

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

IN RE: Lawrence and Memorial Corporation of New London, CT d/b/a  
Lawrence and Memorial Hospital  
Address 365 Montauk Avenue  
New London, CT 06320

CONSENT ORDER

WHEREAS, Lawrence and Memorial Corporation of New London, CT (hereinafter the "Licensee"), has been issued License No.0047 to operate a general hospital known as Lawrence and Memorial Hospital, (hereinafter the "Facility") under Connecticut General Statutes 19a-490 by the Department of Public Health, State of Connecticut (hereinafter the "Department"); and

WHEREAS, the Facility Licensing and Investigations Section (hereinafter "FLIS") of the Department conducted unannounced inspections on various dates commencing on and concluding on March 16, 2006 and

WHEREAS, the Department, during the course of the aforementioned inspections identified violations of the Connecticut General Statutes and/or Regulations of Connecticut State Agencies in a violation letter dated March 23, 2006 (Exhibit A – copy attached); and

WHEREAS, the Licensee is willing to enter into this Consent Order and agrees to the conditions set forth herein.

WHEREAS, the execution of this Consent Order, any provision of this Consent Order, any payment made by Licensee in accordance with this Consent Order, and any statements or discussions leading to the execution of this Consent Order, shall not constitute or be construed to constitute any admission or adjudication of any wrongdoing, regulatory non-compliance or violation of law or regulation, including but not limited to the Regulations of the Connecticut State Agencies, the United States Code or the Code of

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Federal Regulations, by the Licensee, its agents, servants, employees or any other person or entity.

NOW THEREFORE, the FLIS of the Department acting herein and through Joan Leavitt, its Section Chief, and the Licensee, acting herein and through Bruce Cummings, its President, hereby stipulate and agree as follows:

1. Within fourteen (14) days of the execution of this Consent Order, the facility shall develop and/or review and revise, as necessary, policies and procedures related to:
  - a. Electronic fetal monitoring including but not limited to:
    - i. Frequency of monitoring;
    - ii. Monitoring during amnioinfusion;
    - iii. Monitoring during labor induction and augmentation; and
    - iv. Documentation of such monitoring in the clinical record.
  - b. Monitoring of patient vital signs during cervical ripening and labor augmentation procedures; and
  - c. Resuscitation protocols including documentation of proceedings, interventions and medications administered during the resuscitation event.
2. Within sixty (60) days of the execution of this Consent Order, the facility shall develop and/or review and revise, as necessary, policies and procedures related to:
  - a. Completion of discharge summaries for patients with admissions less than forty-eight (48) hours.
3. Within twenty-one (21) days of the review and/or revision of policies identified in paragraph one (1), all facility nursing staff, as applicable, shall be inserviced regarding the following:
  - a. Policies and procedures identified in paragraph number one (1);
  - b. Fetal heart rate assessment using electronic fetal heart monitoring equipment that includes live feed versus hard copy tracings; and
  - c. Stocking and routine monitoring of resuscitation cart equipment and medications in accordance with facility policy.

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4. Within sixty (60) days of the execution of the Consent Order, the Facility's medical staff shall review and revise, as applicable, policies related to physician availability during labor augmentation. Such policies shall be reviewed with all applicable medical staff and documentation of such review shall be maintained by the facility for a period of three years.
5. Within thirty (30) days of the completion of inservice education, the facility shall add to its quality improvement initiatives, measures to assess and ensure compliance with the terms of the Consent Order that includes a process for remediation of staff that is found to not be in compliance with facility policy and procedures. Documentation of all quality improvement activities shall be kept for a minimum of three (3) years and made available for review upon request of the Department.
6. The Licensee, within seven (7) days of the execution of this document, shall designate an individual within the Facility to monitor the requirements of this Consent Order. The name of the designated individual shall be provided to the Department within said timeframe.
7. The individual assigned responsibility for monitoring compliance with the components herein shall submit to the Department monthly summary reports regarding progress related to implementation of the components of the Consent Order.
8. The individual designated as responsible for the implementation and monitoring of this Consent Order shall meet with the Department's designated representative every two (2) months for the first six (6) months and every six (6) months thereafter for the duration of this Consent Order.
9. The Licensee shall pay a monetary penalty to the Department in the amount thirteen thousand dollars (\$13,000.00), by money order or bank check payable to the Treasurer of the State of Connecticut and mailed to the Department within (2) weeks of the effective date of this Consent Order. The money penalty and any reports required by this document shall be directed to:

