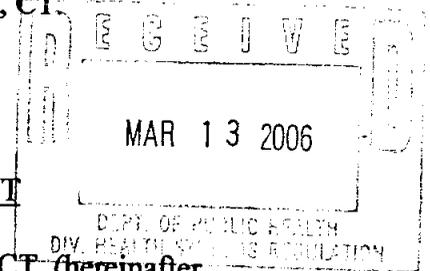


**STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
FACILITY LICENSING AND INVESTIGATIONS SECTION**

IN RE: Saint Francis Hospital and Medical Center of Hartford, CT
St. Francis Hospital & Medical Center
114 Woodland Street
Hartford, CT 06105



MODIFIED STIPULATED AGREEMENT

WHEREAS, Saint Francis Hospital and Medical Center of Hartford, CT. (hereinafter “Licensee”) has been issued License No. 0054 to operate a General Hospital (hereinafter “Facility”) under Connecticut General Statutes Section 19a-490, by the Department of Public Health (hereinafter “Department”); and

WHEREAS, the Licensee has a Stipulated Agreement with the Department which became effective August 19, 2004 (Exhibit A – copy attached); and

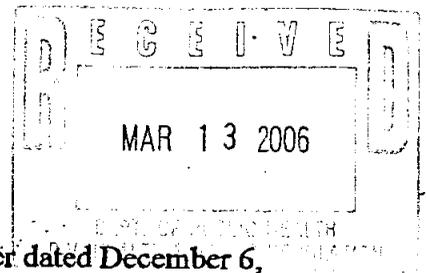
WHEREAS, the Department’s Facility Licensing and Investigations Section (hereinafter “FLIS”) conducted unannounced inspections at the facility for the purpose of conducting investigations, a survey and review of the implementation of the requirements of the Stipulated Agreement effected August 19, 2004; and

WHEREAS, during the course of the aforementioned inspections, violations of the Regulations of Connecticut State Agencies were identified in violation letter dated December 6, 2005 (Exhibit B – copy attached); and

WHEREAS, an office conference regarding the December 6, 2005, violation letter was held between the Department and the Licensee on December 27, 2005; and

WHEREAS, the Licensee executed a Stipulated Agreement with the Department effective August 19, 2004, as the result of a violation letter dated March 30, 2004, which identified violations, related to the use of physical restraints, nursing assessments, comprehensive care planning, triage of Emergency Department (ED) patients and incomplete preoperative documentation; and

Licensee: Saint Francis Hospital and Medical Center of Hartford, CT.
Page 2



WHEREAS, these same issues were again identified in the violation letter dated December 6, 2005 (Exhibit B); and

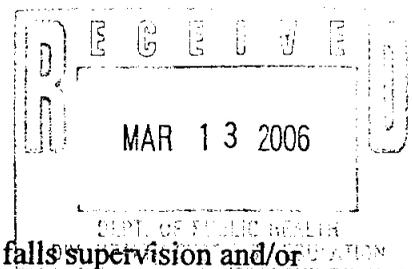
WHEREAS, the Licensee was unable to sustain compliance with the Regulations of Connecticut State Agencies; and

WHEREAS, without admitting any wrongdoing, the Licensee is willing to enter into this Modified Stipulated Agreement.

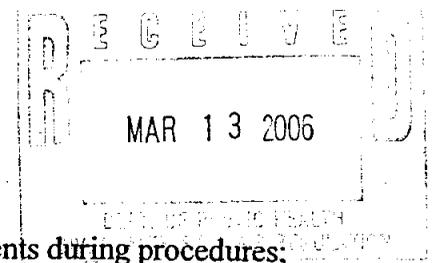
NOW THEREFORE, the FLIS of the Department acting herein and through Joan Leavitt, its Section Chief, and the Licensee, acting herein and through Christopher M. Dadlez, its President and Chief Executive Officer, hereby stipulate and agree as follows:

1. The Stipulated Agreement executed with the Department on August 19, 2004, shall be incorporated and made part of this Modified Stipulated Agreement.
2. The Licensee shall continue to implement provisions for the constant observation of telemetry monitoring device in accordance with the facility's plan of correction.
3. The Licensee shall within ninety (90) days of the execution of the Modified Stipulated Agreement, review or develop and/or revise all policies and procedures as necessary, and/or in accordance with the facility's plan of correction related to:
 - a. Functions and scope of duties assigned to non-licensed staff in a clinical capacity;
 - b. Emergency Department (ED) triage, assessment and/or monitoring of patients and/or interventions when there is a change in patient status;
 - c. Restraint assessment, application and monitoring and/or documentation of patient status during periods of restraint utilization inclusive of:
 - i. The specific interventions to be implemented prior to utilization of physical restraints;
 - ii. Assessment for least restrictive restraint, components of assessment and documentation of said assessment;
 - iii. Identification of professional staff who may order restraints, specification of professional staff who must be present to supervise and assess the application of restraints.

Applying for clinical PRIVILEGES
3/8/06
3/13/06



- d. Fall risk assessment, care planning for patients at risk for falls supervision and/or monitoring of patients at risk;
 - e. Mechanisms to monitor, supervise interns and/or residents to identify their ability to perform various medical procedures and document competency;
 - f. Assessment and monitoring of patients on cardiac monitors, evaluation and maintenance of cardiac monitoring equipment;
 - g. Assessment of patients at risk for skin breakdown, inclusive of documentation, care planning and ongoing evaluation of skin integrity; and
 - h. Assessments and development of comprehensive care plans and/or master treatment plans and ongoing evaluation and documentation of care.
4. The Licensee shall within sixty (60) days of the execution this Modified Stipulated Agreement, implement in-service training programs for staff affected by policies and procedures as noted in paragraphs #2 and #3.
 5. The Licensee shall within ninety (90) days of the execution of this Modified Stipulated Agreement, develop and implement a program to assess staff compliance with above noted policies and procedures identified in paragraphs #2 and #3. The program shall include, but not be limited to, a mechanism whereby remediation of staff occurs for failure to adhere to facility policies and procedures.
 6. The Licensee's Performance Improvement Program shall, within thirty (30) days of the execution of this Modified Stipulated Agreement, be reviewed and revised, as necessary, to include the monitoring of the following components:
 - a. The adoption or revision of policies, as applicable, addressing state and federal laws and regulations related to:
 - i. Non-licensed staff duties and responsibilities and scope of practice;
 - ii. Monitoring of equipment and material counts during surgical procedures;
 - iii. Triage, assessment and care of patients in ED;
 - iv. Restraint utilization and monitoring;
 - v. Fall risk assessments, care planning and monitoring of patients at risk for falls;



- vi. Monitoring and evaluation of interns and residents during procedures;
 - vii. Maintenance of cardiac monitoring equipment;
 - viii. Assessment/monitoring of telemetry devices;
 - ix. Assessments, care planning and ongoing evaluation of skin integrity;
and
 - x. Nursing assessment and comprehensive care planning and assessment
and documentation of interventions.
7. The Licensee shall designate a designee a Chief Executive Officer (CEO) and/or a Chief Operating Officer (COO) to meet with the Department every eight (8) weeks for the first six (6) months this document is in effect and quarterly thereafter for a period of one (1) year.
 8. The Licensee shall designate an individual to be responsible for the implementation of this Agreement. Said individual shall submit reports to the Department and the Chairperson of the Quality and Medical Affairs Committee of the Board of Directors of the hospital on a monthly basis for the first six (6) months and every three (3) months thereafter which reflect the Licensee's efforts to comply with the Agreement and Exhibit A.
 9. The Licensee agrees to pay a payment of twenty thousand dollars (\$20,000.00) which shall be payable by 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 modified stipulated agreement. Said check shall be directed to Judy McDonald, Supervising Nurse Consultant at the address identified in this document.
 10. Reports and meeting required by this document shall be sent to:

Judy McDonald, R.N.
Supervising Nurse Consultant
Department of Public Health
Facility Licensing and Investigations Section
410 Capitol Avenue, MS #12HSR
P.O. Box 340308
Hartford, CT 06134-0308
 11. All parties agree that this Modified Stipulated 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 License 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 Modified Stipulated 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.

12. 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.
13. The terms of this Modified Stipulated Agreement and the Agreement executed on August 19, 2004, shall remain in effect for a period of two (2) years from the effective date of this document.
14. The Licensee had an opportunity to consult with an attorney prior to executing this document.

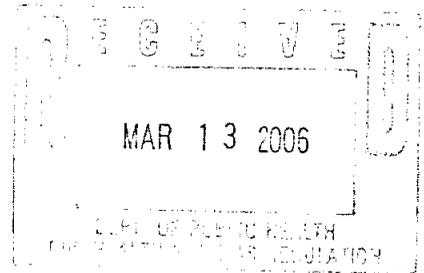
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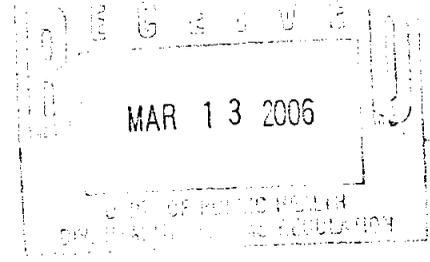
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IN WITNESS WHEREOF, the parties hereto have caused this Modified Stipulated Agreement to be executed by their respective officers and officials, which Modified Stipulated Agreement is to be effective as of the later of the two dates noted below.

Saint Francis Hospital and Medical Center of
Hartford, CT. - Licensee

3/13/06
Date

By: [Signature]
Christopher M. Dadlez, President and CEO

STATE OF Connecticut

County of Hartford) ss March 13 2006

Personally appeared the above named Christopher M. Dadlez and made oath to the truth of the statements contained herein.

My Commission Expires: 5/31/09
(If Notary Public)

Martha E. Hartle
Notary Public
Justice of the Peace
Town Clerk
Commissioner of the Superior Court

MARTHA E. HARTLE
NOTARY PUBLIC
MY COMMISSION EXPIRES MAY 31, 2009

STATE OF CONNECTICUT,
DEPARTMENT OF PUBLIC HEALTH

March 13, 2006
Date

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

Stipulated Agreement

In Re: Saint Francis Hospital and Medical Center
114 Woodland Street
Hartford, CT 06105

WHEREAS, Saint Francis Hospital and Medical Center of Hartford, CT, (hereinafter the "Licensee") has been issued License No. 0054 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 commencing October 21, 2003 and concluding February 2, 2004 for the purposes of conducting multiple investigations, State licensure and Federal validation surveys; and

WHEREAS, during the course of the aforementioned inspections, violations of the Regulations of Connecticut State Agencies were identified in a violation letter dated March 30, 2004 (Exhibit A - copy attached); and

WHEREAS, the Licensee responded with corrective action plans in a letter dated April 15, 2004 (Exhibit B - copy attached) and

WHEREAS, an office conference regarding the March 30, 2004 violation letter was held between the Department and the Licensee on April 15, 2004; and

WHEREAS, it is expressly understood that the execution of this Agreement, any provision of the Agreement, any monetary or educational contribution made by the 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 person or entity; and

WHEREAS, the Licensee without admitting wrongdoing is willing to enter into this 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 Dr. David D'Eramo, its President and Chief Executive Officer hereby stipulate and agree as follows:

1. The Licensee shall within thirty (30) days of the execution of this Agreement effect a contract with an established Medical Management Consultant Firm (MMCF) that has expertise in professional and medical health care services. Said MMCF shall be contracted to:

- a. Review the adequacy of current professional and institution mechanisms for sharing patient information when multiple disciplines are involved in the care of a patient (e.g. information sharing, coordination of services, interdisciplinary plan of care).
 - b. Review of policies/procedures and analyze via observations and interviews of staff Emergency Department (ED) functions including assessments and the communication process between ED professionals and various departments within the Facility.
 - c. Review of current Patient Safety processes, including the Patient Safety Committee and use of tools for patient safety improvement.
 - d. Review, via observations and interviews, patient safety in the Emergency Department and Operating Rooms, with specific emphasis on fire safety, and utilization of devices.
 - e. Review policies and procedures and analyze via observations and interviews of staff, the communication process between surgical and anesthesia services, with specific emphasis on how an integrated plan of care is coordinated and delivered.
2. The MMCF and the Facility shall formalize through a written contract the requirements of this document inclusive of time frames for the initial evaluation, number and credentials of individuals conducting the review, time frames for the analysis and development of recommendations. Said contract shall also specify that the MMCF shall return to the Facility seven (7) months after the issuance of its initial report to review the Facility's implementation and monitoring of recommendations. The MMCF shall have thirty (30) days post the completion of said initial onsite review and thirty (30) days post follow-up review to develop reports and provide copies to the Licensee and Department. Neither party shall be provided with the opportunity to review the draft reports and both parties shall receive copies of the documents simultaneously.
 3. The MMCF shall prepare a report which shall be provided to the Department and the Licensee. Said report shall identify methods utilized for the analysis, areas reviewed and process, findings and recommendations.
 4. The Department shall approve the MMCF selected by the Licensee and shall be provided with materials specified in paragraph #2 prior to contracting with and/or approving the MMCF.
 5. The Licensee shall provide the Department with a response to the MMCF recommendations with which the Licensee agrees and a time frame for implementation of the MMCF recommendations with which the Licensee agrees within twenty-one (21) days of receipt of the report. In the event that the Licensee disagrees with any MMCF recommendations, the Licensee, the MMCF and the Department shall meet to discuss the disagreement and develop a mutually agreeable alternative recommendation.
 6. Any record maintained by the Licensee in accordance with any state or federal law or regulation or as required by this Agreement shall be made available to the Department upon request.
 7. Within forty-five (45) days of the execution of this 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; and
 - d. Specification of professional staff that must be present to supervise and observe the application of restraints.
 - e. Said requirements of paragraph #7 shall be subject to MMCF review.
8. The Licensee shall designate one individual who shall assume the overall responsibility for full implementation of this Agreement. The Department shall be notified as to the identity of this person within seven (7) days of the effective date of this 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 Licensee.
9. The Licensee agrees to pay twenty-five thousand (\$25,000) 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 Ann Marie Montemerlo, Supervising Nurse Consultant at the address identified in this document. In addition, the Licensee agrees to collaborate with the Department to develop a series of patient safety education seminars for Department staff and/or health care providers. Such seminars will be at the sole expense of the Licensee and will include topics that will be mutually agreed upon. The monetary value of the seminars shall be \$75,000.
10. Reports and meeting required by this document shall be sent to:
- Ann Marie Montemerlo, R.N.
Supervising Nurse Consultant
Department of Public Health
Division of Health Systems Regulation
410 Capitol Avenue, MS#12GSR
P.O.Box 340308
Hartford, CT 06134-0308
11. All parties agree that this Agreement shall have the same effect as 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 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.

- 12. 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.
- 13. The terms of this Agreement shall remain in effect for a period of two (2) years from the effective date of this document.

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

SAINT FRANCIS HOSPITAL AND MEDICAL
CENTER of Hartford, CT

August 18, 2004
Date

By: [Signature]
David D'Eramo, Ph.D., President and Chief
Executive Officer

State of Connecticut)
County of Hartford

ss August 18 2004

Personally appeared the above named David D'Eramo and made oath to the truth of the statements contained herein.

My Commission Expires: March 31, 2009

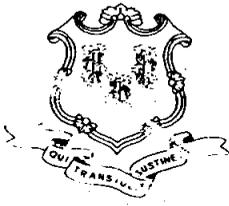
Notary Public	<input checked="" type="checkbox"/>
Justice of the Peace	<input type="checkbox"/>
Town Clerk	<input type="checkbox"/>
Commissioner of the Superior Court	<input type="checkbox"/>

MARTHA E. HARTLE
NOTARY PUBLIC
MY COMMISSION EXPIRES MAY 31, 2009

STATE OF CONNECTICUT,
DEPARTMENT OF PUBLIC HEALTH

August 19, 2004
Date

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



STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

EXHIBIT A
PAGE 5 OF 40

March 30, 2004

David D'Eramo, President & CEO
St. Francis Hospital & Medical Center
114 Woodland Street
Hartford, CT 06105

Dear President & CEO:

Unannounced visits were made to St. Francis Hospital & Medical Center on October 31, November 17, 18, 19, 20, 21, 24, 25, December 3, 7, January 6, 22 and February 2, 2004, by representatives of the Division of Health Systems Regulation for the purposes of conducting multiple investigations, a licensure and validation survey with additional information received through March 23, 2004.

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 April 15, 2004 at 2:00 P.M. in the Division of Health Systems Regulation Conference Room, Department of Public Health, 410 Capitol Avenue, Second Floor, Hartford, Connecticut.

Please prepare a written Plan of Correction for the above mentioned violation(s) 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

Judy McDonald, R.N.
Supervising Nurse Consultant
Division of Health Systems Regulation

JFM:PMG:LAG:DSR:DMO:ESA
CAT:JCT:SHN:PJA:AMB:lsf

cc: Director of Nurses
Medical Director
President
vlstfrancishospisl.doc
#2002-1094, #2002-1182, #2002-1194, #2002-1195, #2002-1199, #2002-1228, #2002-1108, #2002-1108, #2002-1141, #2002-1156,
#2002-1161, #2002-1206, #2002-1207, #2003-0820, #2003-1310, #2003-0256, #2003-0036, #2003-0935, #2003-1024, #2003-0950,
#2003-0949, #2003-0891, #2003-0883, #2003-0405, #2003-0368, #2003-0717, #2003-1196, #2003-1339, #2003-0623, #2003-0061,
#2003-0646, #2003-0951, #2003-0686, #2003-1006, #2003-0996, #2003-1311, #2003-1417, CT-2315



Phone:
Telephone Device for the Deaf: (860) 509-7191
410 Capitol Avenue - MS # _____
P.O. Box 340308 Hartford, CT 06134

Affirmative Action / An Equal Opportunity Employer

FACILITY: St. Francis Hospital & Medical Center

DATES OF VISIT: October 31, November 17, 18, 19, 20, 21, 24, 25, December 3, 7, January 6, 22 and February 2, 2004

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

1. Review of the chlorine/chloramines log for the acute care hemodialysis unit indicated that for the period of 10/1/03 through 11/18/03 evidence was lacking that the water was tested on twelve occasions (10/10, 10/16, 10/17, 10/20, 10/24, 10/25, 10/29, 11/4, 11/5, 11/6, 11/14, and 11/15). Review of Gambro policy indicated that water testing should be completed each day prior to starting the first patient.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (e) Nursing Service (1) and/or (i) General (7).

