed to ensure the medical record contained documentation of treatment by physicians.
- a. Patient #8 was admitted to the facility on 10/12/02 for syncope, ventricular tachycardia, and left bundle branch block. A left femoral pseudoaneurysm developed after an electrophysiology study and on 10/18/02 attempts at an ultrasound compression and thrombin injection were unsuccessful. A review of nursing progress notes identified the patient had severe groin pain, low blood

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pressure readings, a paced rhythm of 80, a dropping hematocrit and hemoglobin, received blood and plasma, was cool, clammy, diaphoretic, and nauseous. The patient also had an increase in the size of the hematoma, a decreased urine output to only 17 cc's, became anxious, agitated, confused at times, respiratory rates of 30 to 40, acidotic, hypothermic, oliguric, and no oxygen saturations were obtainable. There were multiple references to contacting MDs #12, #13, and #14 who were made fully aware of the patient's condition and managed the patient's care during the night. Documentation was lacking of any assessments by MDs #12, 13, and 14 during the night. During an interview, MD #12 stated he was busy, meant to write a note and neglected to do so. MD #13 stated she wrote a note at 7:30 a.m. when she realized no notes had been written.

9. Based on a review of the medical record of Patient #28, a review of the Mammography Technologist job description, and interviews with hospital staff, the hospital failed to ensure that a qualified mammography technician was approved to perform a mammogram. The findings include:
 - a. Patient #28 had a routine screening mammogram on 3/27/03. Although Patient #28's mammography screening report dated 3/37/03 identified that the mammogram was performed by Radiology Technician (RT) #1 (a certified, qualified mammography technician), seven films were taken initially by RT #2 followed by two more films taken by RT #1. RT #1 stated that she was aware that RT #2 was in training, but thought she only needed to check her films. RT #2 stated that she was not aware that she could not perform mammograms independently. The Chief Mammogram Technician stated that two films of each breast are taken for a routine mammogram. The Chief Mammogram Technician stated that although RT #2 was certified in mammography, she was still in training and should not have performed the mammogram independently.
10. For two (2) of three (3) medical records reviewed, the facility failed to ensure timely assessment for Patient #35 and Patient #39 who presented in the ED with complaints of pain in accordance with the policy and procedure. The findings are based on review of the clinical records, review of policy and procedure, and staff interview and include:
 - a. Patient #35 was triaged in the ED on 12/9/01 at 1240 with an assessment which included a continuous migraine headache which had been evaluated the previous day in the ED. The patient was reporting pain at a level of ten (10) on a scale of 0-10. The assessment identified that the patient now had a subconjunctival hemorrhage in the right eye and was assigned a patient classification of level II and

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a level III. Review of the clinical record identified that the patient was summoned for further assessment at 1620 (3 hours and 40 minutes subsequent to the triage assessment), 1625, and 1630 with no response from the patient and it was concluded that the patient "walked out". Review of the policy and procedure assessment of patients specific to the ED identified that with a level II classification there is a need to initiate therapy to prevent further compromise and reassessment is needed every fifteen minutes. Severe pain results in an upgrade of a lesser complaint to a level II. Level III classification identified that if the patient must wait to be brought to the treatment area, then reassessment by the triage nurse must occur at 2 hour intervals. Review of the clinical record identified that although the patient received a triage designation of a level II and a level III, attempts to evaluate the patient were not initiated until 3 hours and 40 minutes subsequent to the triage assessment.

- b. Patient #39 was triaged in the ED on 12/19/02, 2048 and presented with complaints of substernal chest pain, reporting the pain at a level of 8 on a scale of 0-10 with a blood pressure of 204/116 and a pulse of 101. The triage assessment additionally identified that the patient was short of breath, complaining of right arm weakness, positive for diaphoresis at home, obese, and was assigned a triage classification of level II. The ED flow sheet identified that at 2059 (eleven (11) minutes subsequent to triage) the patient was in the registration area while a bed was made available. At 2104 (16 minutes subsequent to triage) the patient was unresponsive and transferred into the ED. Review of the ED record identified that at 2105 resuscitative efforts were initiated with subsequent efforts continuing until 2132 when the code was called and the patient was pronounced. Review of the ED policy and procedure for assessment of patients, identified a level II classification as requiring the need to initiate therapy to prevent further compromise, that the patient is unstable and needs reassessment every fifteen minutes or more frequently as determined by the Registered Nurse. Patients in this category have a potential threat to life or limb and are suffering extreme pain. Generally, they will become unstable and deteriorate if not treated within 15 minutes. During an interview with the ED Director on 4/25/03 at 9:00 AM, she stated that the ED was very busy that evening. Nineteen patients were waiting to be admitted, sixteen patients were triaged and waiting in the waiting room, and there were no stretchers available. She further stated that although they were very busy, sending Patient #39 to registration was not the best decision.