2.
 - a. Patient #4 was admitted to the hospital on 2/19/03 at 5:05 PM for induction of labor. Review of MD #40's progress note dated 2/20/03 at 11:15 PM identified that second stage labor was three plus hours with slow progression of descent and would proceed to an operative delivery. Interview with and review of the operative note with MD #39 (assisted MD #40 with delivery) identified that the first application of the Tucker Forceps was applied by MD #39, then reapplied by MD #40 with all pulls performed by MD #40. After several pulls with the Tucker Forceps, Simpson Forceps were replaced by MD #40 and Patient #4a (infant) was delivered in the occipital posterior position. At birth the infant required positive pressure ventilation, responded and was monitored in the NICU. Review of APRN #1 (NICU) and RN #23's progress notes dated 2/20/03 identified the baby was born in the anterior posterior position. MD #40's delivery note dated 2/21/03 identified a discrepancy with regards to the presenting part at the time of birth. Review of the clinical record failed to identify the presentation and the position of the fetal head prior to the application of the forceps. Review of APRN #1's (NICU) physical examination identified severe caput formation and forcep marks on the left forehead and at the right temple. Review of the NICU nursing admission data base dated 2/21/03 at 1:00 AM identified that forcep lacerations were observed on the infant's right temporal area, left frontal region and the sclera of the left eye was noted to have a small hemorrhage. Approximately three hours after delivery, the infant developed hypovolemia, coagulopathy and neurological decline with a head CT performed at 9:35 AM that identified significant intracranial hemorrhage involving the subarachnoid and subdural spaces, intracerebral hemorrhage in the left frontal lobe and diffuse brain edema. Follow-up head CT scan at 5:35 PM identified a fracture through the roof of the left orbit, with displacement of a piece of bone into the left frontal lobe and left frontal

FACILITY: St. Francis Hospital & Medical Center

DATES OF VISIT: October 31, November 17, 18, 19, 20, 21, 24, 25, December 3, 7, January 6, 22 and February 2, 2004

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

- hematoma. Review of the clinical record identified that the infant was transferred to another acute care hospital at 7:00 PM for further evaluation and management of care. Review of the receiving hospitals medical record identified that the infant experienced a traumatic forcep delivery and presented as hypotonic with no spontaneous activity and progressed to a flat line EEG. On 2/23/03 the infant expired. The autopsy findings support an ischemic or hypotensive event with multisystem failure.
- b. Patient #33's diagnosis included Down's Syndrome. Review of the ED report dated 06/06/03 identified that the patient arrived at the ED with complaints of left thigh pain for one week. The report further identified that a family member reported that the patient had fallen one week prior to the ED visit, that the pain now affected the patient's balance, that the leg had become increasingly weak and that the patient was having difficulty ambulating. Interview with Person #3 on 11/24/03 identified that although Patient #33's baseline ambulation status was independent, the patient required the use of a wheelchair upon arrival and discharge from the ED due to the inability to ambulate without pain. Interview with MD #4 on 11/19/03 identified that Patient #33's primary physician had sent the patient to the ED based on reports by the family of the presenting symptoms. MD #4 identified that the patient's primary physician had asked that a Doppler Scan be done to rule out a Deep Vein Thrombosis (DVT). Review of the ED record identified after an initial physical examination, blood work and a bilateral venous Doppler scan was performed and that the scan was reported as negative. No further diagnostic tests were ordered and/or performed and Patient #33 was discharged from the ED with a diagnosis of a left leg contusion. Patient #33 returned to the facility on 06/14/03 with diagnosis of a left hip fracture and subsequently underwent a left hip replacement.
- c. Patient #23 presented to the Emergency Department (ED) with diagnoses inclusive of hyperglycemia and fever. Review of the ED physical exam dated 8/7/03, 5:01 PM, identified that an assessment of the patient's systems and a physical examination was conducted. An assessment and examination of multiple systems was conducted, however an examination of endocrine, gastrointestinal, and skin systems was lacking. Review of the clinical record identified that Patient #23 was transferred to a medical floor on 8/7/03. The physician's physical examination dated 8/7/03, 9:30 PM identified a healing ulcer. On 8/8/03 pressure ulcer documentation identified a fifty cent size black area on the left heel. Review of the policy and procedure for structure and standards in the ED

FACILITY: St. Francis Hospital & Medical Center

DATES OF VISIT: October 31, November 17, 18, 19, 20, 21, 24, 25, December 3, 7, January 6, 22 and February 2, 2004

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

- identified that all patients will be given appropriate treatment. The physician documentation policy directed that all physical findings should be described.
- d. Patient #17 a minor child, was admitted with diagnoses inclusive of oppositional defiance disorder, attention deficit hyperactivity disorder, and legally blind in left eye. Although review of the clinical record identified that psychotropic medication changes were prescribed on 6/3/03, 6/4/03, 6/5/03, 6/6/03, 6/7/03, and 6/9/03, progress notes identified that the patient's mother was notified of the changes on 6/6/03 and 6/9/03. Review of the policy and procedure for consent of medication directed that the physician discuss with the patient and appropriate family members the medications and side effects of prescribed medications. The physician shall document that medication was discussed and patient agreed to take the medication. In the case of children and adolescents, parental or guardian consent will be documented in the medical record by the physician. MD #20 stated during an interview on 11/25/03 that although he discussed changes with the patient's parent, it was not always reflected in the medical record. In reviewing his notes outside of the clinical record, he stated that in addition to what is documented in the clinical record, he discussed changes in the patient's medication regime with the patient's parent on 6/4/03.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (d) Medical Records (3).

- 3.
- a. Patient #8 underwent an endoscopy and colonoscopy on 9/3/02. Review of the endoscopy flowsheet identified that the patient was non-English speaking and that the daughter was utilized to interpret during the procedure. Review of the admission nursing assessment identified that the patient's primary language was Italian, the daughter was utilized for interpretation and that eight alcoholic drinks per day were consumed by the patient. The Withdrawal Assessment for Alcohol (CIWA) protocol identified that the CIWA scale would be used for all patients who have greater than three drink equivalents per day as assessed on the interdisciplinary Patient Admission Database. Admission physician's orders were obtained and directed that the CIWA scale be performed every one hour with a score above 12, every 2 hours with a score of 8 through 12 and every 4 hours with a score of less than 8. On 9/5/02, the Delirium Tremers protocol was

FACILITY: St. Francis Hospital & Medical Center

DATES OF VISIT: October 31, November 17, 18, 19, 20, 21, 24, 25, December 3, 7, January 6, 22 and February 2, 2004

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

- instituted with a physicians order that directed Valium 5mg IV be administered every two hours PRN for breakthrough symptoms (CIWA score >8).
- b. Patient #8 had a CIWA scale dated 9/3/02 at 6PM, 10PM and on 9/4/02 at 2AM and 6AM that indicated the patient did not understand the question pertaining to orientation and sensorium. Additionally, questions relating to nausea, auditory, tactile and visual disturbances were required to be ascertained as part of the assessment. Although scores were documented, these assessments failed to adequately reflect the patient's status due a documented language barrier. Review of the clinical record with Nurse Manager #1 identified that although the patient's family had visited almost constantly, documentation was lacking that identified family members were utilized and/or other means of communication occurred with the patient to complete these assessments. Interview with the Chemical Dependency Counselor identified that on 9/5/02 a recommendation was made to utilize the DT protocol due to the patient's inability to participate in these assessments.
 - c. On 9/5/02 at 1AM and 3AM the CIWA assessment identified scores of 19. Review of the clinical record from 9/5/02 (3AM) identified that a CIWA assessment was not conducted again until 9/7/02 at 9AM with a score of 11 documented.
 - d. Review of the CIWA assessment dated 9/7/02 identified that an assessment was conducted at 5PM and not again until 9/8/02 at 9AM at which time an assessment was not conducted but documented that the patient was sleeping.
 - e. Review of the CIWA assessment dated 9/8/02 at 4PM identified the assessment was not completed.
 - f. CIWA assessment on 9/9/02 at 12:40AM identified a score of 12 with the next assessment completed on 9/10/02 at 8:30AM with a score of 12 documented.
 - g. Review of the CIWA assessments completed from 9/3/02 at 6PM through 9/10/02 at 8:30 AM failed to identify that the CIWA scores were conducted and/or completed in accordance with physicians orders.
 - h. Review of Patient #15's Moderate Sedation Preprocedure Record dated 10/29/02 and interview with the Interventional Radiology Nurse Manager reflected that the Moderate Sedation Preprocedure Record lacked documentation for the patient's last oral intake to include date/time and a nurse's signature to verify that the pre-sedation checklist was completed. Review of the Moderate Sedation Policy directs that the monitoring personnel (Nurse, MD, Dentist) confirm completed

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- history and physical, presence of informed consent for procedure and moderate sedation, completion of required preanesthetic requirements, and last oral intake.
- i. Patient #16 was admitted to the facility on 10/18/02 with a diagnosis of right lower quadrant phlegmon. On 10/29/02, the patient had a modified Barium Swallow, which identified that the patient was at a very high risk of aspiration. The patient also had a history of aspiration. Orders dated 11/6/02 at 9:52 am directed nothing by mouth. Review of facility documentation and interview with RN #2 identified that NA #1 fed the patient ice cream on 11/6/02 at 7 pm. The Nurse Aide did not receive a report from RN #2 at the beginning of her shift and review her NA worksheet prior to providing care for Patient #16. Review of the NA worksheet identified Patient #16's diet as nothing by mouth. Nurse's progress notes dated 11/6/02 identified that at 7 pm; the patient's oxygen saturation dropped to 79% on 5 liters of oxygen (was 94 % on 3 liters) and the patient had a congested cough. The patient was transferred to the intensive care unit for observation due to aspiration and was intubated at 10:30 pm.
 - j. Patient #24 arrived in the emergency department on 7/20/03 at 3:52 pm with a complaint of a painful finger due to a sewing machine needle that perforated the left thumb. The patient received Tylox by mouth for pain at 6:44 pm and was discharged to home at 9:50 pm. Review of the nursing assessment lacked a pain assessment upon admission, at the time of Tylox administration, and after the administration of pain medication. Review of the Pain Assessment and Management Policy directs assessment and documentation of pain on admission and after each pain management intervention once a sufficient time has elapsed for the treatment to reach effect.
 - k. Review of the medical record for Patient # 45 indicated that the patient was admitted with new onset paraplegia and a history of obesity. The nurse's flow sheet dated 11/14/03 indicated that the patient had a stage II ulcer on his left buttock however documentation of the size, depth and characteristics of the wound were lacking. The flow sheet dated 11/15/03 indicated that the patient had a one and one half inch by one and one half inch breakdown. The flow sheet dated 11/16/03 failed to indicate that the patient had any skin breakdown. Review of the facility policy indicated that upon identification of a pressure ulcer a pressure ulcer assessment should be completed and then once every twenty-four hours with dressing changes.
 - l. Patient #13 was admitted to the facility on 10/23/02 for a laparoscopic appendectomy. The perioperative record identified that an indwelling foley

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- catheter was inserted during surgery. The catheter drained sixty milliliters of clear amber colored urine and was removed prior to transfer to the Post Anesthesia Care Unit (PACU). The postoperative nursing progress notes failed to identify documentation that a genitourinary assessment was completed or post catheter voiding occurred prior to discharge. The discharge instructions identified that genitourinary instructions were not applicable. On 10/26/02 Patient #13 was readmitted to the facility with a diagnosis of acute renal failure and perforation of the bladder that was sustained during the laparoscopic appendectomy. Treatment included the placement of an indwelling catheter for ten days. Although an indwelling catheter was inserted perioperative on 10/23/02, the clinical record failed to identify documentation that a genitourinary assessment was completed or post catheter voiding occurred prior to discharge. Registered Nurse #24 stated upon interview the criteria for a laparoscopic appendectomy does not identify that a patient must void prior to discharge.
- m. Patient #33 had diagnosis that included Down's Syndrome. Review of the ED report dated 06/06/03 identified that the patient arrived at the ED with complaints of left thigh pain for one week. The report further identified that a family member reported that the patient had fallen one week prior to the ED visit, that the pain now affected the patient's balance, and that the patient was having difficulty ambulating. Although the ED record identified that Patient #33 complained of left thigh pain on arrival to the ED at 12:23 PM and again at 7:28 PM, the record lacked documentation that Patient #33's level of pain was evaluated in accordance with the facility's policies and/or that interventions for pain relief were provided by facility staff. Review of facility policies on pain management included that pain intensity and relief is assessed in all patients and further provided assessment strategies for patients who were unable to report pain.
- n. Patient #32 had diagnosis that included Coronary Artery Disease (CAD). Review of the medical record identified that Patient #32 underwent a surgical procedure that included Coronary Artery Bypass Graft (CABG) on 03/06/03. Interview with Patient #32 on 11/24/03 identified that the patient complained of numbness of the right hand almost immediately upon awakening and stated that the hand "felt asleep." Review of the documentation in the nursing assessment record dated 03/08/03 to 03/09/03 identified that Patient #32 complained of numbness of the right hand at 4:00 PM on 03/08/03 and again at 12:00 AM on 03/09/03. At 5:30 AM on 03/09/03, Patient #32 was medicated with Toradol 30 mg. for "complaints of right hand numbness and pain." Further review of the record lacked

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- documentation that the physician was notified at that time and/or that diagnostic tests were initiated to identify the source of the patient's complaints of numbness. Interview with MD #14 on 12/02/02 identified that he discussed Patient #32's complaints about numbness and pain of the hand on the first visit to the physician's office postoperatively, referred Patient #32 to a neurologist at that time, but did not recall being told of the problem while the patient was still in the hospital. MD #14 identified that Patient #32's symptoms of numbness were not uncommon after this type of surgery, that the problem could have been caused by opening the chest or from pressure under the elbow region, but that he would likely not have done anything about the complaints initially and pursued the complaint only if the symptoms persisted. Review of a consultation report by MD #22 and dated 07/09/03 identified that a nerve conduction study was performed and identified axonal damage within the right ulnar nerve. The consultation report further identified that by a review of the patient's history, it was the opinion of MD #22 that Patient #32's symptoms were related to compression that occurred at or subsequent to, his heart surgery. Review of the medical record of Acute Care Facility #2 identified that Patient #32 underwent a right ulnar nerve release on 11/07/03 for a diagnosis of right ulnar neuropathy.
- o. Patient #64 was admitted to the emergency department on 9/30/03 with a complaint of abdominal pain. The clinical record lacked a pain assessment on admission and although the patient received IV pain medication, there was no pain assessment before administration, and/or the effect of the medication was not documented. Patient #64 identified that she was discharged into the waiting room, vomiting from the effects of the pain medications. Hospital policy identified that a pain assessment was to be conducted on admission and after a pain management intervention.
 - p. Patient #14 had elective abdominal surgery on 9/28/01 and received a spinal epidural for pain control. MD orders identified to assess the patient's sensory and motor function of the lower extremities and to notify anesthesiology if the patient is unable to move his thighs or legs. Although on 9/28/01 at 4 PM nurses' notes identified the patient was unable to move his left leg and complained of increasing pain, the anesthesiologist was not notified until 8 PM. At that time, the anesthesiologist identified the catheter was displaced, removed and a PCA was started. Further, there was no evidence in the clinical record that Patient #14 was assessed by a nurse between the hours of 9:30 PM on 9/29/01 and 3 AM on 9/30/01. At 3 AM on 9/30/01 Patient #14 was found slumped over in bed,

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- pulseless and not breathing. The patient was revived, intubated, and transferred to the ICU. Further tests identified that brain death had occurred, life support was withdrawn, and the patient expired on 10/1/01 at 12 Noon. Interview with RN #11 identified that she had not seen the patient between 11 PM on 9/29/01 and 3 AM on 9/30/01. RN #11 stated that her first encounter with the patient was when he was noted to be slumped over in bed at 3 AM. RN #11 stated that although the patient's vital signs were documented at 1 AM, they were reported to her by a patient tech. Hospital policy for a patient receiving pain medications via an epidural identified to assess the patient every one hour, and if receiving pain medications via a PCA, every two hours.
- q. Patient #7 was admitted with diagnoses of chest pain. The Emergency Department (ED) records dated 4/24/03 identified allergies inclusive of Lasix. Progress notes dated 4/25/03, 8:00PM identified that the patient's blood pressure was 197/101 with the physician's assistant notified and Lasix ordered. A physician order dated 4/25/03, 20:22 prescribed Lasix 60 milligrams intravenous push, now. A subsequent progress note identified that the medication was prepared and offered at 8:45PM, however the patient refused the intravenous Lasix. The policy and procedure for drug interactions and allergies identified that an "alert" screen will appear with all drug interactions and allergies identified at the time of order entry. The Pharmacy Director on 11/25/03 stated during interview that although the medication administration system identifies allergies at the time of order entry, it will not prohibit dispensing the medication. She stated that the system is reliant on the individual practitioner to review the patient allergy in the system and on their computerized worksheet. RN # 5 stated during an interview on 11/20/03 that she entered the order prior to administration and could not recall if she reviewed the patient allergy.
- r.
- i. Patient #23 presented to the Emergency Department (ED) with diagnoses inclusive of hyperglycemia and fever. Review of the clinical record identified that Patient #23 was transferred to a medical floor on 8/7/03. A Braden Scale skin assessment dated 8/7/03 identified a score of fourteen indicating that the patient was at risk for pressure ulcer development. The physician's physical examination dated 8/7/03 at 9:30PM identified a healing ulcer,

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- however location of the healing ulcer was not identified. The patient admission database dated 8/7/03, 10:00PM identified no skin decubitus. On 8/8/03, pressure ulcer documentation identified a "fifty cent" size black area on the left heel. Further pressure ulcer documentation dated 8/9/03 and 8/10/03 identified a blackened, one-centimeter area on the left heel. Patient care flow sheets from 8/9/03 through 8/10/03 identified scant serosanguineous drainage from the blackened left heel with treatments administered in accordance with the policy and procedure. Review of an interagency patient referral report dated 8/11/03 indicated that the patient was transferred to an extended care facility and identified a reddened left heel, and to keep the foot off the bed.
- ii. An ED triage assessment dated 8/15/03 identified that the patient had been transferred back to the facility from an extended care facility for mental status changes. Nursing documentation on the triage assessment identified a stage two, two inch break in skin integrity on the left medial thigh and kerlix around the left heel. A Braden scale skin assessment dated 8/15/03 identified a score of nine indicating a high risk for pressure sore development. Review of progress notes and consults from 8/16/03 through 8/20/03 identified a left heel ulcer with the heel bone exposed, necrotic blisters on the lower third of the patient's calf, with a plan for a left above the knee amputation. A progress note dated 8/20/03 identified that the patient's family made a decision not to proceed with the above the knee amputation and to change the patient's plan of care to hospice care. The patient expired on 8/25/03.

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- iii. Review of the policy and procedure for skin integrity identified that a nursing assessment inclusive of a Braden Scale assessment will be completed at discharge. The clinical nurse specialist will be notified of existing skin breakdown who will determine if a therapeutic bed intervention is necessary and/or dressing options, and/or need for sharp surgical debridement. In addition, in the presence of eschar, elevate the heels off the mattress using pillows.
- iv. Interview and review of the clinical record with Clinical Director #9 failed to identify that the patient's skin had been assessed utilizing the Braden Scale and that the pressure ulcer had been assessed on 8/11/03 the day of discharge in accordance with the policy and procedure. Clinical Director #9 stated during an interview that a clinical nurse specialist should have been notified of the blackened area to the left heel and a consult requested on the admission from 8/7/03 through 8/11/03. In addition, although a patient care flow sheet dated 8/9/03 identified that the left heel was elevated on a pillow, review of the clinical record inclusive of the care plan failed to consistently identify that the feet were elevated on a pillow and/or that interventions had been developed to reduce pressure on the bilateral heels.
- v. RN #7 stated during interview on 11/19/03 that although she documented on the 8/11/03 interagency referral report that the left heel was reddened, she could not recall if she had assessed the wound. She stated that most often as the discharge planner she relies on the information that is communicated to her by the unit staff and generally does not assess the wound herself unless it has a very complicated treatment and/or if it has

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- been communicated to her that it is a significant wound.
- vi. Although the policy and procedure identified that a pressure ulcer assessment should be completed once in every twenty four hours, review of the clinical record from 8/16/03 through 8/25/03 failed to identify any assessment of the pressure ulcer subsequent to the 8/15/03 assessment.
- s. Patient #22 was admitted with a diagnosis inclusive of morbid obesity. An operative report dated 8/13/03 identified that a laparoscopic gastric bypass was completed. The operative report stated that the patient tolerated the procedure well without any complications. The Post Anesthesia Care Unit (PACU) record dated 8/13/03 from 11:03AM through 4:30PM identified Jackson Pratt drainage of 560cc, a Hemaglobin of 11.3 (normal 12.5-16.0), Hematocrit of 33.0 (normal 37-47), and a blood pressure and pulse at discharge from the PACU of 120/60 and 100 respectively. The patient was transferred to a surgical floor at 4:30PM. Review of the patient care flow sheet dated 8/13/03 from 5:45PM through 7:15PM identified a blood pressure range of 73-101/42-61 and a pulse range of 115-125. Further review of the clinical record identified that although the patient's blood pressure had decreased and the pulse increased, the physician was not notified until 7:40PM and consequently intravenous fluids were increased with the plan to include returning the patient to the operating room for exploration. MD #9 stated during an interview on 11/20/03 that to his recollection he had not been notified of the patient's decreased blood pressure and tachycardia on 8/13/03 from 5:45PM through 7:15PM. He further stated, had he been notified he would have ordered laboratory work, blood transfusions, and increased intravenous fluids prior to 7:40PM.
- t. Patient #17 was admitted on 6/2/03 with diagnoses of oppositional defiance disorder, attention deficit hyperactivity disorder, and legally blind in his left eye. A physical examination dated 6/2/03 identified a temperature of 97.6, pulse of 104, respirations of 46, blood pressure of 119/69, and a height of 46 inches. Review of the vital signs record identified that vital signs inclusive of blood pressure, pulse, respirations, and temperature were obtained on 6/3/03, 6/4/03, and 6/7/03. Further review of the clinical record inclusive of the vital sign record with Registered Nurse #8 identified that the patient's weight had not been obtained until 6/8/03 (six days subsequent to admission) with a weight of forty six

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- pounds. RN #25 stated during an interview on 12/8/03 that the scale had been broken and during that time period they were borrowing a scale from another unit when a weight needed to be obtained, she had apparently not done it in this case. Review of the policy and procedure for vital signs and weight identified that vital signs will be obtained at admission for baseline measurement including othostatic blood pressure, pulse checks, height, and weight.
- u. Patient #31 was admitted with diagnoses inclusive of post traumatic stress disorder and bi-polar disorder. A restraint/seclusion record dated 11/3/03, 7:00PM identified that when the patient was asked to take a shower, he refused and became agitated striking Mental Health Worker (MHW) #1 in the shoulder. Patient #31 was placed in a basket hold and escorted to the patient's room. Documentation identified that the patient upon return to the room became agitated banging on the door. While the patient was in the room, the patient charged the door striking his face. The patient then wielded a wooden board and began banging on the window. The patient was placed into seclusion. Review of a nurse's progress note dated 11/3/03, 23:00 identified that the patient was in seclusion for forty five minutes with seclusion ending at 7:45PM and identified that the patient's tooth was broken in half. A physician assistant assessment dated 11/3/03, 7:45PM identified that the patient was complaining of a chipped left front tooth which was sustained during the time the patient was running into the closed door. The assessment identified that half of the left front tooth was missing with the pulp exposed with no active bleeding. Tylenol #3 (analgesic) one tablet was ordered every four hours when necessary. A medication administration record identified that Tylenol 325 milligrams was given on 11/4/03 at 10:10AM for complaints of dental pain. Registered Nurse (RN) #16 stated during interview on 11/19/03 at 2:30PM that when the patient got angry it was difficult to engage him. He stated that he responded to the incident immediately after MHW #1 summoned him. Upon arrival to the patient's room he observed Patient #31 in the room striking the window in the door with a large board that he had apparently obtained after breaking a piece of furniture in the room. RN #16 stated that upon his arrival the patient reported that the "tooth was broken" and was assessed as needing seclusion. Because there was no blood noted and the patient was agitated, he deferred assessment of the tooth. The patient was then walked to seclusion where he remained for forty five minutes. Subsequent to coming out of seclusion, RN #16 stated that he informed Physician Assistant (PA) #1 of the patient's report of a "broken tooth" who assessed half of the tooth as

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- missing. Review of the clinical record identified that although the incident occurred at approximately 7:00PM and the patient reported immediately that he had broken his tooth, the patient was not assessed until forty five minutes subsequent to the incident. He further stated that he did not assess the patient's pain as these types of patients generally report physical pain right away. Review of the policy and procedure for pain assessment and management policy identified that pain intensity and relief will be assessed after any known pain-producing event. Although half of the patient's tooth had been assessed as missing with the pulp exposed and an analgesic ordered, review identified that pain assessments had not been conducted until 11/4/03 at 10:10AM and/or assessed subsequent to 11/4/03 at 10:10AM. He further stated that he did not assess the patient's pain as these types of patients generally report any physical pain right away.
- v. Review of the medication administration record (MAR) for Patient #44 indicated that the patient received Dilaudid 4mg every four hours as needed for pain. The MAR indicated that on 11/15/03 the patient received Dilaudid at 10 PM and on 11/16/03 at 9 AM, 4 PM and 9 PM for pain levels of 5-7. Review of the flow sheet and the nurse's notes failed to indicate the effectiveness of the intervention. Review of the facility policy indicated that the post assessment should be documented on the back of the nursing flow sheet.
- w. Patient #24 arrived in the emergency department on 7/20/03 at 3:52 pm with a complaint of a painful finger from a sewing machine needle through the left thumb. An x-ray of the left first digit identified a metallic needle type density projecting in soft tissues. The patient received Tylox by mouth for pain at 6:44 pm. Interview with MD #4 reflected that pain relief should happen as soon as possible without delay and that there was no reason that the patient did not receive pain relief earlier. Review of the Pain Assessment and Management Policy directs to respect and support the patient's right to optimal pain assessment and management.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (2) and/or (3) and/or (e) Nursing Service (1) and/or (i) General (7) and/or (j) Emergencies (2).

4.

- a. Patient #8 underwent an endoscopy and colonoscopy on 9/3/02. Review of the endoscopy flowsheet identified that the patient was non-English speaking. Review

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- of the admission nursing assessment identified that the patients primary language was Italian and that the daughter was utilized for interpretation. Review of CIWA assessments dated 9/3/02 at 6PM and 10PM and 9/4/02 at 2AM and 6AM indicated the patient did not understand the question pertaining to orientation and sensorium. Review of the plan of care failed to address the patients language barrier and how the CIWA assessments would be conducted based upon this information.
- b. Review of the medical record for Patient # 45 indicated that the patient was admitted with new onset paraplegia and a history of obesity. Review of the Braden Scale completed on 11/11/03 indicated a score of 15 identifying the patient as a low risk for development of pressure ulcers. The braden scale was revised on 11/12/03 and indicated a score of 13 identifying the patient as a moderate risk for skin breakdown. The nurse's flow sheet dated 11/14/03 indicated that the patient's had a stage II ulcer on his left buttock. Review of the general surgical clinical pathway indicated that the patients skin needs had not been addressed. Review of the pathway on 11/17/03 indicated that problems, preventative measures and/or interventions related to the patients new breakdown were not addressed. Review of facility policy indicated that on admission each patient should have completed an individualized care plan addressing there needs completed.
- c. Patient #10 was identified on admission on 9/30/03 with intact skin and at minimal risk for pressure sores. Following an emergency re-vascularization of the right femoral artery on 10/2/03, the patient was transferred to the ICU where an ecchymotic stage one pressure sore was noted on the coccyx. Although a care plan was initiated that identified skin integrity, only the IV line site and surgical wounds were addressed. The wound tracking flow sheets identified that the pressure sore progressed to a stage two on 10/3/03 and treatment and/or pressure relieving measures were not initiated until 10/11/03. The patient was discharged on 11/22/03 with the stage II pressure sore.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1).

5.

- a. During a tour of 8-1 on 11/17/03 at 11:35 AM, an intravenous bag containing a Magnesium Sulfate solution mixture and two tablets of medication, Diflucan 100

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milligrams (mg) and Oxycodone 5 mg. were observed to be left unattended on the counter of the open nourishment room. Interview with the Nurse Manager of 8-1 on 11/19/03 identified that RN #1 had carried the medications into the nourishment room to obtain ice cream for a patient and had inadvertently left the medications on the counter.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (e) Nursing Service (1) and/or (i) General (7).

6.

- a. Patient #14 had elective abdominal surgery on 9/28/01 and had a spinal epidural for pain control. On 9/29/01 between 4 PM and 8 PM the epidural flow sheet failed to identify the amount of epidural pain medication, if any, the patient received. The facility policy for use of an epidural flow sheet identified to document the milligrams of medication administered in an 8 hour period. In addition, at 7 PM on 9/29/01 Patient #14 was given 30 mg of IV Toradol for complaints of increasing pain, followed by two (2) doses of IV Dilaudid at 8 PM and 9 PM. A patient controlled anesthesia PCA pump was started at 9:30 PM. The PCA order identified two different Basal Rates, 0.5 mg and 1 mg per hour. The nurse failed to question the order and the PCA was set at the higher dose of 1 mg per hour. Further, the documented amount of PCA pain medications the patient received between 9:30 PM on 9/29/01 and 3 AM on 9/30/01 was obliterated and re-written. The facility policy for correcting documentation errors identified that entries may not be obliterated. The facility policy for use of an epidural flow sheet identified to document the milligrams of medication administered in an 8 hour period. Interview with MD #23 identified that PCA orders should include only one basal rate, and in this instance, the basal rate was intended to be 1 mg.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1).

7.

- a. Review of Patient #15's medical record and interview with the Nursing Director of Surgery reflected that multiple blood product Transfusion Records lacked

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complete documentation, which included transfusion checklist and transfusion reaction. Review of the Blood Component Therapy Protocol directs to complete the Transfusion Checklist on the blood component bag.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3).

8. During tour of the multiple clinics at the 1000 Asylum building, the following was observed:
 - a. Three (3) of four (4) records (Patient #57, 58, 59, 60) reviewed in the Pediatric/Adolescent Clinic lacked a signed consent to treat form.
 - b. One (1) of four (4) records (Patient #49) reviewed in the Medical/Surgical Clinic lacked information of past medical history, current medications and/or a problem list.

The above is a violation of the Regulations of Connecticut State Agencies (d) Medical Records (3).

9. Based on review of the medical record and review of facility policy, the facility failed to ensure that documentation was complete for Patient #8 and/or failed to ensure that Patient #15's codesheet identified signatures for the recorder and the physician in charge. The findings include:
 - a. Patient #8 had alcohol withdrawal assessments that lacked dates and times the assessments were conducted. Review of a CIWA assessment with LPN #1 who conducted the assessment identified that the date of this assessment was lacking (located on the same sheet as the 9/4/02 assessment) the time was not legible and the sum of the score incorrect.
 - b. Patient #15 had a liver biopsy on 10/29/02 and had a cardiac arrest on 10/29/02 at 5:15 pm. Review of the Cardiopulmonary Arrest Flowsheet and interview with the 7-1 Nurse Manager reflected that the codesheet lacked signatures for the recorder and the physician in charge. Review of the Codes Policy directs that the physician team captain will sign the code record and the caregiver nurse on the area of the arrest will prepare medications, equipment, and record events.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1).

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10. Based on a review of medical records and facility policy and procedure, the facility failed to ensure for two patients that the admission database was complete.
 - a. Patient #18 underwent an anterior cervical discectomy and fusion. The patient developed a hematoma and pulmonary edema in the recovery room that required a return to the OR drainage of the incisional hematoma. A review of the patient's admission database identified it was incomplete. The admission data bases for Patient's #18 and 19 lacked information that included abuse and/or substance use, nutrition, fall risk and/or speech, occupational or physical therapy and lacked an RN signature, title and date done.
 - b. Patient #19 underwent a right thyroidectomy and isthmusectomy with postoperative bleeding that required a return to the OR for ligation of bleeding from the left inferior thyroid artery. A review of the patient's admission database identified it was incomplete. A review of the facility policy for guidelines for use of interdisciplinary patient admission database identified the database must be completed within twenty-four hours of admission. If unable to obtain information from the patient, documentation in the Progress Notes should reflect this and be completed when the assessment is completed.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (2) and/or (3) and/or (e) Nursing Service (1).

11. The facility failed to ensure that the clinical record for Patient #6 contained documentation of all physician orders and/or that the record of Patient #11 included documentation during a Code Blue. The findings include.
 - a. Patient #6, a Department of Mental Retardation client and group home resident, was admitted to the Emergency Department on 11/8/02 at approximately 9:00 p.m. after it was determined that his jejunostomy tube had become displaced. The patient's J-tube was replaced the following morning and the patient was discharged back to the group home at approximately 2:30 pm. The clinical record indicated that a Foley catheter was placed for incontinence without documentation of physician orders.
 - b. Patient #11 presented to the Emergency Department (ED) on 12/28/02 at 11:20pm complaining of an asthma attack with an inability to speak. MD #31's examination identified a diagnosis of extremis, status asthmaticus with an oxygen saturation of sixty-six percent (normal greater than 96%) on ambient air. A nurse progress note

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revealed that subsequent to pulseless electrical activity cardiopulmonary resuscitation was initiated. Although a Code Blue was called, a review of the clinical record failed to identify documentation that a recording of the events was maintained. Hospital "Code Blue" Policy identified that the events of a code are recorded on the "Code Blue" record, signed by the Physician and placed in the medical record.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1).

12. During a tour of the acute hemodialysis unit on 11/18/03, the following was identified:
- The storeroom lacked a lock and contained syringes, needles and some medications.
 - The door to the medication room was wedged open.
 - The medication refrigerator was observed to contain food items.

13. During a tour of the acute hemodialysis unit on 11/18/03, the following was identified:
- Blood collection tubes (green tops) in the storeroom were noted to have expired in September 2002.
 - Pre mixed bags of heparin in the storeroom were noted to have expired on September 2002.
 - During a tour of the acute hemodialysis unit on 11/18/03, intravenous bags of 100cc and 250cc of normal saline had been removed from their protective covering and were being stored in a box.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (e) Nursing Service (1) and/or (i) General (7).

14. The facility failed to ensure that the appropriate dishwasher temperatures were achieved.
- A review of the facility documentation for 11/1/03 through 11/19/03 indicated that on twelve occasions (evening meal) the dishwasher failed to reach the 150-degree threshold required. The flow sheet indicated temperatures of 142, 145 and 140 degrees on ten (10) occasions. Interview with the supervisor indicated she was unaware of the issue and that although there is a policy the policy does not indicate how long after the dishwasher is started the temperature should be

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monitored. The policy indicated that if a temperature is below the acceptable range the supervisor should notify engineering immediately.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (h) Dietary Service (3) and/or (i) General (7).