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11. Based on review of policy and procedure and interviews for one patient, (Patient #28), the hospital failed to ensure that the confidentiality and privacy of the patient was maintained. The findings include:
 - a. Patient #28 had a mammogram on 3/27/03. Radiology Technician #1 stated that although she completed the history sheet for Patient #28, she did not enter the information from the history sheet into the computer system. Radiology Technician #1 stated that the receptionist usually enters the information into the computer and at that time, she had not been trained in that area. Radiology Technician #1 also stated that she was not aware that Patient #28 had a change of address and did not know if there was a separate form for that information. The Chief Mammography Technician stated that the computer system does not indicate old and new addresses. The Chief Mammography Technician also stated that if a receptionist was not present, the technologist might not have entered an address change. Subsequently, a note was sent to the wrong address (which was intended for Patient #28) that contained private information regarding Patient #28's mammogram procedure. The Patients' Rights Policy identified that the patient has the right to every consideration of privacy concerning his/her medical program and that the patient has the right to have all communications pertaining to his/her care treated as confidential.

12. Based on review of policy and procedure and interviews for one patient, (Patient #32), the hospital failed to ensure that the confidentiality of the patient's records was maintained. The findings include:
 - a. Patient #32 had diagnoses that included non-reassuring fetal heart rate tracing, sickle cell betathalassemia, and profound anemia. Progress notes dated 3/3/03 identified that Patient #32 had an emergency Cesarean section at 11:55 a.m. and that two pictures were taken to demonstrate the uterus with a yellow discoloration. Nurse Manager #10 stated that she was notified at 4:40 p.m. that Patient #32's family was upset because the pictures (with Patient #32's name on the bottom) were left on the counter in the recovery room. Nurse Manager #10 stated that she spoke to Patient #32's family and notified the physician. Physician's progress notes identified that the physician was notified on 3/3/03 at 4:45 p.m. by the Labor and Delivery manager that Patient #32's family was upset after seeing two Labor and Delivery attendants viewing the pictures. The progress notes also identified that the physician reviewed the reasons for the pictures and the importance of patient confidentiality. Subsequently, Nurse Manager #10 stated that she in-serviced staff regarding patient confidentiality and that the pictures should not have been left out

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on the counter. The Guidelines for Patient Confidentiality identified that medical records should not be left open at the nurses' station. The Patients' Rights Policy identified that the patient has the right to have all records pertaining to his/her care treated as confidential.

The above are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (d) Medical Records (3) and/or (e) Nursing Service (1) and/or (i) General (7) and/or (j) Emergencies (2) and/or (l) Infection Control (1).



STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

October 31, 2003

Joseph A. Zaccagnino, President and CEO
Yale - New Haven Hospital
20 York Street
New Haven, CT 06504

Dear Mr. Zaccagnino:

Unannounced visits were made to Yale - New Haven Hospital on July 29, 30, 31, August 12 and September 4, 2003 by representatives of the Division of Health Systems Regulation for the purpose of conducting a Medicare survey at the request of CMS, a licensing renewal inspection and multiple investigations with additional information received through October 21, 2003.

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.

You may wish to dispute the violations and you may be provided with the opportunity to be heard. If the violations are not responded to by November 10, 2003 or if a request for a meeting is not made by the stipulated date, the violations shall be deemed admitted.

Please address each violation with a prospective plan of correction which includes the following components:

1. Measures to prevent the recurrence of the identified violation, (e.g., policy/procedure, inservice program, repairs, etc.).
2. Date corrective measure will be effected.
3. Identify the staff member, by title, who has been designated the responsibility for monitoring the individual plan of correction submitted for each violation.

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

Respectfully,

Ann Marie Montemeri, RN
Supervising Nurse Consultant
Division of Health Systems Regulation

AMM: [unclear]

cc: Director of Nurse
Vicarious [unclear]

20030187	20030188	20030189	20030190	20030191	20030192
20030193	20030194	20030195	20030196	20030197	20030198
20030199	20030200	20030201	20030202	20030203	20030204