15. Based on observations, medical record reviews and review of facility policies the facility failed to ensure an infection control officer or officers implemented policies governing control of infections. The findings include:
- a. Patient #42 had diagnosis that included cancer of the breast. During a tour of unit 8-1 on 11/17/03 at 11:25 AM, an intravenous (IV) solution was observed to be infusing via a pump into Patient #42. The IV tubing that delivered the solution was observed to be dated as initiated on 11/12/03 and due to be changed on 11/15/03. Review of the facility's policy on changing of intravenous tubing identified that IV tubing would be changed every seventy two hours.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (e) Nursing Service (1) and/or (i) General (7) and/or (l) Infection Control (1).

16. During tour of the Endoscopy area on 11/17/03, the facility failed to show documented evidence that the Cidex OPA was changed according to facility policy. Review of the monitoring logs documented that Cidex changes occurred intermittently, in some instances after 28 days of use, specifically on 7/24/03, 9/3/03 and 10/28/03. Review of the facility policy for Cidex OPA Solution Change revealed that the solution should be changed every 14 days. Scopes hanging in the cabinet between treatment rooms #5 & #6 were observed to be coiled and with tips of scopes lying on the base of the cabinet.
17. During tour of the Operating Suite the following was observed:
- a. A rack for the sterilizer in the Ambulatory Surgical Unit was observed to be lying on the floor propped against the wall.
 - b. Disinfectant coverage spray was observed to be stocked in the same bin/cubicle as the patient care solutions such as Hibiclens and Betadine.
 - c. The main operating room steris failed to have consistent daily biological monitoring.

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- d. Throughout the Operating Suite head coverings of personnel, including some directly involved at the surgical site were observed to not cover the entire head of hair.
18. The St. Francis Campus Ambulatory Surgical Unit biological monitoring of the flash autoclaves was incomplete for incubation and results of test and control on several days including 8/25/03, 8/26/03 and 8/30/03.
 19. During tour of the Mt. Sinai Campus Central Sterile on 11/19/03, the following was observed:
 - a. One (1) of two (2) washers for the central sterile area was located in the midst of the "clean area" necessitating staff to travel through the clean wrapping area with soiled equipment. The facility failed to monitor the temperatures reached during the cleaning cycle of the unit and the unit lacked an automatic printout. Additionally, this washer was wrapped on one side with layers of cellophane tape.
 - b. The storage for sterilized case packs was separated from the "soiled area" by a curtain.
 - c. Wrapped, non-sterile packs are stored on shelves in the staff lounge and locker area.
 - d. Soiled heavy equipment (Baxter pumps, wall suction, venodynes, etc.) are cleaned in the "clean area" and the cleaned equipment was observed to be recharging next to the open trash can.
 - e. The facility failed to show evidence that the sterilizers are on a cleaning schedule.
 - f. The floor of the Central Sterile area was soiled.
 20. Review of the biological monitoring of the autoclaves in the Burgdorf Dental Clinic, kept at the Mt. Sinai campus, revealed no evidence that a control test was utilized during the biological testing monitor.
 21. During tour of the multiple clinics at the 1000 Asylum building the following was observed:
 - a. Review of the Dental Clinic monitoring logs revealed inconsistent monitoring of the biological testing of the six autoclaves (five functional) in the clinic. Review of the monitoring logs on 11/18/03 revealed multiple styles of recording test results rendering it impossible to tell which test was completed for which autoclave. In addition, 11/5/03 lacked any recorded test results. Suction

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canisters, sani-wipes and miscellaneous items were observed to be stored beneath the sink in the Dental Clinic.

The above are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (e) Nursing Service (1) and/or (i) General (7) and/or (l) Infection Control (1).

22.

- a. Patient #27 underwent a laparoscopy and due to severe endometriosis and adhesions and an open laparotomy was required. Perioperative notes written by RN #3 identified during the change over from laparoscopic to open laparotomy, MD #11 placed the laparoscope with the light cord attached and on, on the patient's upper body. When the cord shifted the end of the scope rested on the drape and scorched through the drape and burned the patient's left shoulder. A review of the manufacturer's warnings and precautions identified that prolonged contact of the scope tip with flammable materials should be avoided due to high intensity light transmission that results in high temperatures. A review of the 2002 AORN Standards, Recommended Practices, and Guidelines identified that illuminated endoscopic light cords should not be allowed to remain in contact with drapes, patient's skin or any flammable material as the heat from the light cords may cause drapes to burn. During interviews the Director of Surgical Services, RN #3, and the CST all stated the laparoscope should have been handed to the CST so the light source could be shut off and handed off the surgical field to RN #3 but MD #11 placed it on the patient's chest with the light source on.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2)(B) and/or (4)(A).

23. For Patient #12 the facility failed to ensure that the medical record contained a complete history and physical prior to surgery. The findings include:

- a. Patient #12 underwent an outpatient laparoscopic inguinal hernia repair on 11/15/02. Although the laparoscopic inguinal hernia repair was performed on 11/15/02, the preoperative History and Physical was dated 9/11/02. The hospital Medical Staff Rules and Regulations detailing the requirements for History and Physical prior to surgery identified that a history and physical is valid for thirty days only if an update is documented on the History and Physical within seven days of surgery.

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The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 © Medical Staff (2)(B) and/or (d) Medical Records (2) and/or (3).

24. For Patients (#9, #12 and #13) in the survey sample, the facility failed to ensure that physician services were provided in accordance with hospital policies and procedures. The findings are based on a review of the clinical records, staff interviews, review of facility policies and procedures and include the following.
- a. Patient # 13 was admitted to the hospital on 10/23/02 for a laparoscopic appendectomy. Although the informed consent identified a physician signature, it failed to indicate the date the physician signed the form. Facility Consent Policy identified that signed inform consents are valid for thirty days from signature.
 - b. Patient # 9 was admitted on 5/21/02 for a laparoscopic gastric banding procedure. An informed consent dated 5/2/02 identified the original procedure/operation indicated on the informed consent was crossed through several times and a laparoscopic gastric banding procedure added. The consent form failed to identify documentation of the date the type of procedure/operation was changed or the person who initiated the change. MD #19 stated upon interview that the informed consent forms are pre-printed with operations/procedures and are signed in the physician's office prior to surgery. MD #19 further stated the change in procedure was initiated on 5/2/02 when the Patients signature was obtained. The facility Standards of Documentation identified that errors are corrected by writing the word "error" above the error and drawing a single line through it, adding the correct information and writing signature and status.
 - c. Patient #12 underwent an outpatient laparoscopic inguinal hernia repair on 11/15/02. The informed consent for the procedure was signed by Patient #12 and MD#7 on 9/11/02 . Review of the hospital Consent Policy identified that signed informed consent forms shall be valid for thirty days. MD # 7 stated the informed consent was signed in September 2002, with the surgery scheduled electively at the convenience of the patient.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (8).

25. Based on a review of the medical records, review of facility policies and procedures, and interviews, the facility failed to ensure for two patients (Patient #27 and Patient #12) that

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the operative report accurately reflected all complications that occurred during surgery were documented. The findings include:

- a. Patient #27 underwent a laparoscopy and due to severe endometriosis and adhesions an open laparotomy was required. Perioperative notes written by RN #3 that identified during the change over from laparoscopic to open laparotomy, MD #11 placed the laparoscope with the light cord attached and on, on the patient's upper body. When the cord shifted the end of the scope rested on the drape and scorched through the drape and burned the patient's left shoulder. During interviews the Director of Surgical Services, RN #3, and the CST all stated the laparoscope should have been handed to the CST so the light source could be shut off and handed off the surgical field to RN #3 but MD #11 placed it on the patient's chest with the light source on. Saline gauze, bacitracin, and a Band-Aid were applied in the OR on verbal orders from the physician. A review of the operative report written by MD #11 identified documentation was lacking that any burn injury occurred during the surgery.
- b. Patient #12 underwent an outpatient laparoscopic inguinal hernia repair on 11/15/02. An intraoperative injury to the bladder occurred and a Urology Service consultation was conducted to repair the injury to the bladder. A conversion to an open procedure was required to perform the repair. The clinical record failed to identify documentation that the Urology Service completed a dictated or written Operative Report detailing the surgical repair of the bladder. Upon request, a dictated operative report dated 11/24/03 was provided by the facility. The hospital Medical Staff Rules and Regulations detailing the requirements for Operative Notes (15.e.) identified that the Operative Report is documented in the medical record immediately after surgery.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3).

26.

- a. Patient #28 was admitted on 7/28/03 for operative procedures that included transanal pull through secondary to Hirshsprungs disease and a circumcision. Pre-procedure vital signs at 6:40 AM identified a blood pressure of 94/40, pulse rate was 168 beats per minute and respirations of 60 per minute. Review of the admission database identified that the patient was last fed pedialyte at midnight on 7/28/03. Review of the Anesthesia Record dated 7/28/03 identified that Patient

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#28 arrived in the OR at 7:28 AM, underwent mask induction and was intubated. Review of the operative report with MD #36 (surgeon) identified that a right broviac catheter (central line) was inserted secondary to lack of a peripheral site. Interview with MD #36 identified that the right internal jugular vein was tied after the broviac catheter was inserted and that this procedure is routinely performed and has no bearing on blood flow to and/or from the brain. Further review of the operative report identified that the patient was placed in the lithotomy position. Interview with MD #36 and MD #47, indicated that Patient #28 was positioned supine, bilateral legs were folded up onto the abdomen, taped lightly, a small towel was placed under the patients buttocks and that the Trendelenberg position was not utilized. Review of the perioperative record and interview with RN #19 (circulating nurse) indicated that MD #36 and MD #47 positioned the patient for surgery. RN #19 documented that the position of the patient was lithotomy and described this as, "arms by the side, legs in fetal position on abdomen wrapped in kerlix with abdominal pad in-between legs and secured with two-inch adhesive tape." Interview stated that the patient's head was in good alignment and that the patient was not placed in Trendelenberg. Review of the vital signs while in the operating room identified that the blood pressures ranged from 70/22 to 40/15 from 7:45 AM through 12:19 PM. At 12:46 PM, the patient arrived in the PACU with a blood pressure of 114/52, pulse of 155 and respiratory rate of 20. Review of the PACU record identified that the patient was observed with a weak cry, cyanotic, with some periodic desaturations to the mid 80's, with tonic/clonic type movements, became apneic and required re-intubation and transfer to another hospital for further care. Review of the receiving hospitals medical record identified Patient #28 had diffuse cerebral edema related to an ischemic event and identified low blood pressures intraoperatively. Interview with MD #48 (neurologist) at the receiving hospital indicated that low perfusion and intraoperatively blood pressures contributed to the above mentioned diagnoses. Interview with MD #36 identified that he was not informed of the blood pressures intraoperatively, stated that central venous pressure could have been assessed to explore reasons for low pressures and would have been discussed with anesthesia staff in order to make a determination whether the elective circumcision should have been done. Interview with MD #35 (anesthesiologist), MD #37 (anesthesiologist) and Nurse Anesthetist #1 identified that they were not concerned with the above mentioned blood pressures therefore did not communicate this information to the surgeon. The anesthesia staff expressed

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concern in regarding to the right internal jugular vein being tied following the insertion of the Broviac catheter and position of the baby which they described as "steep Trendelenberg", "extreme lithotomy" and "virtually standing on head" which possibly contributed to the cerebral edema. In addition, prior to the surgical procedure, a urinary catheter was inserted by MD #36. Review of the Intake and Urinary output record with Nurse Anesthetist #1 identified that 220 cc's of Ringers lactate intravenous solution had infused during surgery and no urinary output was recorded. Interview with Nurse Anesthetist #1 attributed the lack of urinary output to the steep Trendelenberg and Lithotomy position the patient maintained intraoperatively. MD #36 (surgeon) stated during interview that positioning was not a factor contributing to lack of urinary output and that a dialogue should have occurred between anesthesia staff and himself in relation to lack of urinary output. Review of the perioperative record identified that the Foley catheter was removed postoperatively. Review of the post anesthesia care unit (PACU) record identified that Patient #28 arrived in the PACU at 12:46 PM with Ringers Lactate solution infusing via the central intravenous line. At 5:50 PM, an indwelling Foley catheter was reinserted prior to the transfer to another hospital. Review of the PACU record failed to identify urinary output.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical Staff (2)(B) and/or (4)(A).

27.

- a. Patient #11 presented to the Emergency Department (ED) on 12/28/02 at 11:20pm complaining of an asthma attack with an inability to speak. MD #31's (ED Physician) examination identified a diagnosis of extremis, status asthmaticus and an oxygen saturation of 66% (normal greater than 96%). Combivent nebulizer treatments were administered at 11:20pm and 11:25pm. Intravenous solumedrol and epinephrine were administered at 11:45pm. At 11:50pm and 12:00am oxygen saturation levels while receiving 100% oxygen were recorded at 90%. A nurse progress note identified that beginning at 12:00am, MD #31 made multiple unsuccessful attempts to insert an endotracheal tube. Additionally, Paramedic #1 made several unsuccessful attempts to pass the endotracheal tube. At 12:40am continued attempts at intubation were unsuccessful and cyanosis of the face and upper trunk was identified. At 12:56am pulseless electrical activity was identified and cardiopulmonary resuscitation was initiated. A cricothyroidotomy was

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- performed at 1:15am to provide an airway. Resuscitation efforts were unsuccessful and Patient #11 expired at 1:30am. According to ambulance dispatch documentation, the request to transport Patient #11 to the acute care hospital was received on 12/29/02 at 12:14am. Although Patient #11 was diagnosed with status asthmaticus (defined as an emergent condition in the hospital Triage Guidelines) and a high potentiality to require treatment at a higher level of care, the Emergency Department Physician failed to request ambulance transportation for 54 minutes after presentation to the Emergency Department. Furthermore after multiple intubation attempts were unsuccessful and cyanosis was identified at 12:40am, a cricothyroidotomy was not performed until 1:15am (thirty-five minutes after the identified respiratory distress). MD # 4 (Director of the ED) stated that a cricothyroidotomy is performed when the patients' oxygen saturation is 90% or lower and a "couple" of attempts to insert an endotracheal tube are unsuccessful. Additionally MD #4 stated the condition of the airway also determines the necessity to perform a cricothyroidotomy. MD #31 stated the airway was visualized as edematous with no opening realized. At least seven or eight attempts were made to insert the endotracheal tube prior to the decision to perform a cricothyroidotomy. MD # 31 further stated that under his direction, Paramedic #1 performed the cricothyroidotomy because he had prior experience in performing the procedure. Upon interview, Paramedic #1 stated he performed three separate intubations with proper placement confirmed by MD #31. Paramedic #1 stated that although clinical signs, (elevation in oxygen saturation, audible breathe sounds and improvement in color) indicated successful intubation had been accomplished, MD #31 ordered extubation of the three endotracheal tubes inserted. Although x-ray was available, it was not utilized to confirm placement prior to extubation. Paramedic #1 further stated that MD #31 instructed him to perform the cricothyroidotomy even though he was aware that although trained, he had never performed the procedure.
- b. Patient #24 arrived in the emergency department on 7/20/03 at 3:52 pm with a complaint of a painful finger from a sewing machine needle which penetrated the left thumb. An x-ray of the left first digit identified a metallic needle type density projecting in soft tissues. The patient received Tylox by mouth for pain at 6:44 pm. Review of the medical record and interview with the Director of the Emergency Department, MD #4, reflected that an orthopedic physician, MD #19, was unable to come to the hospital to evaluate the patient. The record further identified that the patient's plan was discussed with MD #19 by telephone and the

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patient was instructed to call MD #19's office on 7/21/03 for follow up. The embedded sewing machine needle was left in the patient and the patient was discharged home at 9:50 pm with instructions for pain medication and antibiotics. The facility failed to provide adequate medical care and treatment while in the emergency department on 7/20/03.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (i) General (7) and/or (j) Emergencies (2).

28. The facility failed to ensure that necessary medical information was provided upon transfer of two patients (patients #6 and #66) from the Emergency Department and/or inpatient unit to another facility.
- a. Patient #6, a Department of Mental Retardation client and group home resident, was admitted to the Emergency Department on 11/8/02 at approximately 9:00 p.m. after it was determined that his jejunostomy tube had become displaced. The patient took nothing by mouth and was dependent on J-tube feedings and medication administration. The patient's J-tube was replaced the following morning and the patient was discharged back to the group home at approximately 2:30 pm. ED documentation indicated that the patient received intravenous fluids and that oxygen was administered at 6:25 am following an oxygen saturation reading of 93 percent. Although nursing documentation indicated that discharge instructions were given, the clinical record lacked a completed interagency referral form and/or written discharge instructions upon the patient's discharge back to the group home.
 - b. Patient #66 was admitted to the facility from a nursing home on 11/13/03 with symptoms that included a new onset of jaundice, elevated temperature, and change in level of alertness. Review of the medical record identified that on 11/15/03, Patient #66 had blood work reported as positive for the Hepatitis B Surface Antigen. Review of the progress note dated 11/18/03 identified that Patient #66 had an unclear presentation, that the patient was positive for Hepatitis B, and that the physician questioned whether the Hepatitis B was acute or chronic. Review of the Interagency Referral Form dated 11/20/03 lacked documentation of the positive Hepatitis B finding. In addition, review of the dictated discharge summary dated 11/13/03 lacked documentation of the positive Hepatitis B finding. Interview with the Infection Control Nurse (ICN) at the nursing home

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identified that the nursing home was not aware of the new diagnosis for five days when additional blood work drawn at the extended care facility identified the virus.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1).

29. Based on record review and interviews, the hospital failed to address Patient #64's complaint in a timely manner. The findings include:
- a. Patient #64 filed a written complaint, dated 10/4/03, with the facility regarding care and services in the emergency department on 9/30/03. The hospital failed to address the patient's complaint within ten (10) business days, per their policy. Interview with the Chief of Emergency Services identified that there was a breakdown in communication that prevented him from receiving the complaint in a timely manner. Once he received the complaint, he addressed the complaint with Person #64. Interview with Person #64 identified that it took repeated calls to the facility before the complaint was addressed.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administrator (2).

30. Based on review of the clinical record, review of facility policies, and interviews, the facility failed to ensure that a comprehensive assessment was performed that identified the need for restraints for one Patient (#8) and includes the following:
- a. Patient #8 had a physician's order dated 9/4/02 at 7:37 PM that identified an order for soft wrist, ankle and a vest restraint to prevent falling. Review of the restraint/constant observation flowsheet dated 9/4/02 at 11:00PM identified that a vest restraint and 4-point restraints were applied at 11:00PM. Review of the clinical record with the Nurse Manager identified that a nursing assessment and observed behaviors were lacking prior to the institution of these restraints. Review of facility policy for restraint use identified that an assessment by a RN would be conducted and documented to identify potential behavioral and environmental risk factors so as to reduce and/or limit the use of restraints.

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31. Based on review of the clinical record, review of facility policies, and interviews, the facility failed to ensure that a plan of care for restraint usage was implemented for one patient (#8) and includes the following:
- a. Patient #8 was admitted on 9/3/02 with a documented language barrier, history of alcohol use with the fall risk assessment not completed. On 9/4/02 an order to utilize soft wrist, ankle and a vest restraint was obtained to prevent falling. Review of the clinical pathways and/or plan of care with the Director of Quality failed to identify that restraint use was addressed.

The above are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1).

32. Based on review of the clinical record, review of facility policies, and interviews, the facility failed to ensure that restraints were utilized in the least restrictive manner for Patient #8 and includes the following:
- a. Patient #8 had a physician's order dated 9/4/02 at 7:37 PM that identified an order for soft wrist, ankle and a vest restraint to prevent falling. Review of the restraint/constant observation flowsheet dated 9/4/02 at 11:00 PM through 9/5/03 at 5:45 AM with the nurse manager failed to identify what alternative measures were attempted prior to the initiation of a vest restraint and 4-point restraints. Review of the clinical record from 9/5/02 through 9/10/02 identified the patient continued to utilize restraints without the benefit of alternative measures tried. Review of the facility policy for restraint use identified that alternatives or less restrictive interventions must be determined by the patient's assessed needs, tried and clearly documented. Restraint use must be limited to those situations with adequate and appropriate clinical justification and selected only when other less restrictive measures have been found ineffective.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (e) Nursing Service (1).

33. Based on review of the clinical record and review of facility policy, the facility failed to ensure that for Patients #8 and 65 that staff continually assessed, monitored restraint use and/or re-evaluated in accordance with facility policy and includes the following:
- a. Review of the restraint/constant observation flowsheet dated 9/6/02 at 2:45 PM identified that Patient #8 utilized 4-point restraints and was observed to be

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- physically aggressive towards others. During the 3:00 PM through 11:45 PM shift the facility failed to identify that an assessment was conducted. Review of the policy for restraint use identified that the patient's condition would be monitored and documented at least every two hours.
- b. Patient #65 presented to the Emergency Department (ED) with an altered mental status. An ED nurse's note dated 11/25/03, 3:10 AM through 3:19 AM identified combativeness and that the patient continues to escalate with two point restraints applied at 3:19 AM. Review of nurse's notes dated 11/25/03 from 3:19 AM through 9:30 AM (six hours and eleven minutes) identified that two point restraints were utilized with a nurse's noted dated 11/25/03, 4:34 AM identifying that the patient is beginning to settle down and resting quietly on the stretcher. Patient #65 was cleared medically and was transferred to the secured behavioral health unit located at a satellite campus on 11/25/03 at 1:00 PM. Review of the restraint/seclusion policy for behavior management in a non-behavioral health unit identified restraint or seclusion may be used in response to emergent, dangerous behavior, as a protective intervention to planned medical-surgical care or as a component of an approved protocol. An assessment by a Registered Nurse, Physician, or Licensed Independent Practitioner is conducted and documented to identify potential behavior and environmental risk factors to reduce and/or limit the use of the restraint. An order for a restraint is necessary. Patient care includes offering food and fluid, opportunity to eliminate, range of motion and repositioning with skin integrity checks and circulation every two hours, patient monitoring and condition is completed every fifteen minutes and an assessment is conducted by the RN every hour to determine mental status, cognitive functioning, and readiness to release the restraint. The patient's condition is monitored and documented by a trained individual every fifteen minutes and assessed/documentated by an RN every thirty minutes. Review identified that although restraints were utilized in the ED, the clinical record lacked an assessment which indicated that the patient was a danger to self and/or others, any efforts to release the restraints, and patient care relative to restraint utilization in accordance with the policy and procedure.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1).

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- 34. Based on review of the clinical record, a review of facility policy and procedures, and staff interviews, the facility failed to implement seclusion in accordance with the policy and procedure. The findings include:
 - a. Patient #65 presented to the Emergency Department (ED) with an altered mental status. An ED nurse's note dated 11/25/03, 3:10 AM through 3:19 AM identified combativeness and that the patient continues to escalate with two point restraints applied at 3:19 AM. Review of nurse's notes dated 11/25/03 from 3:19 AM through 9:30 AM (six hours and eleven minutes) identified that two point restraints were utilized with a nurse's noted dated 11/25/03, 4:34 AM identifying that the patient is beginning to settle down and resting quietly on the stretcher. Patient #65 was cleared medically and was transferred to the secured behavioral health unit located at a satellite campus on 11/25/03 at 1:00 PM. Review of the behavioral health physical examination dated 11/25/03 at 3:50 PM identified that the patient was admitted subsequent to a physician emergency certificate with paranoid delusions and a diagnosis inclusive of bipolar disorder. Admission orders included monitoring every fifteen minutes. A nurse's note dated 11/25/03 identified that at 4:00 PM the patient was delusional stating that he wanted to go downstairs and walked towards the exit door (secured door). The patient complied with verbal redirection to walk to the seclusion/monitoring room and the physician was notified at 5:00 PM. Intra-muscular psychotropic medications and seclusion were ordered and the patient was compliant with the administration and implementation of such. A restraint/seclusion record dated 11/25/03, 5:00 PM identified that the patient was placed in locked seclusion from 5:00 PM to 6:00 PM with assessments completed at 5:30 PM, 5:45 PM, and 6:00 PM. RN #18 stated during interview on 12/3/03 at 4:30 PM that she was assigned to care for Patient #65 subsequent to admission to the secured behavioral health unit. Shortly before 5:00 PM the patient was delusional and expressed a desire to leave the unit. She stated that the patient was verbally redirected to the seclusion and/or monitoring room to err on the side of caution and "to prevent something from happening", however could not identify any dangerous behaviors. Once in the seclusion/monitoring room the patient continued to insist upon leaving the secured unit. She stated that because the patient would not agree to stay in the room and insisted on leaving the secured unit, locked seclusion was implemented from 5:00 PM to 6:00 PM. Although the policy and procedure for seclusion identified that restraint or seclusion may be used in response to emergent, dangerous behavior as a protective intervention, review of the clinical record and

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staff interview failed to identify the patient's behaviors as such when seclusion was implemented on 11/25/03 from 5:00 PM to 6:00 PM.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1).

35. Based on review of the clinical record, a review of policy and procedures, and staff interview, the facility failed to obtain an order for the implementation of restraints for two patients (Patients #17 and #65) in accordance with the policy and procedure. The findings include:
- a. Patient #17 was admitted with diagnoses inclusive of oppositional defiance disorder, attention deficit hyperactivity disorder, and legally blind in his left eye. A nursing progress note dated 6/5/03 identified that the patient's peer made a comment and the patient lost control. The patient was verbally abusive in a time out, became assaultive to staff, and was placed in a two minute therapeutic hold. Review of the policy and procedure for restraint and/or seclusion use for behavior management on the behavioral health unit identified an assessment by a Registered Nurse, Physician, or Licensed Independent Practitioner is conducted and documented to identify potential behavior and environmental risk factors to reduce and/or limit the use of the restraint. An order for a restraint is necessary. Review of the clinical record with RN #8 failed to identify that an assessment and/or physician order for the therapeutic hold was completed and/or obtained in accordance with the policy and procedure.
 - b. Patient #65 presented to the Emergency Department (ED) with an altered mental status. An ED nurse's note dated 11/25/03, 3:10 AM through 3:19 AM identified combativeness and that the patient continues to escalate with two point restraints applied at 3:19 AM. Review of nurse's notes dated 11/25/03 from 3:19 AM through 9:30 AM (six hours and eleven minutes) identified that two point restraints were utilized with a nurse's noted dated 11/25/03, 4:34 AM identifying that the patient is beginning to settle down and resting quietly on the stretcher. Patient #65 was cleared medically and was transferred to the secured behavioral health unit located at a satellite campus on 11/25/03 at 1:00 PM. Review of the restraint/seclusion policy for behavior management in a non-behavioral health unit identified restraint or seclusion may be used in response to emergent, dangerous behavior, as a protective intervention to planned medical-surgical care or as a component of an approved protocol. An assessment by a Registered

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Nurse, Physician, or Licensed Independent Practitioner is conducted and documented to identify potential behavior and environmental risk factors to reduce and/or limit the use of the restraint. An order for a restraint is necessary. Patient care includes offering food and fluid, opportunity to eliminate, range of motion and repositioning with skin integrity checks and circulation every two hours, patient monitoring and condition is completed every fifteen minutes and an assessment is conducted by the RN every hour to determine mental status, cognitive functioning, and readiness to release the restraint. The patient's condition is monitored and documented by a trained individual every fifteen minutes and assessed/documentated by an RN every thirty minutes. Review identified that although restraints were utilized in the ED, the clinical record lacked a physician order directing the use of the restraints.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1).

- 36. Based on observation, the facility failed to provide recreation and/or activity equipment in a good state of repair. The findings include:
 - a. Observation of the activity room on 11/18/03 identified floor mats utilized for a recreation activity to be in poor condition. Mats were noted to have torn areas with the foam padding exposed with one mat noted to be worn to the threading. The Behavioral Health Director stated during interview on 11/18/03 stated that the mats were in poor condition and replacement mats had been ordered. Subsequent to interview, the Behavioral Health Director, directed the unit staff to remove the thread worn mat from the activity room.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (i) General (7).

- 37. Based on review of the clinical record and staff interview, the facility failed to ascertain current medications for Patient #17 when admitted to a behavioral health unit. The findings include:
 - a. Patient #17, a minor patient, was admitted with diagnoses inclusive of oppositional defiance disorder, attention deficit hyperactivity disorder, and legally blind in his left eye. A bio-psychosocial assessment dated 6/2/03 identified current medications of Topomax 25 milligrams (mg) at hour of sleep and

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Risperdal .25mg twice a day. A physician's order dated 6/4/03 prescribed Atropine 1%, one drop in the left eye starting at 7:00AM on 6/5/03. A physician's progress note dated 6/10/03 identified that the patient's mother expressed concerns over the patient's medications with a plan to administer the eye drops as directed by the ophthalmologist. MD #20 stated during an interview on 11/25/03 that he met with the patient's mother to discuss concerns that she had regarding a delay in ordering the patient's Atropine eye drops that had been routinely administered prior to admission to the unit. He stated that he maintains and/or manages the psychotropic medications and it is the responsibility of the clinical team to manage the patient's medical needs. He further stated that although he is not sure why they didn't get ordered on admission, he "didn't blame her for being upset". Interview with the Clinical Director of the Behavioral Health Unit on 12/16/03 identified that a pre-admission assessment is done prior to the patient's arrival to the unit through the Clinical Assessment Center (CAC). An inquiry is made regarding current medications and medical history at that time and then again shortly after arriving when the physical examination is done. She stated that often the minor patients come unaccompanied and they have to rely on the pre-admission bio-psychosocial assessment that is completed. During an interview with CAC Intake Coordinator #1 on 12/11/03, she stated most often the information for the bio-psychosocial assessment is obtained from a crisis worker at the transferring facility who in many cases is not aware of current medications or medical history. She further stated that an inquiry or follow up with the patient's family and/or guardian is not generally made to ascertain a current medical history of the patient or current medications. RN #25 stated during an interview on 12/8/03 that she admitted Patient #17 and during the admission process she typically makes an inquiry and reviews the bio-psychosocial assessment with whomever has accompanied the patient as to current medications and medical history. She further stated that if the patient's mother had mentioned the Atropine eye drops she has to assume she would note it, but could not recall in this case. Review and interview failed to identify a mechanism and/or system to attempt to obtain accurate medical history and/or current medications when a minor patient was admitted to the behavioral health unit unaccompanied.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (d) Medical Records (2) and/or (i) General (7).

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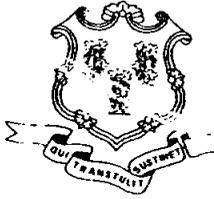
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38. A clinical record review identified that Patients #67, #68, #70 and #71 did not receive clinician biopsychosocial assessments within 24 hours per hospital policy. Also, there were no clinician notes on Patients #67 and #68 for two (2) days and on Patient #70 for four (4) days. The hospital policy identified that clinicians would document daily, on each patient Monday through Friday and as needed. Interview with staff identified that a Licensed Alcohol and Drug Counselor, LADC #1, was out sick on 1/15/04 and 1/16/04. During the absence, other social workers or counselors were to pick up LADC #1's 5 patients. Interview with the Clinician Manager identified that the remaining clinicians should have split up LADC #1's patients on 1/15/04 and 1/16/04 and provide care the patient's may have needed, including biopsychosocial assessments and daily documentation. Interviews with Clinician Managers also identified that clinician led group meetings scheduled on 1/15/04 and 1/16/04 did not occur, as they should have. These groups were to be attended by all patients on the unit deemed capable of attending.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3) and/or (i) General (7).

39. The facility did not assure that width of aisles or corridors (clear and unobstructed) serving as exit access was at least (select the proper width depending upon use of either Existing or New, ie. 4 or 8) feet as required by the referenced LSC. On 11/18/03 at 1:15PM. the surveyor observed that the Seventh and Eighth floors had clutter throughout the full length of the corridor.
40. The facility did not assure that width of aisles or corridors (clear and unobstructed) serving as exit access was at least (select the proper width depending upon use of either Existing or New, ie. 4 or 8) feet as required by the referenced LSC. On 11/18/03 at 2:00PM. the surveyor observed that the full length of the nursing corridor was cluttered with nursing equipment.

The above are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (a) Physical plant (2).



STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

December 6, 2005

Christopher M. Dadlez, President and CEO
St. Francis Hospital & Medical Center
114 Woodland Street
Hartford, CT 06105

Dear Mr. Dadlez:

Unannounced visits were made at various dates to St. Francis Hospital & Medical Center commencing on July 18, 2005 through July 28, 2005 by representatives of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting a Licensing Renewal Inspection, follow-up to the violation letter dated June 15, 2005 and implementation of the stipulated agreement dated August 19, 2004 and to conduct multiple investigations with additional information received through November 21, 2005.

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

An office conference has been scheduled for December 27, 2005 at 10:00 AM in the Facility Licensing and Investigations Section of the Department of Public Health, 410 Capitol Avenue, Second Floor, Hartford, Connecticut.

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

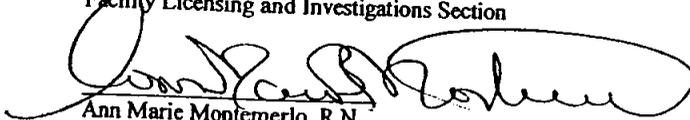
Each violation must be addressed with a prospective Plan of Correction, which includes the following components:

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,


 Joan D. Leavitt, R.N., M.S.
 Public Health Services Manager
 Facility Licensing and Investigations Section


 Ann Marie Montemerlo, R.N.
 Supervising Nurse Consultant
 Facility Licensing and Investigations Section

JDL:AMM:zbj

- c: Director of Nurses
 vl.stfrancis2.doc
 CT #3969, CT #4008, CT #4105, CT #4115, CT #4190,
 CT #4206, CT #4274, CT #4329, CT #4350, CT #4351, CT #4352



Phone:
 Telephone Device for the Deaf: (860) 509-7191
 410 Capitol Avenue - MS # _____
 P.O. Box 340308 Hartford, CT 06134
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The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (3) and/or (c) Medical staff (2)(A).

1. Based on interview with facility personnel and review of credentialing files, it was identified that the facility credentialed a non licensed individual to complete surgical tasks. The findings are as follows:

- *
 - a. During interview the Manager of the Operating Room stated that one Certified Surgical Technologist (CST #2) was credentialed to act as a First Assistant (FA) to a sponsoring orthopedic surgeon (MD# 33). Review of Certified Surgical Technician (CST) #2's credentialing file identified that privileges were granted on 1/24/05. A review of the delineation of privileges for CST #2 identified that closure of body planes, exposition/visualization of the operative field including digital manipulation of tissue, use of cautery, clips, ligation, scissors, ties and tourniquet were granted. CST #2 performed services that require licensure.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical records (2) and/or (3) and/or (e) Nursing service (1) and/or a violation of the Connecticut General Statutes Section 46a-152 (d)(2) and/or (e).