Ms. #

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1. The facility failed to ensure that physician services were provided in accordance with standards of acceptable practice. The findings are based on a review of the medical record and interviews with facility personnel and include the following:
 - a. Patient #60 was admitted to the hospital on 5/15/03 with complaints of headache, fever, neck pain and nausea of a two day duration. A review of the admission physician assessment identified a diagnosis of viral versus bacterial meningitis. A lumbar puncture was performed on 5/15/03 and specimens obtained for culture, viral studies and lyme disease. The record identified a negative culture for bacteria report was received on 5/16/03 and Patient #60 was discharged to home. Additionally a physician progress note dated 5/16/03 indicated discharge was appropriate because all cultures were negative. Further record review revealed that four hours after discharge, Patient #60 was notified to return to the hospital due to the identification of herpes simplex virus in the lumbar puncture fluid. Review of the record on 7/30/03 identified that although bacterial culture reports were negative, the virology report was not available prior to discharge. The Administrative Director of Patient Services in an interview on 7/30/03 stated the virology laboratory is not operational twenty four hours a day and did not accept the specimen until 5/16/03 at 7:13 AM. MD #25 in an interview on 7/30/03 stated he was initially notified by the "House Staff" of the plan to discharge the patient because all lumbar puncture cultures were negative. MD #25 stated he received further notification a few hours later that a positive herpes simplex virus report had been received and Patient #60 was notified to return to the hospital.
 - b. Patient #52 presented to the Emergency Department (ED) on 6/19/03 with injuries that included lacerations to the thumb, index and third finger of the right hand. A review of the ED triage sheet identified the patient received treatment that included a repair of the soft tissue lacerations and was subsequently discharged. A review of a physician progress note dated 6/26/03 revealed that during an orthopedic follow up visit on 6/26/03, the third digit of the right hand was assessed as dusky, without capillary refill and painful upon range of motion. Further examination revealed the presence of a tourniquet, used during treatment provided in the ED on 6/19/03, remained in place. Patient #52 was admitted to the hospital to attempt to save the digit and/or a possible amputation. Review of the discharge summary dated 6/30/03 identified that although heparinization was initiated on 6/26/03, an amputation of the third digit of the right hand was necessary due to vascular compromise and gangrene.

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2. The facility failed to ensure a registered nurse supervised and/or evaluated the nursing care for each patient and/or that nursing services were provided in accordance with hospital policies and procedures and/or standards of care. The findings include the following:
 - a. Patient #60 was admitted to the hospital on 5/16/03 with diagnoses inclusive of meningitis with disposition to home on 5/21/03. Although changes in the patient's medical condition were identified in a review of the clinical record on 7/30/03, documentation was lacking to reflect that nursing progress notes were entered during the period of 5/16/03 through 5/21/03. Review of the hospital nursing documentation policy identified that pertinent assessment data related to the patient's problem and/or response to interventions and progress towards goals are to be documented in the "history and progress" section of the medical record. In addition the policy identified that any untoward event or incident should be documented in that section. A review of the clinical record identified a physician order dated 5/20/03 for an electroencephalogram (EEG) as soon as possible. The record identified that discharge was to occur dependent on the EEG results. The 7-5 Manager in an interview on 7/30/03 stated that although the EEG was scheduled for 5/20/03, due to an issue with personnel, transportation did not occur at the scheduled time and the EEG was rescheduled for 5/21/03. The 7-5 Manager further stated that the patient was not able to be discharged as scheduled due to the change in the EEG appointment.
 - b. Patient #62 was admitted to the hospital on 3/10/03 with diagnoses inclusive of right hip and humerus fracture. A review of the nursing admission assessment identified a high risk for impaired skin integrity. A nurse progress note dated 3/11/03 identified a stage two pressure sore on the coccyx, however a measurement of the area was not documented. A skin integrity consultation dated 3/18/03 described the pressure sore as 5cm by 9cm and a red-yellow color was identified at the base with a central area of black. A review of the clinical record on 7/30/03 failed to identify that from 3/10/03 to 3/18/03 (seven days) an assessment and or measurement of the pressure sore was completed. A review of the facility pressure sore treatment policy identified that a measurement of the pressure sore size and an assessment of the response to treatment will be completed and documented in the record on Monday and Thursday.
 - c. Patient #70 was an elderly male, admitted on 2/5/03 for treatment of left sided chest pain and had a diagnosis of moderate dementia. A nursing assessment dated 2/5/03 identified the patient as independent with assistance for ambulation and toilet use, and his skin was clear. Progress notes dated between 2/7/03 and 2/9/03

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identified the patient had periods of lethargy and was obtunded secondary to residual effects of Haldol. The patient became bedridden, staff failed to reassess the patient, and preventative measures were not taken to protect the patient's skin. On 2/11/03 a wound specialist identified several facility acquired stage II areas over the patient's sacrum. On 2/13/03 a plastic surgeon identified the areas as stage II-III. Interview with the nurse manager identified that although the nurses documented the patient's skin as clear, he actually had a bed sore on admission. Also, Patient #70 did not have a swallowing problem on admission, but following multiple doses of Haldol on 2/7/03, the patient was noted to be spitting out saliva, became increasingly sleepy, and unable to feed himself. There was no evidence that staff reassessed the patient and preventative measures were not taken to avoid an aspiration until 2/8/03 when the patient was diagnosed with a right base infiltrate consistent with aspiration. Although the nurse manager stated the staff monitor for aspiration as a standard of proactive, the medical record lacked evidence that this was done.