2. Based on medical record review, facility policy and staff interviews the following was identified for Patients #57, #74 and #124 who utilized restraints. The findings include:

- *
 - a. Patient #57 was admitted to the hospital on 12/10/04 for an elective lumbar laminectomy due to low back and leg pain. The patient's past medical history included Parkinson's Disease and non-insulin dependent diabetes Type II. Review of the clinical record indicated that the patient was alert and oriented on post-operative day (POD) #1 and was meeting outcomes identified in the lumbar laminectomy clinical pathway. Review of the Patient Care Flowsheet and interview with RN #41 identified that both side-rails (SR) were up, the call bell was in reach and the bed was in low position during the night shift on 12/13/04. Record review and interview with RN #41 identified that she found the patient sitting on the floor, at the foot of the bed, by the door at 3:00 AM on 12/13/04. Further record review and interview revealed that RN #41 had observed the patient sleeping prior to the fall and could not recall when she first assessed the patient or if the patient was confused before the fall. RN #41 indicated that the patient was agitated and confused. RN #41 did not recall asking the patient if he hit his head and she did not see any bruises on the patient's head. The covering physician, MD # 37 was notified at 3:30 AM and vest and wrists restraints were

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ordered. Review of the Restraint/Seclusion Policy identified that alternatives or less restrictive interventions must be determined by the patient's assessed needs, tried and clearly documented. Review of the record and interviews with hospital staff identified that the record lacked patient assessment for alternatives and less restrictive interventions.

- *
- b. Patient #124 was admitted to the hospital on 5/11/05 with Seizures and Metabolic/Toxic Encephalopathy. Patient #124 was being treated for alcohol withdrawal and was a level II (high fall risk). Review of the nurses notes dated 5/12/05 indicated that at 5:00 AM, Patient #124 was found next to his bed with urine on the floor. Patient #124 sustained a scrape under his right eye approximately 4cm. Further review failed to provide evidence that an assessment and/or interventions for the least restrictive restraint was utilized. Subsequently, at 8:00 AM a restraint was applied to Patient #124. Review of the progress notes dated 5/13/05-5/14/05 indicated that Patient #124 was confused, restless and had attempted to exit the bed. On 5/14/05 at 1:00 AM, Patient #124's restraints were removed for a trial release and remained off when Patient #124 was found on the floor next to his chair at 11:00 AM. Patient #124 stated that he was trying to go to the bathroom and lost his balance. Patient #124 had no other alternative interventions to prevent falls noted. Review of nurses notes and flowsheets dated 5/14/05-5/15/05 failed to provide documentation that Patient #124 was monitored consistently after the restraint trial release since the patient was assessed to be impulsive and had frequent bed/chair exits without assistance. Patient #124 complained of right shoulder pain with a small bruise and swelling noted to the right shoulder. The x-ray report dated 5/15/05 indicated that the patient had a fracture humeral neck extending into the head. Review of facility policy identified that to discontinue restraint protocol, the patient should be alert, oriented and free of agitation/combatative behaviors and less restrictive interventions have proven effective for maintaining the integrity and dignity of the patient. Further review identified that alternatives or less restrictive interventions must be determined by the patient's assessed needs, tried and clearly documented. Interview with RN #38 identified that even though Patient #124 had a call bell, no alternative interventions to prevent the fall had been implemented.
- *
- c. Patient #74 had an aortic valve replacement on 7/14/05 and experienced a cerebral vascular accident post operatively. Review of the critical care flow sheet indicated that the patient had wrist restraints on 7/14/05 from 12:00 PM - 10:00 PM and a vest restraint on 7/16/05 for the period of 10:00 PM - 7:00 AM. On 7/17/05, the flow sheet indicated that the patient had not been restrained for the

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period of 8:00 AM -10:00 PM after which time the patient was restrained again. Interview with the staff indicated that the patient was restrained under the medical immobilization protocol, however review of the chart failed to reflect that a physician's order had been obtained to initiate the protocol. Additionally, Review of the critical care flow sheet indicated that the patient had wrist restraints on 7/14/05. The flow sheet further indicated that the patient had not been restrained for the period of 11:00 PM -11:00 AM on 7/15/05 and that restraints were back in place on 7/15/05 from 12:00 PM -10:00 PM. Patient #74 had been restrained with a vest restraint on 7/16/05 for the period of 10:00 PM - 7:00 AM. On 7/17/05, the patient had not been restrained for the period of 8:00 AM - 10:00 PM at which time the patient was restrained again. Interview with the staff indicated that the patient was restrained under the medical immobilization protocol. Review of the facility policy indicated that the policy failed to address the need for a new order/assessment for reapplication once the restraint had been discontinued.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (d) Medical records (2) and/or (3) and/or (e) Nursing service (1).

3. The facility failed to ensure that nursing services supervised and/or evaluated the nursing care for each patient. Based on medical record review, tours of the facility, staff interview and review of facility policy and procedure, the findings include the following:
 - a. During a tour of the Emergency Department (ED) on 7/19/05 from 9:30 AM to 12:05 PM with the Director of Nursing for Emergency Services, it was identified that in a patient care area four bags of intravenous (IV) fluids were open and ready for administration without any identifying information. Interview with the Director of Nursing for Emergency Services on 7/19/05 identified that the IV fluids should be marked with the date opened and a staff member was assigned to complete that task daily. Review of facility documentation titled "Trauma Room Checklist" dated 7/19/05 and signed by ED staff, identified that the open IV fluids were dated. It was also identified during this tour that two patients, who were receiving IV fluids, did not have any identifying information on their IV fluid bag or on the IV tubing-connecting the IV fluid bag to the patient(s).
 - b. Patient #62 was admitted to the ED on 7/19/05 with the complaint of chest tightness and difficulty breathing. Review of the clinical record identified that at 8:20 AM, Patient #62 was experiencing pain at a level of 9 (on a pain scale of 10). Documentation was lacking to identify the source of the pain, and that the patient was reassessed for pain and/or that an intervention was initiated to reduce the

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- pain. According to facility policy titled "Pain Assessment and Management Policy", the clinical staff are to periodically reassess the patient for pain relief and there should be an intervention to reduce pain if the pain is greater than a 4/10. Review of the clinical record also identified that a respiratory assessment was completed and a bronchodilator medication, via nebulizer, was administered at 8:21 AM. Documentation was lacking that identified respiratory assessments post medication administration and/or the times of the administration of the nebulizer treatments.
- c. Patient #60 was admitted to the hospital on 7/17/05 for cellulitis of the lower extremities. Review of Patient #60's medical record indicated that the patient's pain level was a 5/10 for which the patient received Oxycodone at 10:00 PM. Patient #60's medical record lacked a reassessment for pain. Review of hospital policy identified that all patients were to be reassessed for pain after receiving pain medication.
- d. Review of the medical record for Patient #75 indicated that the patient had been admitted on 7/5/05 with syncope after sustaining a fall. Review of the non-surgical wound form indicated that on 7/7/05 and 7/8/05 the patient had skin breakdown on his left face, right lateral and medial inner arm and right antecubital. The physician orders identified the patient to have a Viglion dressing twice a day. Further review indicated that the patient's next skin assessment was on 7/17/05, however, the areas addressed were the patient's left arm only. Review of the nurse's notes for the period of 7/8/05 through 7/20/05 indicated that the dressings had been completed but failed to indicate sizing of the wounds, drainage, etc. Review of the facility policy indicated that for non-surgical wounds the area should be assessed daily or with dressing changes. Interview with the nurse who was caring for Patient #75 on 7/19/05 indicated that the patient had breakdown on both arms but the right occurred prior to the left side and both were related to when the patient fell prior to admission.
- e. Patient #58 had diagnoses of Alzheimer's, hypertension, osteoporosis, and atrial fibrillation. The patient was admitted to the facility on 3/19/05 after a fall at the long term care facility where she resided and for respiratory problems. A review of the patient nursing admission assessment identified multiple sections were incomplete. A review of progress notes identified documentation was lacking for a daily nursing progress note relative to the patient's problems of fall risk, COPD, and subdural hematoma. During an interview RN #35 stated the admission database was incomplete because the patient was unable to answer the questions however, documentation was lacking as to the reason for not completing the document or exploration of other avenues to obtain the information. The clinical pathway failed to reflect the patient's active problems and interventions relative to

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falls, subdural hematoma, and restraint use. A review of the facility's policy for clinical pathways and nursing documentation guidelines identified the clinical pathways were the format for the patient plan of care. Charting was done once a day in the progress notes and organized in the problem, evaluation and summary format for each active problem. In addition an admission acceptance note should be written in summary format and all entries must be dated and timed. Additionally, a review of Patient #58's medical record identified bilateral wrist restraints were applied on 3/20/05 at 2:00 PM and at 6:00 PM, a Posey vest was also applied for safety. The nurse's flowsheet identified the bed exit system was in place. The patient was found on the floor out of all restraints at 7:30 PM. MD #32 evaluated the patient, found no injuries and placed the patient on 1:1 observation. The next morning the patient became unresponsive and a CT head scan identified a large subdural hematoma. The patient was made a DNR/DNI and transferred to hospice care on 3/22/05. During an interview RN #34 stated when she found the patient after being alerted by a passerby that a patient was on the floor, she was at the foot of the bed, and the restraints were still tied to the bed. The bed exit system did not alarm. During an interview Clinical Manager #7 stated the bed exit system should have alarmed when the patient got out of bed and had no idea why it wasn't functioning. Staff should have considered other interventions when the wrist restraints did not work. During an interview APRN #2 stated if restraints were not effective staff should remove them and initiate constant observation.

- *
- f. Patient #114 had a history of hypertension, and weight loss, and was admitted to the facility on 12/23/04 due to dizziness, weakness and slurred speech. A review of the medical record identified the patient was transferred from the MICA (Medical Intermediate Care Area) to the cardiac step down unit on 12/29/04 and placed on continuous cardiac monitoring in accordance with physician orders. A review of the medical record identified the monitor strip record run at 6:25 PM identified the transmitter battery was weak. Nurse and physician notes identified the patient was found unresponsive in his bed after an unknown period of time by Monitor Technician #5 about 10:50 PM. The patient was resuscitated, transferred to CICU, diagnosed with a severe anoxic brain injury, and expired when removed from life support on 1/4/05. A review of the facility policy on alarm standards identified the charge RN carried the alarm beeper whenever the monitor technician was away from his/her duties at the central monitor desk and was responsible to assess and respond to 3 star alarms (life-threatening arrhythmias). During an interview RN #30 stated she last saw the patient around 10:00 PM, recalled observing a weak battery signal on the monitor about 9:30 PM, advised

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- Monitor Technician #5 to change the battery, and could not identify when the weak battery signal first appeared. During an interview Monitor Tech #5 stated she carried a beeper alarm that signaled any life threatening arrhythmias when away from the central monitoring station doing other duties that included taking EKGs, placing patients on and off the telemetry units, replacing batteries, and patient care duties directed by nursing. She first identified a weak battery signal for Patient #114 about 7:30 or 8:00 PM. Because the new battery was placed in the telemetry unit when the patient was transferred to the unit at 5:30 PM, Monitor Tech #5 felt there should be at least six to seven hours of battery life remaining and did not change the battery at that time. She estimated she had been away from the central monitors for about fifteen minutes when she returned to the central monitoring station about 10:50 PM to find no telemetry signal coming from Patient #114. When she checked the patient he was unresponsive. Monitor Tech #5 stated she carried the beeper alarm because there was no one else to watch the monitors when she was away from the desk, and there had been ongoing concerns regarding the frequent battery failures for the telemetry units. During an interview the Director of Clinical and Electrical Engineering stated the cardiac monitor used on Patient #114 identified the battery was dead on the patient's telemetry unit as of 10:17 PM and the beeper alarm system was not programmed to alarm for a dead battery. In addition there had been multiple reports of batteries going dead after a short amount of time in use. Upon investigation subsequent to this incident, the facility's distributor identified there was a batch of defective batteries from the manufacturer, brands were changed, and currently batteries lasted at least twenty-four hours. During an interview, Risk Manager #1 stated as a result of this incident monitor tech duties were changed so they only attend to the monitors, never used the pager alarm, and someone is always present at the central monitor bank. However, observation during a tour of Unit 8-9 on 7/22/05 identified Monitor Tech #3 away from the central monitoring system with the beeper alarm on his person preparing telemetry leads for application on a patient. During an interview Monitor Tech #3 stated he was going to put the leads on a new patient and carried the beeper alarm with him to alert him to any emergencies. During an interview Monitor Tech #4 stated on Unit 9-9 she was aware the beeper alarm was used during the night shift. During an interview Monitor Tech #2 on Unit 10-9 stated he still used the pager alarm when a telemetry battery needed to be changed because sometimes there was no one to relieve him.
- g. Patient #123 was admitted to the hospital Emergency Department (ED) on 5/15/05 following a fall at home resulting in a left wrist fracture. Patient #123 was kept in the ED overnight pending further evaluation for placement in a

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- nursing home. Patient #123 was alert and oriented, urinal in place, siderails, and a call bell within reach. On 5/16/05 at 3:45 AM, Patient #123 was found on the floor next to his bed. Patient #123 stated that he was trying to get out of bed to go to the bathroom. Patient #123 complained of pain in the left hip. The x-ray report dated 5/16/05 revealed an intertrochanteric fracture with minimal displacement of the fracture fragments. Patient #123 underwent an open reduction and internal fixation of the left hip on 5/17/05. Review of medication administration record dated 5/15/05-5/16/05 identified that Patient #123 had received Dilaudid 2mg IV at 4:55 PM, 2:30 AM and at 5:15 AM. Patient #123 had also received Ambien 5mg at 10:00 pm and Zoloft 100mg at 8:56 PM. Review of vital sign records dated 5/15/05-5/16/05 identified that Patient #123's pain level was 0 except at 8:36 PM, which showed a level 4. Review of the nurses notes dated 5/15/05-5/16/05 identified that Patient #123 was not assessed for pain prior to 4:55 PM dose of Dilaudid. Review of the nurses notes also identified that Patient #123 had received a dose of Dilaudid IV at 8:56 PM but was not on the medication administration record as given at that time. Further review identified that a late entry was noted at 4:16 AM that Patient #123 was reassessed for pain after the fall at 3:45 AM. Review of the nurses' notes and the vital sign records dated 5/15/05-5/16/05 identified many inconsistencies in relation to Patient #123 being assessed and reassessed for pain management. Review of facility policy identified that the assessment of pain will include the onset, duration, location, intensity, quality, and the patient's acceptable level of pain using a pain scale from 0-10. If pain is rated >4/10 there will be an intervention to reduce the pain. Also, pain intensity and relief will be assessed and documented after each pain management treatment has reached peak effect. Interview with RN #37 identified that pain data is gathered by the nursing technicians and documented on the vital sign record.
- h. Patient #124 was admitted to the hospital on 5/11/05 with Seizures and Metabolic/Toxic Encephalopathy. Patient #124 was being treated for alcohol withdrawal and was to be monitored using the Withdrawal Assessment for Alcohol (CIWA scale). Review of the CIWA protocol and the physician orders dated 5/12/05 identified that Patient #124 was to be given Ativan 4mg every hour whenever necessary if the CIWA score was between 18-29, Ativan 2mg every hour if CIWA score was between 13-17, Ativan 2mg every two hours if CIWA score was between 8-12 with the CIWA score to be rechecked either every hour or two hours. If the CIWA score was less than 8 no medications were to be given but the CIWA score would need to be rechecked in 4 hours. Review of the Withdrawal Assessment for alcohol dated 5/12/05-5/18/05 identified that on multiple occasions (14 times) the CIWA protocol monitoring was not followed

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- for Patient #124 including inconsistent monitoring of vital signs (12 times) per protocol. Review of the facility CIWA protocol identified that the CIWA should be repeated at regular intervals when history and observation indicate alcohol withdrawal problems. Further review indicated that vital signs are to be taken with each assessment. Interview with the Chemical Dependency Education Specialist on 7/26/05 indicated that the CIWA score should have been rechecked more frequently based on Patient #124's score numbers.
- i. Patient #57 was admitted to the hospital on 12/01/04 for elective lumbar laminectomy due to low back and leg pain. Physician Orders directed that Percocet, 2 tablets, be administered by mouth (po) every 4 hours, as necessary (prn) for pain, as well as Morphine 5 milligrams (mg) subcutaneous (sq) prn for pain every 4 hours. A Pharmacy Computer (Pyxis) Report revealed that Patient #57 received, postoperatively (12/10-12/12/04), a total of Morphine 20 milligrams (mg) sq and 13 tablets of Percocet (65 mg oxycodone) prior to the fall. The hospital pharmacy did not have a range dosing policy. Review of the Pain Assessment and Management Policy identified that the pain assessment would include the onset, duration, location, intensity, quality and the patient's acceptable level of pain using a pain scale 0-10 (0-no pain, 10-worst pain). If pain was rated >4/10 there would be an intervention to reduce pain and that pain intensity and relief would be assessed and documented after each pain management treatment. Review of the Pain Management Assessment form dated 12/12/04 and interview with RN #29 revealed the patient's pain was assessed at 1 on a 0-10 pain scale at 8 AM and 10:45 AM. RN #29 indicated that, although the patient's pain level was only a 1 and the patient was on bed-rest, she administered the Percocet because pain was subjective and she felt the patient needed the Percocet.
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- j. Patient #56 arrived via ambulance to the hospital Emergency Department (ED) on 12/13/04 at 12:44 PM complaining of acute abdominal pain with nausea and vomiting. Review of the clinical record indicated the patient had a recent admission the prior month for right upper abdominal pain and was diagnosed with gastritis. The patient's past medical history included chronic hepatitis C, cirrhosis (secondary to the hepatitis C), pancreatitis and pancytopenia. Review of the record and interview with RN #39 revealed that the patient had stable vital signs and was triaged as "non-urgent" into the waiting room with a reported pain level of 7/10 on a pain scale of 0 (no pain) - 10 (worst pain). Three hours later, at 3:45 PM, orthostatic vital signs were documented sitting: pulse (P) 98, respirations (R) 16, blood pressure (BP) 112/61; standing: P 105, R 16, BP 98/60 and the patient's pain had increase to 8/10. Vital signs were repeated over 3 hours later at 7:06

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PM: P: 106, R 18, BP 139/56 with no documentation of pain assessment. Record review and interview with Director of Patient Care Services revealed that the patient was transferred to the ED East Wing Bed #17 at 4:04 PM. Review of the ED Triage Guidelines identified that a triage categorized as "urgent" indicated that the disorder requires urgent intervention to minimize pain, establish a timely diagnosis and care plan and the patient should be placed as soon as possible into an appropriate care setting if such was available. Also noted, gastrointestinal disorders with vomiting and stable vital signs were categorized as "urgent." Interview with the Director of Patient Care Services revealed that the patient was incorrectly triaged as "non-urgent" rather than "urgent." Further interview also revealed it would be expected that vital signs would be performed every two hours and not every three hours. Clinical record review identified an arterial blood gas PO₂ of 39 mmHg (normal 80-100 mmHg) on room air at 5:01 PM with no respirations noted and interview with RN #42 failed to reveal any intervention. Review of physician orders for Patient #56 directed that intravenous (IV) normal saline 500 cc x 1 now at 4:47 PM, fresh frozen plasma (FFP) once at 6:55 PM be administered and strict intake & output be performed. An ED Nurses' Note indicated that the patient had vomited 250 cc cranberry/coffee ground material that was guaiac positive. Although The ED record revealed the fluid administration was initiated, review of the record and interview with the Director of Patient Care Services identified that the patient's record lacked the required intake and output documentation.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical records (3) and/or (e) Nursing service (1).