- d. Patient #71 was admitted on 5/27/03 for a total abdominal hysterectomy and had a past history of chronic pain, asthma, and apnea following surgery and/or extubation. During and immediately following the surgical procedure Patient #71 received 22 mg of Morphine and 75 mg of Fentanyl. On admission to the floor at 2:15 PM the patient was assessed as alert, oriented, vital signs stable, phenergan was administered for a complaint of nausea with good effect, and a morphine PCA pump was initiated. There was no further evidence in the record that Resident #71's Morphine usage and/or response including sedation and respiratory rate were monitored. At 5:30 PM the patient was unresponsive and pulseless, anesthesia was called to the floor, administered Narcan twice, began CPR, and intubated the patient. Physician documentation identified the cause of the unresponsiveness was most likely respiratory depression due to narcotics. Patient #71 was diagnosed with hypoxic encephalopathy, hospitalized for an additional 9 days, and discharged on 6/5/03 to a rehabilitation facility. Interview with RN #1 identified she was aware of the total amount of Morphine the patient received prior to receiving her on the floor, recalled the patient used an additional 4 mg via the PCA pump, and did not document the patient's condition leading up to the code but gave a verbal report to the ICU nurse. Patient #71 received a total of 26 mg of Morphine and 325 mg of Fentanyl between 11:15 AM and 5:30 PM.
- e. Patient #74 had diagnoses that included metastatic carcinoid tumor was admitted to the hospital on 5/6/03 for hepatic embolization procedure. Review of the medical record and interview with Nurse Manager #16 identified that the patient

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- received morphine sulfate 4 mg IV on 5/6/03 at 10:28 PM without documentation of a pain level assessment at the time of medication administration or reassessment, in addition. Dilaudid 4 mg was administered orally on 5/7/03 at 8:51 am without documentation of pain reassessment after the medication administration, and Dilaudid 4 mg was given orally on 5/7/03 at 1:13 PM without documentation of a pain level assessment at the time of medication administration or reassessment. Review of the Acute Pain Policy directs a pain assessment before analgesics are administered and within one hour reassess the effectiveness of the intervention.
- f. The medical record for Patient #84 who was admitted with bilateral leg cellulitis indicated that the patient was receiving pain medication as needed (prn) for leg pain. The flow sheet indicated that on 7/28/03 the patient received pain medication on three occasions and on 7/29/03 on three occasions. The medical record failed to reflect the patient's response to the medication and/or a re-evaluation of the patient's level of pain. Review of the facility policy indicated that the patient's pain level should be reassessed one hour after the administration of analgesics until the patient reports a pain level then a 4 or adequate pain control.
- g. Patient #63 was admitted to the hospital on 2/12/03 for a posterior fusion and instrumentation of the spine for idiopathic neuromuscular scoliosis. A review of the admission nursing assessment identified a low risk for pressure sore development. A review of a physician progress note dated 2/14/03 identified an area of erythema on the right buttock that may be incipient pressure sore. An orthopedic attending progress note on 2/14/03 identified the area was ecchymotic and required observation. On 2/18/03 a skin integrity consultation note described a 6.5cm by 4.5 cm black eschar area on the right buttock. A review of the clinical record on 7/31/03 failed to identify that after a pressure sore was identified on 2/14/03, a reassessment of risk factors was completed and or interventions implemented to address the potential for further skin breakdown. A review of the facility skin integrity policy identified that a reassessment will be completed when the patients condition changes. In addition the record will include documentation of the treatment plan and ongoing management interventions.
3. Based on record review and interviews, the facility failed to administer medications within accepted standards of practice for Patient #70, and in accordance with the orders of the practitioner for one patient, Patient #72. The findings include:

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- a. Patient #70 was an elderly male, admitted on 2/5/03 for treatment of left sided chest pain and had a diagnosis of moderate dementia. A nursing assessment dated 2/5/03 identified the patient as confused, impulsive, and independent with assistance for ambulation and toilet use. The patient experienced periods of confusion, agitation, and attempted to get out of bed. On 2/7/03 between 1:00 AM and 5:00 AM the patient received 7 mg of Haldol IV due to restlessness and climbing out of bed. The patient was noted to be spitting out saliva between 4 and 6 AM. Throughout the day the patient became increasingly sleepy, incontinent, and unable to feed himself. Progress notes dated 2/8/03 identified the patient was obtunded and required loud verbal stimuli to respond secondary to residual effects of the Haldol. Periods of lethargy continued through 2/9/03. During this period of time, the patient developed a stage II pressure sore and aspiration pneumonia. The facility policy for medication administration identified the nurse, prior to administration, was to know a medication's usual dosage, route, action, and side effects. According to the Nursing 2002 Drug Handbook, elderly and/or debilitated patients should receive 0.5 to 2.0 mg by mouth two or three times a day with gradual increases as needed. The medication could cause confusion, sedation, and lethargy.
 - b. Patient #72 was receiving Heparin injections BID post abdominal surgery. On 3/19/03 RN #2 mistakenly administered a Lovenox injection instead of Heparin to the patient. The physician and pharmacy were notified, and blood work was obtained to determine the patient's anticoagulation response to the Lovenox. The laboratory results identified no adverse effects of the patient's anticoagulation. Interview with RN #2 identified he received an order for another patient to discontinue Heparin and begin Lovenox but he mistakenly carried out the order on Patient #72. RN #2 notified the pharmacy who noted that the effects of the Lovenox would be up to 6 hours after the administration. In addition, a review of Patient #72's medication administration record identified Heparin was ordered BID and was only administered once a day on 3/20/03, 3/21/03, and 3/22/03. Interview with the patient service manager identified staff use the Heparin prophylactically. Once the patient ambulates, the nurse stops giving the Heparin. The facility's medication policy identified a nurse administered prescribed medications by checking the medication prescription. The policy did not identify that Heparin could be withheld by a nurse once ambulation occurred.
4. The facility failed to ensure that medical records were retained and accessible. The findings include the following:

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- a. Patient #52 presented to the Emergency Department on 6/19/03 with traumatic injuries to the digits of the right hand. Although a copy of the triage sheet was provided upon request on 8/12/03, the facility was unable to locate or provide the entire clinical record.
 - b. Review of the ambulance run sheet #1 dated 1/14/03 identified that upon transport of Patient #99 to St. Mary's Hospital for dialysis, the patient requested and was brought to Yale New Haven Hospital emergency department (ED) arriving at approximately 5:00 PM. Review of ambulance run sheet #2 dated 1/14/03 identified that Patient #99 was picked up at the Yale New Haven Hospital at approximately 5:30 PM and transported to St. Mary's Hospital. Review of the hospital emergency room log failed to indicate Patient #99 name. Interview with the Assistant Counsel Legal Affairs indicated that upon investigation staff indicated that Patient #99 did come to the ED on 1/14/03, was seen in triage and evaluated with his chief complaint being he wanted dialysis and sent on to St. Mary's Hospital as that had been the plan. The facility was unable to produce documentation of this visit.
5. Based on review of the medical record, review of facility policies, and interviews, the facility failed to ensure that the intraoperative records of two patients, Patient #97 and Patient #98, contained complete and accurate documentation of postoperative sponge count assessments. The findings included:
- a. Review of Patient #97's intraoperative record dated 01/28/03 identified postoperative documentation that all sponge counts were correct. Interview with Scrub Technician #1 on 09/04/03 identified that she did not recall having participated in the final sponge count for Patient #97. Interview with RN #27 on 09/04/03 identified that although her name appeared in the intraoperative record as having done the sponge counts with the Scrub Technician, she could not recall doing the final sponge counts. Interview with RN #28 on 09/04/03 identified that she was responsible for the "paperwork" during the intraoperative phase and that she documented both Scrub Technician #1 and RN #27's names as having completed the sponge counts. Interview with the Nursing Director of Perioperative Services identified that the method of documentation of sponge counts as practiced by RN #27 and RN #28 was currently acceptable in the intraoperative phase of a surgical procedure and that there were no current policies requiring additional initialing and or signatures of the actual parties who completed the sponge counts.

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- d. Although the anesthesia supply room in the Ambulatory Surgical Suite had locking capability, the room was observed during tour to be unlocked. Medications were accessible on open shelves. In addition, an unlocked anesthesia cart was observed stored in the back section of PACU.
8. A tour of the hemodialysis unit on 7/29/03 indicated that in the medication room there were twelve (12) vials of mannitol that had expired on 12/02.
9. Patient #67 was admitted to the Emergency Department (ED) on 1/26/03 for treatment following a motor vehicle accident. The patient complained of right shoulder pain, an x-ray was obtained and the patient was medically cleared and subsequently discharged at 2:25 PM by the ED Medical Resident. A final reading of the X-ray on 1/26/03 at 5:20 PM by the attending Radiologist identified findings strongly suggestive of acromioclavicular joint separation. According to Radiologist #1, the ED Radiology Section Chief, the proper protocol for X-ray readings in the ED require that all Radiology Residents' readings be reviewed by an attending Radiologist by the end of the current shift. An attending ED physician may make treatment decisions based on the initial reading but the official reading is signed by the attending Radiologist and any discrepancies are communicated to appropriate clinical staff. In the case of Patient #67, the official x-ray reading deviated from the initial reading and communication to ED clinical staff for follow-up with the patient was lacking.
10. During tour of the scope and/or instrument disinfecting wrapping area of the Operating Suite (OR) with the Manager of the OR, the surveyor entered the "dirty" collecting room to find the glass windowed partition open while hospital staff on the opposite side of the window wrapped cleaned instruments. Upon the surveyor's entry the window was closed abruptly by the staff on the clean side.
11. The facility failed to ensure that for Patients #93, #97, and #98 who were reviewed for surgical procedures, that the hospital policy for Surgical Invasive Procedure and Site Verification was followed and or that sponge counts were correct postoperatively for two patients who subsequently required additional surgery to remove retained foreign objects. Based on review of the medical record and review of facility policy, the findings include the following:
 - a. Patient #93 was transferred to the hospital from another hospital for the clipping an aneurysm on 7 25 03. A review of the medical record on 7 30 03 with the Manager of the NICU revealed that the "time-out" documentation prior to surgical