4. The hospital failed to ensure that nursing staff developed and/or kept current a nursing care plan for each patient. Based on medical record review, staff interview, tours of the facility and review of facility policy and procedure, the findings include the following:
 - a. Patient #57 was admitted to the hospital on 12/10/04 for an elective lumbar laminectomy due to low back and leg pain. The patient's past medical history included Parkinson's Disease and non-insulin dependent diabetes Type II. Review of the clinical record indicated that the 84 year old was alert and oriented on post-operative day (POD) #1 and was meeting outcomes identified in the lumbar laminectomy clinical pathway. Record review and interview with RN #41 identified that she found the patient sitting up on the floor, at the foot of the bed, by the door at 3 AM on 12/13/04. RN #41 indicated that the patient was agitated and confused. The covering physician, MD # 37 was notified at 3:30 AM and restraints were ordered. A Computed Tomography (CT) reports dated 12/13/04 &

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12/14/04 identified bilateral subarachnoid hemorrhages and an intraparenchymal hemorrhage. Further record review and interview revealed that RN #41 had observed the patient sleeping prior to the fall and could not recall when she first assessed the patient or if the patient was confused before the fall. Review of the Patient Care Flowsheet and interview with RN #41 identified both siderails (SR) were up, the call bell was in reach and the bed was in low position during the night shift on 12/13/04. Interview with RN #40 revealed that the patient had a mental status change during the evening shift prior to the fall and she had communicated it to the night nurse. RN #40 indicated, "a few words were off," the patient was disoriented to place, but that the patient's "neuro's were intact". The hospital's Fall Prevention Protocol identified that all patients were assessed at Level I, universal risk for fall and Level II were those patients who had demonstrated deficit in cognitive, sensory or mobility and were high risk for fall. The Protocol also identified that patients were assessed with any change in condition. Review of the record and interview Clinical Manager #8 identified that Patient #57's record lacked documentation of the mental status change and the neurological checks and that the patient was incorrectly assessed as a Level I on 12/12/04 from 7 AM - 11 PM and would have expected the Fall Risk be elevated to a Level II with a change in mental status. Additionally, review of the record indicated that Patient #57 fell again on 1/26/05. Although a Case Management Flow Sheet dated 1/25/05 identified the one to one sitter for Patient #57 was discontinued and discharge was anticipated towards the end of the week, the record lacked documentation regarding fall risk assessment upon discontinuation of the sitter.

- b. Patient #58 had a history of Alzheimer's, and was admitted to the facility on 3/19/05 due to a fall at the long-term care facility she resided in and for respiratory problems. A review of the patient's nursing admission assessment identified problems relative to pain, falls, bruising of the face and knuckles, respiratory difficulty, and Alzheimer's dementia. During the hospitalization the patient was placed on a fall protocol and in restraints when needed due to risk of falling, pulling at lines and oxygen mask, and attempts to climb out of bed. The patient fell and suffered a subdural hematoma and was placed on hospice care. A review of the critical pathway initiated on 3/19/05 identified the patient was on a COPD (chronic obstructive pulmonary disease) pathway. Documentation was lacking relative to any problems or interventions for Alzheimer's dementia, fall protocol, skin assessments, or pain, and for updates to the plan/pathway after 3/19/05 for restraint use, subdural hematoma, and hospice care. A review of the facility's policy for clinical pathways and nursing documentation guidelines for use identified the clinical pathways were the format for the patient

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- plan of care which must be individualized, all variances and key patient problems must be listed on the last page of the clinical pathway with appropriate interventions and outcomes identified.
- c. Patient #59 was admitted to the hospital on 7/14/05 for a urinary tract infection. Review of Patient #59's medical record revealed documentation was lacking on 7/16/05 and 7/17/05 of the patients plan of care and/or interventions needed on the clinical pathway. Review of the hospital policy identified that clinical pathway variances and problems will have interventions placed on the pathway and evaluated each day.
 - d. Patients #87 and #88 were admitted to the oncology unit on 7/11/05 and 7/5/05 respectively. Their plans of care, also called pathways, were reviewed with the nurse manager and risk manager and found to be inconsistently completed. Staff were either leaving blank, check marking, circling and/or crossing out preprinted interventions. The hospital policy for using a pathway identified to draw a line through interventions not ordered and add interventions as needed.
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 - e. Patient #97 was admitted into the hospital on 7/5/05 with diagnosis that included schizophrenia with paranoia, Traumatic Brain Injury, Diabetes Mellitus and a pregnancy of 28 weeks gestation. Review of the medical record identified that the patient had a 1:1 sitter, had periods of aggressive behavior and paranoia. The progress note dated 7/17/05 at 8:10 PM noted that the patient had returned to the unit, yelling, swearing, pacing and threatening aggressiveness. Review of the plan of care also called clinical pathways identified that the patient did have childlike behavior but failed to identify the patient's aggressive behavior and interventions. Observation of the unit census board noted that the patient was not allowed a phone. Interview with the Nurse Manager on 7/19/05 noted that a treatment plan had been outlined by the multi-team on 7/18/05 and that the patient was not allowed to have a phone in the room secondary to calling males to her room. The plan of care failed to identify this behavior. Review of the hospital policy identified that the clinical pathway variances and problems would have interventions placed on the pathway and evaluated each day.
 - f. Patient #56 arrived via ambulance to the hospital Emergency Department (ED) on 12/13/04 at 12:44 PM complaining of acute abdominal pain with nausea and vomiting. Review of the record and interview with RN #39 revealed that the patient had stable vital signs with a reported pain level of 7 on a 0-10 pain scale (0 no pain -10 worst pain). No intervention was noted. Record review revealed the patient's pain assessment at 3:45 PM was 8 on the 0-10 scale, with no intervention noted. Review of the record revealed that vital signs were repeated at 7:06 PM with no pain assessment. Review of the hospital's Pain Assessment and

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Management Policy identified that the pain assessment would include the onset, duration, location, intensity, quality and the patient's acceptable level of pain using a pain scale 0-10. If pain was rated >4/10 there would be an intervention to reduce pain and that pain intensity and relief would be assessed and documented after each pain management treatment. Review of Patient #56's ED record and interview with the Director of Patient Care Services identified that a pain intervention was not implemented for the patient and the record lacked documentation regarding pain reassessment according to the hospital's Pain Assessment Policy.

5. Based on clinical record review, staff interviews and a review of the facility policies and procedures for one patient who was receiving pain medication and had a change in mental status, the hospital failed to document pain medication administration and narcotic waste according to hospital policy and in accordance with Federal and State law. The findings include:
 - a. Patient #57 was admitted to the hospital on 12/10/04 for an elective lumbar laminectomy. Review of the Pharmacy Record, the Pain Assessment Form and interview with RN #40 identified that the Patient #57's pain increased to 8/10 during the evening shift on 12/12/04 and the patient received Morphine 5 mg sq at 4:25 PM, 2 Percocet po at 6:23 PM and 2 Percocet po at 10:34 PM. Interview with RN #40 revealed that she did not administer the 10:34 PM Percocet dose because the patient had a change in mental status, but could not recall wasting it with another staff member. Interview with Clinical Manager #8 revealed that the disposal of the narcotic waste did not follow hospital policy. The Pain Management Assessment form dated 12/12/04 lacked documentation of Percocet administration for 5:16 AM, 2:44 PM and 10:34 PM. Further interview also identified the patient's record lacked documentation of the Morphine and Percocet on the Medication Charted Summary dated 12/12/04 between 4:25 PM to 10:34 PM.

6. Based on medical record review and staff interview, the hospital failed to ensure for one (1) of four (4) patients reviewed, that Patient #84 who received blood products, had vital signs monitored per facility policy. The findings include:
 - a. Patient #84 was a current patient receiving care and services in the cancer center. The patient's record was reviewed with the manager and noted that between 1/1/05 and 7/21/05, the patient received ten (10) blood and/or blood product transfusions. During three (3) of the transfusions, Patient #84's vital signs were not monitored per policy.

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The following is a violation of Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (d) Medical records (2).

7. The facility failed to ensure that histories and physicals were completed for Patients #73 and #76 and that an oral and regional exam was completed for Patient #102 as per facility policy. Based on medical record review of twenty-three (23) non-surgical patients and review of facility policy, the findings include the following:
 - a. Review of the medical record on 7/18/05 for Patient #73, who was admitted on 7/6/05, indicated that there was a partially completed history & physical (H&P) on the record that also lacked a physician's signature. The medical record reviewed for Patient #76, who was admitted on 7/6/05, failed to contain an H&P. Review of the facility policy indicated that all patients should have an H&P completed on admission.
 - b. Review of one (1) of two (2) dental records at Burgdorf clinic identified that the dental record for Patient #102 lacked a completed oral and regional exam. Review of the facility policy indicated that on admission all patients should have an oral and regional exam completed.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical staff (2)(B) and/or (d) Medical record (7).

8. Based on medical record review and review of facility policy and procedure, the facility failed to ensure for two (2) of two (2) patients reviewed, that the discharge summaries were completed as per facility policy. The findings include the following:
 - a. Patient #58 with a history of Alzheimer's dementia and atrial fibrillation was admitted to the facility after a fall at the long term care facility she resided in. A review of the medical record identified that the patient's discharge date was 3/22/05, that the discharge summary was dictated on 5/9/05, and that the record was electronically signed on 6/13/05.
 - b. Patient #114 with a history of hypertension, and weight loss was admitted to the facility on 12/23/04 due to dizziness, weakness and slurred speech. A review of the medical record identified that the patient expired on 1/4/05. The discharge summary was dictated on 2/23/05 and that the record was electronically signed on 3/1/05. A review of the facility's medical staff by laws identified that medical records shall be completed upon discharge of the patient. If the medical record was not completed within thirty days of being made available to the physician, it would result in the physicians suspension of hospital privileges.

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The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (g) Pharmacy (1) and/or (4) and/or (i) General (7).

9. The facility failed to ensure that drugs were kept in a locked storage area. Based on observation, review of facility policy and interview of facility personnel, the following was identified:
 - a. During tour of the Main Operating Suite on 7/18/05, a pre-drawn syringe labeled as containing an antibiotic was found by a surveyor on the bench of the men's locker room.
 - b. Tour of the Trauma Room on 7/18/05 identified that the anesthesia medication cart was unlocked and unattended.
 - c. During tour of the Perfusion Room on 7/18/05, the cabinet containing Heparin, needles and syringes was observed to be unlocked with the key in the lock. During interview the Manager of the OR stated that the cabinet should be locked when the room was unattended and that the keys should remain with the perfusionist.
 - d. A tour of the women's clinic in the Gengras Building conducted on 7/21/05 with the clinic manager identified that the medication storage room contained a wall-mounted medication storage box that was observed to have the key to the box inserted into the lock. A licensed staff member was not in attendance. Interview with the manager identified that there could be times that non-licensed staff members were allowed into this room.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical staff (4)(C) and/or (e) Nursing service (1) and/or (g) Pharmacy (1) and/or (4) and/or (i) General (7).

10. The facility failed to ensure that outdated drugs and/or biologicals were not available for patient use. Based on observation and interview with facility staff, the findings include the following:
 - a. During tour of the Interventional Radiology Suite on 7/19/05 observation revealed Narcan with an expiration date of 7/1/05, pre-drawn saline syringes with expiration dates of April 2005 and blood tubes with expiration dates of February 2003. During interview the Manager of the Interventional Radiology Suite stated that each nurse was responsible for reviewing medications located in their medication box and that the outdated syringes and blood tubes were located in a cabinet not currently used.
 - b. During tour of the Neonatal Intensive Care Unit (NICU) on 7/18/05, the medication room was observed to contain spiked IV solution bags with expiration

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- date labels of 7/15/05 and 7/16/05. The medication refrigerator contained three (3) heprin IV solutions with expiration dates of 7/14/05. Interview with the Charge Nurse noted that these expired solutions should have been removed.
- c. During tour of the medication room on 4-9S on 7/18/05, an opened Novolog insulin vial dated 5/18/05 was observed. The label identified to discard after 28 days. Interview with the Unit Manager noted that this vial should have been discarded.
 - d. Observation during tour on 7/18/05 of the C-Section OR #1 identified that the anesthesia cart contained two (2) pre-drawn labeled syringes dated 7/4 and 7/14. OR #2's anesthesia cart was observed to contain two (2) expired vials of Oxycontin, e.g. 3/05 and 5/05, and seven (7) pre-drawn labeled syringes dated 7/15/05. Interview with the Director of Anesthesia services identified that pre-drawn medications should be discarded if not used after a case.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (h) Dietary service (3) and/or (i) General (7).

11. Based on observation and staff interview, the hospital failed to ensure sanitary practice for the handling and serving of food. The findings include:
 - a. During the dietary trayline observation on 7/20/05, Dietary Aide #1 was observed handling the turkey with gloved hands then placing the turkey on the plates. This dietary aide then preceded to open a refrigerator door, that was observed to have caked debris on the handle, and with the same gloved hand go back to the trayline picking up pieces of turkey and placing them onto the plates. Dietary Aide #1 was also observed leaning forward over the plates containing food, with the sleeves of her shirt brushing the food items.
 - b. Trayline observation of Dietary Aide #2 identified that the hairnet failed to completely cover her head allowing for exposure of her long hair. An open tray cart of salads was noted directly behind her and to the right of her as she served on the trayline. Interview with the Director of Dietary identified that the dietary aide should have the hairnet placed to cover the entire head.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (e) Nursing service (1) and/or (i) General (7) and/or (l) Infection Control (4)(E).

12. The facility failed to ensure that the facilities, supplies and/or equipment was maintained to ensure an acceptable level of safety and quality. Based on observation, review of facility policy and staff interview, the findings include the following:

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- a. During tour of the Cardiac Catheterization Lab, two scrub areas were observed to lack clocks with which to time their scrubs. During interview the Director of the Cath Lab stated that there was no published evidence that cardiac cases had to scrub in the same timed manner that operative cases required. The facility was unable to produce a policy that directed use and timing of scrubs in the Cardiac Cath Lab, however, the facility's policy for Scrubbing, Gowning and Gloving in a Surgery Procedure directed that the surgical hand scrub procedure was standardized for all personnel. Further review identified that staff may use either a standardized anatomical timed scrub or a counted stroke method according to manufacturer's direction. According to the AORN Recommended Practice Standards, each practice setting within the facility should establish policy and procedure in conjunction with the infection control committee to establish directives for hand hygiene.
- b. During tour, the alarm for the electronic thermometer utilized for the Main OR anesthesia room refrigerator was observed to be in the "off" position. A review of the temperature log on 7/18/05 for the month of July 2005 identified that the refrigerator's daily temperature check was logged in at 46 degrees e.g. the high end of desired temperature for medications. When the Anesthesia Tech turned the alarm to the "on" position, it alarmed continuously. The Tech stated it was in the "off" position because of the alarm ringing when the door was opened.
- c. During a tour of Unit 10-9, a review of the daily defibrillator checklist for July 2005 identified documentation was lacking for the checks performed on 7/12/05 thru 7/15/05 in the SICA and MICA areas. A review of the medication refrigerator temperature log identified documentation was lacking for the temperatures between 7/12/05 to 7/15/05. A review of the facility policy on Equipment Mandatory Daily Checks-Patient Care Services identified the defibrillator must be tested and logged on a daily basis and the medication refrigerator temperature must be checked and logged daily.
- d. During a tour of Unit 10-9, prefilled syringes with needles attached were observed unsecured on the windowsill in a patient's room. During interview, Clinical Manager #7 stated that the syringes should not have been left there and discarded them.
- e. Tour of the out-patient rehabilitation facility identified that the hydrocolator lacked consistent temperature monitoring and cleaning. Hydrocolator #1's temperature had been last logged as monitored on 4/20/05 and last cleaned on 5/20/05. Hydrocolator #2's temperature had been last logged as monitored on 6/22/05. Review of the facility policy on the cleaning of the hydrocolator identified monthly cleaning. Review of the temperature monitoring policy for the hydrocolator identified that it was to be taken each working day and recorded.