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- incision was incomplete. The document lacked pre-operative procedure confirmation and final verification information. The surgeons listed on the document as surgical team members differed from the physician listed as providing a medical record notation. The document was signed by the circulating nurse with a notation that read "Patient draped when I entered the room with procedure starting." Review of the facility policy for Surgical Invasive Procedure: Correct Patient and Site Verification revealed that this procedure is required on all cases and for all invasive procedure. Further it directs that if an emergency exists with deviation from the expected documentation, a verification notation in the medical record should be written by the attending surgeon performing the procedure.
- b. Patient #97 had diagnoses that included endometrial cancer. Review of the medical record identified that MD #2 in conjunction with MD #3 performed a total abdominal hysterectomy with vaginal reconstruction on 01/28/03 and that Surgical Technician #1 and RN #27 were the scrub person and circulating nurse respectively. Although a review of the intraoperative record dated 01/28/03 identified documentation that all sponge counts were correct, Patient #97 required additional exploratory surgery on 05/17/03 to remove a retained lap sponge identified after an x-ray at another facility. Interview with MD #3 on 09/08/03 identified that Patient #97 had experienced some vaginal discharge since the 01/28/03 surgery that may have been related to the retained sponge.
- c. Patient #98 had diagnoses that included ovarian cancer. Review of the medical record identified that MD #2 performed a total abdominal hysterectomy on 07/10/03 and that Surgical Technician #1 and RN #27 were the scrub person and circulating nurse respectively. Although a review of the intraoperative record dated 07/10/03 identified documentation that all sponge counts were correct, Patient #98 required additional exploratory surgery on 07/17/03 to remove a retained lap sponge identified when an abdominal x-ray was taken after the Patient developed a postoperative ileus. Interview with MD #2 on 09/05/03 identified that after his portion of the surgical procedure for Patient #97 was completed, he left the operating room and that the case was then continued by MD #3. Interview with MD #3 on 09/08/03 identified that he decided not to work through Patient #97's abdominal area and that he then closed the abdominal area after a routine search of the open cavity for any foreign materials. In addition, both MD #2 and MD #3 identified through interview that they rely heavily on the facility system of counting sponges by the scrub team and further that the sponge counts were reported to them as correct by the scrub team. Review of the

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facility's policies identified that sponge counts will be done both verbally and visually, that the counts will be done systematically, and that the circulator will document the results in the record. Interviews with Scrub Technician #1 and RN #27 on 09/04/03 identified that they identified that they were responsible for the sponges counts on both cases and that although they had followed the facility's policies for the counts, they could not explain why both patients were later reported to have retained sponges.

12. The facility failed to ensure that for Patients #86 and #87 who received anesthesia had an intra-operative anesthesia record that was complete. Based on review of the clinical record, review of facility policy and interview of facility personnel, the findings include the following:
 - a. A review of the intra-operative anesthesia records for Patients #86 and #87 revealed that neither record documented the time of extubation during the patient's recovery from anesthesia administration. The facility identified that the Anesthesia Department adheres to the American Society of Anesthesiology Standards for Documentation which directed that documentation of techniques be used in a time-based record during perianesthesia. During interview the Medical Director of the Operating Suite stated that he expected to see a documented extubation time.
13. The facility failed to ensure that a post anesthesia follow-up was completed for Patient #93. Based on review of the medical record and review of facility policy, the findings include the following:
 - a. Patient #93 was admitted to the neuro-surgical intensive care unit (NICU) following the clipping of an aneurysm on 7/25/03. A review of the medical record on 7/30/03 revealed that the record lacked evidence that a post-anesthesia follow-up was completed by the anesthesiologist. The facility identified that the Anesthesia Department adheres to the American Society of Anesthesiology Standards for Patient Care in Anesthesiology which directs that any patient remaining postoperatively in the hospital for 48 hours should have one or more anesthesia notes in the medical record after discharge from the PACU.
14. Based on record review and interviews, the facility failed to ensure that restraints were only used when medically necessary for Patients #70 and #75. The findings include:
 - a. Patient #70 was an elderly male, admitted on 2/5/03 for treatment of left sided chest pain and had a diagnosis of moderate dementia. A nursing assessment dated