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- f. Tour of the Cesarean Section OR on 7/18/05 identified the fluid warmer contained approximately forty (40) semi rigid bottles of fluids that were undated. Review of the storage management policy for fluids in semi rigid containers identified that they may be stored in the warming cabinet for a period not longer than 60 days and should be dated when placed in the warmer.
- g. During tour of the Main OR and Ambulatory Surgical Suite numerous fluid warmers were observed to contain undated semi-rigid bottles and flexible bags of fluid. Those that were dated were marked inconsistently e.g. some dated when they were placed in the warmer and some dated as to when they should be removed. Several warmers in Ambulatory Surgery had temperatures at 160 degrees. The facility policy for Blanket and Fluid Warmers in the Perioperative Arena designated that the maximum temperature should be 150 degrees and that items would be dated when placed in the warmer. The same policy failed to delineate usage of flexible bags of fluid.
- h. During tour, it was identified that two Abbott intravenous infuser pumps (#05085, #06613) and a Splint Developer (Form 1000) were found with outdated inspection labels.
- i. During tour of 7-2, an unlocked drawer was found on a medication cart and three syringes with needles were found in an unlocked drawer at the nurses' station.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (1)(A) and/or (1) Infection Control (2).

- 13. Based on a review of facility documentation and staff interviews, the facility failed to ensure that the Infection Control Committee was the ultimate authority and decision maker regarding all infection control and prevention issues. The findings are as follows:
 - a. During a review of the Infection Control Committee minutes for 2004 and 2005 to date, and during interviews with the Infection Control Practitioners, it was identified that the facility's Quality Patient Committee was involved in a review of prophylactic timing of antibiotics for surgical patients of which Infection Control was not involved. Additionally, there was no information from Pharmacy to the Infection Control Committee on a routine basis other than an annual antibiogram and there were a significant number of employee exposures to blood/body fluids reported that lacked Infection Control input or analysis. A review of the facility's policy on Infection Control identified that the Infection Control Committee had the ultimate authority for all decisions with any infection related risks. During interviews, the Infection Control Practitioners stated there was a lot of informal sharing of information about a variety of subjects and

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although they were aware of information, formal reporting to the committee on a routine basis was not done.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (i) General (7) and/or (l) Infection Control (4)(C).

14. Based on observation, staff interview and review of facility policy, the facility failed to ensure that infection control standards were followed. The findings are as follows:
- a. During tour of the dental clinic on 7/20/05 on the Bergdorf campus, it was identified that the small wooden door separation between the clean and dirty side of the instrument sterilization area was open.
 - b. During tour of the MSICU on 7/18/05, it was identified that the stock person in a contact isolation room was stocking the area without gloves on. The stock person further had two large filled supply carts in the room at that time. Interview with the Infection Control nurse indicated that only supplies utilized for the patient should be brought into the room.
 - c. Observation on 7/18/05 identified a respiratory therapist with gloves on, in a contact isolation room on the right side of the bed leaning across the bed. Review of the facility policy indicated that a gown should be worn when there would be patient contact.
 - d. During a tour of Unit 10-9, observation identified staff members utilizing the tops of soiled linen hampers as a writing surface when documenting in the medical record. Clean dialysis supplies were observed stored on the floor in room 932. During an interview Clinical Director #7 stated that although there were no convenient surfaces to chart on near the patient rooms, the linen hampers should not be used.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical staff (4)(B) and/or (D) and/or (e) Nursing service (1) and/or (i) General (2) and/or (7) and/or (l) Infection Control (4)(C).

15. Based on observation, review of facility policy and interview of facility personnel, the facility failed to ensure the achievement and maintenance of high standards of medical practice and patient care. The findings include the following:
- a. Tour of the Trauma Room on 7/18/05 identified visible dust on the overhead surgical lights. Multiple ORs were observed to have open shelving containing papers. During interview the Nurse Manager of the OR stated that nurse aides clean the rooms between cases and that the operating rooms were then cleaned on a rotating basis. A review of the facility policy for Operating Room Cleaning

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- Procedure identified a failure of the policy to define the process of terminal cleaning and how often it should occur. A review of AORN standards identified that surgical procedure rooms and scrub/utility areas should be terminally cleaned daily including the damp dusting of all horizontal surfaces with a hospital disinfectant. The AORN identifies "terminal cleaning" as cleaning performed at the completion of daily surgical schedules.
- b. During tour of multiple sub-sterile rooms on 7/18/05, Fed-Ex boxes e.g. original containers, not broken down, were observed stacked on counters. During interview the Manager of the OR stated that deliveries should be broken down elsewhere and supplies then delivered to the appropriate area.
 - c. The janitor's closet in the Ambulatory Surgical hallway was observed with wet mops lying on the floor next to the drain. During interview the Charge Nurse stated that the mops were clean, pre-dipped and ready to clean the floor of an OR between cases. Review of AORN standards identified that clean mopheads should be dipped into the solution only when it is clean and before the mopping activity is begun. Although the facility policy for Operating Room Cleaning Procedure identified that clean mopheads are used for each cleaning of each OR, the policy failed to address storage and/or handling of mops prior to cleaning.
 - d. Several patient transfer boards were observed on the floor of the scrub area propped against the wall. The boards were splattered with betadine and debris. The Charge Nurse stated the boards were no longer in use.
 - e. Two (2) of two (2) soiled utility rooms were observed to contain clean supplies. One soiled utility room was utilized to store multiple suction tripods used in the ORs. During interview the Charge Nurse stated that the tripods were wiped down prior to use in surgery.
 - f. OR #3 located in Ambulatory Surgery was observed to be utilized as a storage room in one-half of the space with procedures performed in the other half. Carts, equipment, linen, bags of supplies and uncovered porous foam supports were observed to be stored in the room. Suction canister liners were observed lying on the floor. On July 18, 2005 during tour, the door to the anteroom was observed to be propped open (the door was not self-closing). The anteroom opened into the soiled utility room. During interview the Charge Nurse stated that supply space was scant and that discussion had occurred regarding restructuring the area for clean storage.
 - g. During tour of Interventional Radiology, both rooms were observed to contain pre-draped procedural tables that were unattended. During interview the Radiology Tech stated that the tables were set up approximately 30 minutes before the procedure, draped and left until the patient arrived. A review of AORN

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- standards reflects that the sterile field should be established as close as possible to patient arrival and always attended to ensure sterility.
- h. Observation of a sterile procedure in the electrophysiology lab of the Cardiac Cath Lab on July 19, 2005, identified a physician at the sterile field with a head cover that failed to cover hair on the sides and back of his head. The Director of the Cath Lab stated he would expect a head cover to cover all areas of the hair.
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- i. Patient #126 was admitted on 3/9/05 for gastric bypass surgery on 3/9/05 for the diagnosis of morbid obesity. The Director of Bariatric Surgery performed the surgery. Review of the clinical record identified that during the surgery a Jackson Pratt (JP) drain was placed and was removed on 3/12/05, by MD #31, a Post Graduate Year (PGY) one surgery resident, prior to Patient #126 being discharged to home. Patient #126 arrived at the hospital Emergency Department (ED) on 4/21/05 with the complaint of sharp pain in the lower left abdomen and tenderness along the surgical scar. A clinical record review identified that the abdominal x-ray identified that there was a drain present in the upper left quadrant and an abdominal and pelvic CT Scan identified that a JP drain was present in the subcutaneous tissue. Patient #126 underwent surgery on 4/22/05 by MD #18 to remove the JP drain and was discharged to home on 4/26/05. Interview with MD #31, on 8/5/05, identified that he directed Medical Student #1 to remove Patient #126's JP drain. MD #31 further stated that he had supervised and observed the student removing drains before without any difficulty, and the medical student did not report any difficulties to him regarding the JP drain removal for Patient #126. Interview with Medical Student #1, on 08/22/05, identified that he did not recall the patient or removing the J-P Drain for the patient and he would have written a note, in the patient's chart if he had removed the drain.
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- j. Patient #72 was admitted to the hospital for a laparoscopic assisted vaginal hysterectomy (LAVH) on 5/31/05. During the procedure the tenaculum and cannula apparatus began to slip out of the vagina and MD #35 extracted them and handed them to RN #36. RN #36 then put them into the case cart without examining them. The case was then converted to an open supracervical hysterectomy. The instrument count was completed before the conversion, however the instruments in the case cart were never inspected and/or counted by RN #36. RN #36 identified that the acorn tip had become dislodged from the cannula and was not with the pieces put into the cart. RN #36 also noted that when Patient #72's case was completed, MD# 35 failed to examine the vagina prior to sending Patient #72 to the recovery room. Patient #72 was discharged from hospital on 6/2/05. On 6/2/05, Patient #72 telephoned MD #35 and reported

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that a black acorn tip from the uterine manipulator had fallen out of her vagina. Review of facility policy identified that broken or disassembled instruments during a procedure are accounted for their entirety. Further review of facility policy identified that after a gynecologic laparoscopy case the vagina is to be checked to make sure that instruments are removed. Interview with RN #36 identified that she did a count of instruments before they converted to an open hysterectomy but failed to count and/or inspect the instruments in the cart. Interview with Nurse Manager #10 identified that the surgical team failed to count and/or inspect the instruments on the case cart after the case was completed. Further interview with Nurse Manager #10 identified that MD #35 failed to do a visual examination of the vaginal wall to check for tears and bleeding after case was completed. Interview with MD #35 identified that during the case the manipulator fell out of the vagina and was put back on the case cart by RN #36. Further interview identified that when a laparoscopic hysterectomy is completed, the MD is responsible to check the patient vaginally for any tears and /or instruments. MD #35 stated that she did not check the vagina since the case converted to an open case. Review of the AORN (2003) standards identified that members of the surgical team should account for disassembled or broken instruments in their entirety, including all parts of the instruments. Verification of all pieces prevents accidental retention of a foreign body within the patient.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical staff (2)(D) and/or (d) Medical staff (8).

16. Based on review of the medical record, interview with facility personnel and review of the medical bylaws, the facility failed to ensure that for three (3) of seven (7) records reviewed, the history and physical (H&P) was updated prior to surgery and/or a procedure. The findings include the following:
 - a. For Patients #79, #82 and #83 who had undergone surgery, angioplasty and/or cardiac catheterization on 7/19/05, the history and physical failed to be updated. Patient #79's H&P was dated 7/8/05, Patient #82's H&P was dated 6/29/05 and for Patient #83, the H&P's date was illegible. During interview the Manager of the OR stated that all H&Ps must be completed and/or updated by the attending physician within 24 hours prior to any procedure and/or surgery as evidenced by the physician's signature and review date. Although a review of the Rules and Regulations of the Medical Bylaws identified that all history and physicals must be completed within 24 hours after admission, hospital documentation failed to clearly identify the time frame for H&Ps prior to surgery and/or a procedure.

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17. Based on medical record review and review of facility policy, the facility failed to ensure a properly executed informed consent form was in the patient's chart before surgery, except in emergencies. The findings are as follows:
- a. Review of the medical record for Patient #111 indicated an informed consent form signed by the patient on 1/27/05 and by the physician on 7/20/05.
 - b. Patient #50 was admitted to the hospital on 7/15/05 for an Abdominal Hysterectomy. Review of Patient #50's medical record indicated that there lacked a signed informed consent for surgery by Patient #50. Upon surveyor inquiry, the informed consent was signed by the patient on 7/18/05. Review of hospital policy identified that all patients are to have a signed informed consent prior to surgery.
 - c. Patient #126 was admitted on 3/9/05 for gastric bypass surgery on 3/09/05 for the diagnosis of morbid obesity. Review of the clinical record identified that the informed consent for this surgery was signed by Patient #126 on 10/15/04 and signed by the physician on 3/9/05. Facility policy identified that signed informed consent forms would be valid for 30 days.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical records (2)(D).

18. Based on medical record review and review of facility policy, the facility failed to ensure that an operative report was written or dictated immediately following surgery and signed by the surgeon. The findings are as follows:
- a. Patient #50 was admitted to the hospital on 7/15/05 for an abdominal hysterectomy. Review of Patient #50's medical record indicated that an operative note for the surgery was lacking. Upon surveyor inquiry, the operative note was completed on 7/18/05. Review of facility policy identified that all patients are to have an operative note completed.
19. Based on medical record review and staff interview, the facility failed to ensure for three (3) of three (3) records reviewed in the Ambulatory Surgical Satellite of the hospital, that the pre-anesthesia evaluation was completed. The findings include:
- a. Review of the anesthesia records for Patients #111 and #112 indicated that the area for the pre-induction assessment had not been completed. The Anesthesia record for Patients #111, #112 and #113 in the area identified as the post anesthesia note had been left blank. Interview with the manager and the charge nurse indicated that both areas are to be completed, however the facility lacked a policy describing the use of the form.

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20. Based on medical record review and review of facility policy, the facility failed to ensure that a post-anesthesia follow-up report by the individual who administered the anesthesia was written within 48 hours after surgery was provided. The findings include the following:
- a. Patient #50 was admitted to the hospital on 7/15/05 for an abdominal hysterectomy. Review of Patient #50's medical record on 7/18/05 indicated that there lacked a post-anesthesia follow-up note. Review of facility policy identified that all patients should have a post-anesthesia follow-up note post surgery within 48 hours.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical staff (2)(D) and/or (d) Medical record (3) and/or (e) Nursing service (1).

21. Based on a review of the medical record, interviews with facility personnel, and review of facility policies and procedures, the facility failed to ensure for one patient (Patient #108) that a comprehensive master treatment plan and evaluation were documented.
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- a. Patient #108 was admitted to the facility's partial hospital program on 5/20/05 due to ADHD (attention deficit hyperactivity disorder), impulsive control disorder, ODD (oppositional defiant disorder), possible bi-polar disease, and with a history of asthma. A review of the medical record on 7/20/05 identified multidisciplinary treatment plans (MTP) that identified problems of angry outbursts on 5/20/05 with the goal of improving compliance and ODD on 5/27/05 and 6/3/05 with no objectives identified. Documentation was lacking for any MTP's after 6/3/05 or for any problems related to the patient's history of asthma. The facility failed to identify specific treatment modalities and specific safety approaches but instead identified non-specific treatment modalities and approaches which included medical management and individual group/family therapy, teaching coping skills to increase expression of emotions, behavioral modification program, and medication adjustment. A review of the medical record identified the patient was on a medical leave of absence between 6/6/05 and 6/15/05 and was transferred to the IOP (intensive outpatient program) on 7/18/05. Documentation by the physician was lacking to identify the reason or an assessment/evaluation done on his return from the LOA, or the reason for transfer to the IOP. A review of the facility's multidisciplinary treatment plan policy identified the MTP must be completed by the third PHP visit with weekly updates and a progress note done. In addition, an update must be done with any major change in diagnosis, treatment or change in level of care.

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The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical staff (2)(B).

22. For one record reviewed of a patient who required insertion of a central intravenous line, the physician failed to remove the catheter guide-wire after the central line was inserted. Based on medical record review and staff interview, the findings include the following:

- a. Patient #65 was admitted to the Emergency Department (ED) on 5/13/05 at 5:07 PM, after being found outside. Review of the clinical record identified that Patient #65 was unresponsive, the ED staff was assisting the patient's breathing, the patient had a head injury and a blood glucose test result of 17 milligrams per deciliter (mg/dl)-normal range 70-110 mg/dl. The clinical record also identified that two attempts, by the nursing staff, to obtain intravenous (IV) access were unsuccessful, MD #27 inserted a triple lumen catheter (TLC) in the patient's right groin, and a chest x-ray completed at 5:56 PM that identified a wire was projecting over the right chest. Interview with MD #27, on 7/28/05, identified that Patient #65 simultaneously required treatment and/or care for his inconsistent breathing pattern, significant head trauma and hypoglycemia, and the guide-wire from the TLC insertion was not supposed to be left in. Interview with MD #28, on 7/27/05, who removed the guide-wire on 5/14/05 via interventional radiology, identified that Patient #65 did not experience any damage related to the wire being left in with the TLC insertion and the wire was removed without difficulty. Patient #65 was discharged on 5/15/05.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical staff (4)(A) and/or (d) Medical record (3) and/or (e) Nursing service (1).

23. Based on review of the medical record, review of facility documentation, review of facility policy and staff interview, the following was identified for Patient #125 who was readmitted after surgery for a retained surgical sponge.

- a. Patient #125 was admitted on 3/28/05 with ovarian cancer and scheduled for surgery on 3/28/05 that was to be performed by MD #30 and MD #34. Review of the clinical record identified that at the conclusion of the surgery the sponge count was identified as correct by the circulator, RN #33, and the scrub person, Surgical Tech #3. Patient #125 was discharged on 4/4/05. Subsequently on an outpatient visit, Patient #125 identified a mass in her right abdomen and the Computed Tomography (CT) Scan identified that a foreign body was present in the right lower quadrant. Patient #125 was admitted on 7/14/05 for surgical removal of a

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retained surgical sponge on 7/14/05, performed by MD #30. Hospital documentation identified that the patient required a small bowel resection because the bowel had formed a capsule around the sponge. Hospital policy, titled "Sponge, sharp, and instrument count policy," identified that sponges are counted audibly and by visualization by the circulating nurse and the scrub person, including prior to cavity closure and prior to skin/subcutaneous tissue closure, and when the count is completed the count is marked accordingly. Interview with the Nurse Manager of the Operating Room (OR), on 7/27/05, identified that it is the responsibility of the circulating nurse to alert the surgeon if the sponge counts are not correct. Interview with MD #30, on 7/27/05, identified that he started the surgery for Patient #125 and after completing his portion MD #34 continued the surgery, he would expect that the scrub team would alert the surgeon if the sponge counts were not correct, and he followed Patient #125 as an outpatient every three weeks and there was no indication of problems until the patient felt a mass. Interview with MD #34, on 8/03/05, identified that the nurse reported that the first and second sponge counts were correct and MD #34 would expect the nurse to tell him if the count was not correct. Interview with RN #33, on 8/03/05, identified that she could not recall if the final sponge counts were correct for Patient #125.