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2/5/03 identified the patient as confused, impulsive and independent with assistance for ambulation and toilet use. The patient experienced periods of confusion, agitation, and attempted to get out of bed and a vest restraint was applied on 2/5/03. Between 2/5/03 and 2/9/03 staff identified the patient was assessed as requiring a sitter but if a sitter was not available, a vest restraint was used on all of the days. Further, on 2/9/03 at 5:30 PM the patient was placed in a vest restraint due to not having a sitter. At 6:30 AM the patient was noted to stick his legs through the side rails three times and was subsequent 4-point restrained. The patient remained in 4-point restraints until a family member was present and they were reduced to 2-point wrist restraints. All restraints were removed at 11:00 PM when a sitter was present. Interviews with the nurse manager and quality improvement staff identified the restraints were initialed due to a safety risk and there was no medical necessity. The patient was confused and attempting to get out of bed and the staff felt he required a higher level of restraints, besides the vest, to keep him in bed.

- b. Review of the medical record for Patient #75 failed to indicate the reasons that the patient required restraints, the alternatives tried and/or the date and time the restraints had been initiated and discontinued. Review of the facility policy indicated that the medical record should contain the reasons for restraints, alternatives, reasons for continued use and the date and time of release.
15. The facility failed to ensure that Patient #75 had an order by a physician or other Licensed Independent Practitioners (LIP) for the specific restraints utilized. The findings include the following:
- a. Review of the physician's orders for Patient #75 dated 7/21/03 indicated an order for a posey vest. Review of the restraint assessment form indicated that on 7/22/03 at 1:00 AM the patient's sitter had been discontinued and that Patient #75 had bilateral wrist restraints applied. Review of the facility policy indicated that restraints should be applied under the direction of the RN with an appropriate LIP order. Further review of the medical record for Patient #75 indicated that the patient had four side rails up on 7/22/03, 7/23/03 and 7/24/03. Review of the physician orders for this period of time lacked evidence of an order for the restraints. Review of the facility policy indicated that side rails are considered a restraint.
16. Review of the medical record for Patient #75 indicated that the patient had four side rails up on 7/22/03 days and evenings, 7/23/03 and 7/24/03. The medical record lacked

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evidence that a restraint assessment form had been completed. Review of the facility policy indicated that side rails are considered to be a restraint and that on-going patient assessment should be completed assessing skin integrity and range of motion every two hours and to observe the patient hourly.

17. Patient #15 was admitted through a physician's emergency certification on 12/12/02 with a diagnosis of bipolar disorder. The patient was identified as being highly agitated, disorganized, paranoid, and preoccupied and perseverative around the issue of a local police department. The interdisciplinary treatment initiated on 12/10/02 identified a problem of homicidal and aggressive behavior with interventions such as identifying/monitoring triggers and education regarding learning and practicing coping skills. On 12/11/02, the patient was described as being highly agitated and unable to follow redirection. A staff assist was called and security staff arrived. Documentation revealed that the patient would not follow directions and "get into restraint bed." Subsequently, the patient was sprayed with pepper foam and placed in four point restraints. An interview conducted with Hospital Police Officer #2 identified that at the time the pepper foam had been utilized, the patient had shielded his face with a blanket and the Police Officer reached under the blanket and reached up "to spray him." Two police officers each sprayed the patient two times each. Documentation was lacking in the medical record to identify specific de-escalation techniques identified prior to the initiation of the use of pepper foam and subsequent 4-point restraints.
18. Based on record review and interviews, Patient #15's treatment plan was not updated to include the use of restraints and criteria for reduction and or discontinuation. The findings include:
 - a. Patient #15 was admitted through a physician's emergency certificate directly into an intensive observation area room on 12/10/02 for treatment of bipolar disorder. On the morning of 12/11/02 the charge nurse and police lieutenant identified the patient was not only a danger to others, but also a danger to himself due to his violent and aggressive actions, including punching a glass window and door. They identified the need for pepper foam to stop the dangerous behavior; the patient was sprayed with the pepper foam, and placed in 4-point restraints. Although the physician's order for restraints identified criteria for decreasing and discontinuing the restraint, the facility policy identified that the patient's treatment plan would be updated to include the use of the restraint and criteria to reduce and discontinue the restraint. Interview with the patient service manager identified that the treatment plan should have been updated

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19. Based on record review and interviews, the facility failed to ensure Patient #15's restraints were reduced and or eliminated at the earliest possible time. The findings include:
- a. Patient #15 was admitted through a physician's emergency certificate directly into an intensive observation area room on 12/10/02 for treatment of bipolar disorder. On the morning of 12/11/02 the charge nurse and police lieutenant identified the patient was not only a danger to others, but also a danger to himself due to his violent and aggressive actions and was placed in 4-point restraints. Staff attempted to decrease the restraints from 4-point to 2-point at 12:45 PM but Patient #15 continued to threaten to "slit the throats of the staff's children and let them drown in their own blood." The patient remained in 4-point restraints from 9:20 AM to 4:30 PM. Although the patient was identified as resting quietly between 1:45 PM and 2:30 PM, a restraint reduction was not attempted. The patient was again identified as resting quietly between 3:30 and 4:30 PM, but staff did not attempt a decrease or discontinuation until 4:30 PM when they were decreased to 2-points. Again the patient was identified as resting quietly but it wasn't until 5:30 PM that the 2-point restraints were removed. The facility policy for restraint use did not identify criteria for reducing or discontinuing a restraint. Interview with the patient service manager identified the nurse would use their discretion in when to eliminate a restraint.
20. Based on record review and interviews, facility police officers failed to follow procedures for properly documenting a use of force event involving the restraining of Patient #15, in accordance with the facility policy. The findings include:
- a. Patient #15 was admitted through a physician's emergency certificate directly into an intensive observation area room on 12 10 02 for treatment of bipolar disorder. On the morning of 12 11 02 the charge nurse and police lieutenant identified the patient was not only a danger to others, but also a danger to himself due to his violent and aggressive actions, including punching a glass window and door. They identified the need for pepper foam to stop the dangerous behavior; the patient was sprayed by two officers with the pepper foam, and placed in 4-point restraints. Interviews with Hospital Police Officers and nursing staff identified Officers #2 & #3 discharged their pepper foam towards the patient. The facility policy for "use of force" identified a narrative report is completed, and fully describes the incident, including the person's actions that made the use of force necessary. Although Officer #3's report identified the patient was combative and uncooperative, it did not identify the patient's actions. Additionally, the facility

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policy for OC Defensive Foam use identified that all officers involved in the use of the foam are required to complete a detailed report. Officer #2 did not submit a written report. The policy further identified that the supervising officer was to complete an investigation including interviewing all individuals involved in the incident and this was not done. The lieutenant identified since he was present during the use of force, he did not conduct an investigation.

21. A tour of unit 7-3 on 7/29/03 identified that Patient #81 was observed from the hallway receiving peri-care without the benefit of a screen or the door being closed. The unit's clinical manager stated the patient did not have a screen or door closed because the patient was technology dependent and the nurse needed immediate access to the patient in an emergency occurred.
22. A tour of unit 7-2 on 7/29/03 identified a pair of scissors and a key ring left unattended on a housekeeping cart. Interview with the clinical manager and the environment associate identified the key ring contained keys to cleaning supplies and to the laundry chute and neither the scissors nor the key ring should have been unattended.
23. A tour of the adult psychiatric unit on 8/1/03 identified Patient #81 was sleeping in a bed located in an alcove, in the unit's intensive observation area (IOA). Interview with the unit manager and hospital legal council identified the patient did not have a room assigned to her and at that time, the unit did not have a bed to be discharged to, when no longer in need of the IOA area. The unit had a total of 22 beds in the general population and two IOA beds. Patient #81 was not assigned to either of these beds.

The above are violations of the Connecticut General Statutes Section 46a-152 (d) and/or (e) and violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and or (c) Medical Staff (4)(A) and or (C) and or (D) and or (E) and or (d) Medical Records (3) and or (6) and or (8) and or (e) Nursing Service (1) and or (g) Pharmacy (4) and or (i) General (7) and or (j) Emergencies (2) and or (l) Infection Control (6)

24. On 07 31 03 at 10:00 AM, the surveyor observed that there were voids around penetrations and unsealed wire sleeves thru the floors and ceilings of the electrical telecommunication closets on all the floors of East Pavilion and YNH Psychiatric Facility on the Liberty Village and Washington Square Wings.

DATES OF VISIT: July 29, 20, 31; August 12 and September 4, 2003

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

25. On 07/31/03 at 2:45 PM, the surveyor was not provided with documentation that the smoke detector sensitivity testing was being performed on the non-intelligent smoke detectors throughout the facility as required per NFPA 72E 8-2.4.2 and 8-3.4 as part of the facility's preventive maintenance program.
26. On 9/25/03 at 10:00 AM, the surveyor was not provided with documentation that fire drills were conducted on the 2nd shift in the 1st and 3rd quarters of 2003, the 1st shift of the 2nd quarter of 2003 and the 3rd shift of the 4th quarter of 2002 in the YHN Psychiatric Facility on the Liberty Village and Washington Square Wings.

The above are violations of the Regulations of Connecticut State Agencies Section 19-13-D3
(a) Physical Plant (2) and/or (b) Administration (2).