Elizabeth Andstrom, RN, MS  
Supervising Nurse Consultant  
Facility Licensing and Investigations Section

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Department of Public Health  
410 Capitol Avenue, P.O. Box 340308 MS #12HSR  
Hartford, CT 06134-0308

10. All parties agree that this Consent Order is an Order of the Department with all of the rights and obligations pertaining thereto and attendant thereon. Nothing herein shall be construed as limiting the Department's available legal remedies against the Licensee for violations of the Consent Order or of any other statutory or regulatory requirements, which may be sought in lieu of or in addition to the methods of relief listed above, including all options for the issuance of citations, the imposition of civil penalties calculated and assessed in accordance with Section 19a-524 et seq. of the General Statutes, or any other administrative and judicial relief provided by law. This Consent Order 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.
11. 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 Department of Criminal Justice's Statewide Prosecution Bureau.
12. The terms of this Consent Order shall remain in effect for a period of two (2) years from the effective date of this document unless otherwise specified in this document.
13. The Licensee understands that this Consent Order and the terms set forth herein are not subject to reconsideration, collateral attack or judicial review under any form or in any forum including any right to review under the Uniform Administrative Procedure Act, Chapter 368a of the Statutes, Regulations that exists at the time the agreement is executed or may become available in the future, provided that this stipulation shall not deprive the Licensee of any other rights that it may have under the laws of the State of Connecticut or of the United States.
14. The Licensee had the opportunity to consult with an attorney prior to the execution of this Consent Order.

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

LAWRENCE AND MEMORIAL CORPORATION  
OF NEW LONDON, CT. - LICENSEE

June 26, 2006  
Date

By: [Signature]  
Bruce Cummings, its President

STATE OF Connecticut )

County of New London ) ss June 26 2006

Personally appeared the above named Bruce D. Cummings and made oath to the truth of the statements contained herein.

My Commission Expires: 6/30/08 [Signature]  
(If Notary Public) Notary Public   
Justice of the Peace   
Town Clerk   
~~Commissioner of the Superior Court~~

STATE OF CONNECTICUT,  
DEPARTMENT OF PUBLIC HEALTH

July 6, 2006  
Date

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

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March 23, 2006

Bruce Cummings, President and CEO  
Lawrence & Memorial Hospital  
365 Montauk Ave  
New London, CT 06320

Dear Mr. Cummings:

An unannounced visit was made to Lawrence & Memorial Hospital on December 1, 2005 by a representative of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting multiple investigations with additional information received through March 16, 2006.

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 visit.

An office conference has been scheduled for April 13, 2006 at 10:00 AM in the Facility Licensing and Investigations Section of the Department of Public Health, 410 Capitol Avenue, Second Floor, Hartford, Connecticut.

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

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

If there are any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,

  
Elizabeth S. Andstrom, RN, MS  
Supervising Nurse Consultant  
Facility Licensing and Investigations Section

ESDA/DH:jpf

c. Director of Nurses  
Medical Director

Complaints #CT4739 and CT4634



Phone: (860) 509-7400  
Telephone Device for the Deaf (860) 509-7191  
410 Capitol Avenue - MS # 12HSR  
P.O. Box 340308 Hartford, CT 06134  
An Equal Opportunity Employer

DATE OF VISIT: December 1, 2005

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

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2)(3) and/or (c) Medical Staff (2)(B) and/or (D) and/or (4)(B) and/or (d) Medical records (3) and/or Nursing Service (1) and/or (i) General (7).

\*Based on record reviews and interviews, the hospital failed to evaluate and document Electronic Fetal Monitoring (EFM) findings according to hospital EFM policy for one patient. The findings include:

1. Patient #1, a pregnant 27 year old, Gravida 1 Para 0 at 41 2/7 weeks gestation, was admitted to the hospital on 10/9/05 at 12:27 PM for evaluation of contractions and cramping. Review of the record indicated that a male newborn, Patient #2 was delivered on 10/10/05 at 2:28 AM through thick meconium and neonatal resuscitation was performed. Patient #2 was transferred to another hospital (newborn special care unit) on 10/10/05 at 6:15 AM where the parents made a decision to remove the infant from life support. Patient #2's Certificate of Death dated 10/11/05 identified respiratory arrest due to severe encephalopathy and asphyxia as the cause of death. Review of the record identified that Patient #1 had Electronic Fetal Monitoring (EFM) during labor and delivery. The EFM Guidelines indicated that the obstetrician/certified nurse midwife would document on the progress record and/or on the electronic intrapartum record. Review of Patient #2's Discharge Summary identified fetal bradycardia was noted for some time before the delivery and the Labor and Delivery Record identified a non-reassuring FHR (fetal heart tracing suggestive of hypoxia) in the "Complications" section. However, prior to delivery, a certified nurse midwife (CNM) Progress Note dated 10/10/05 reflected a reassuring fetal status at 12:01 AM and at 2:10 AM indicated fetal heart tones (FHTs) 120's-130's with external ultrasound. FHR interpretation discrepancies existed between the CNM Progress Notes and the intrapartum records. A Physician Progress Note dated 10/10/05 at 2:20 AM written by MD #2, the attending obstetrician (OB), lacked FHR documentation. The electronic intrapartum record lacked CNM/MD documentation after 11:02 PM on 10/9/05. The hospital failed to provide evidence that the patient's EFM was evaluated and documented according to EFM Policy.
2. Patient #1, a pregnant 27 year old, Gravida 1 Para 0 at 41 2/7 weeks gestation, was admitted to the hospital on 10/9/05 at 12:27 PM for evaluation of contractions and cramping. Labor Patient Admission Orders dated 10/9/05 at 4 PM directed that Pitocin augmentation be started at 2 milliunit per minute (mU/min), increase by 2 mU/min every 15-20 minutes until adequate labor established, and discontinue for uterine hyperstimulation or non-reassuring fetal status. Review of Patient #1's Detail Notes Log dated 10/9/05 reflected the Pitocin was started at 4:44 PM at 2mU/min, turned off and restarted at 6:26 PM. The Pitocin was increased from 2 mU/min to 3 mU/min at 8:40 PM. Review of the EFM Policy indicated patients that had labor induction and augmentation would have continuous electronic fetal monitoring and findings would be evaluated every 15 minutes in active labor and every 5 minutes during second stage. However, review of the record identified evaluation of the findings was not completed every 15 minutes between 5:49 PM to 6:45 PM and between 8:30 PM to 9:59 PM as per policy. Interview with RN #3 revealed that evaluation of the EFM findings should be completed every 15 minutes as per policy.

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3. Interview with the night shift nurse, RN #2 indicated that she utilized the "live feed" for Patient #1's EFM interpretation, not the hard copy monitor strips. RN #2 identified that, after reviewing the EFM hard copy strips (at a later date), the hard copy monitoring appeared to be different from the "live feed" monitoring. When queried, RN #2 noted that EFM readings could have been interpreted differently between 12:40 AM to 1:00 AM on 10/10/05. Interviews with the Nurse Manager (NM) and the Clinical Coordinator of the LDRP unit indicated the hospital had a new Labor, Delivery, Recovery and Post Partum (LDRP) EFM system implemented in the past month and the "live feed" tracing on the monitor appears more compressed than the "hard copy". Although interviews with both managers revealed the staff had in-service training for the new system, both managers reminded the staff that the "live feed" was not to be used for "diagnosis". Review of the EFM policy lacked information regarding the use of "live feed" or "hard copy" for FHR interpretation.

\*The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical staff (2)(B) and/or (D) and/or (4)(B), and/or (d) Medical records (3), and/or (e) Nursing service (1), and/or (i) General (7).

Based on record reviews and interviews, for one patient receiving an amnioinfusion, the hospital failed to monitor the patient according to the Amnioinfusion and EFM Policies. The findings include:

4. Review of Patient #1's Doctor's Orders dated 10/9/05 at 5 PM directed an amnioinfusion be started at 200 ml followed by 75 ml per hour – normal saline through the intrauterine pressure catheter (IUPC) catheter. Review of the Detail Notes Log identified the amnioinfusion was at 400 ml/hour / IUPC at 5:45 PM, 200 ml bolus given over 30 minutes at 5:46 PM and discontinued at 6:53 PM. At 7:01 PM the amnioinfusion was discontinued, no fluid was noted on the peripad, an increase in the IUPC was noted and the Pitocin was off. The Log indicated that FHR evaluation was completed at 5:48 PM and 6:45 PM. No FHR evaluation was noted after amnioinfusion completion at 7:00 PM when the abdominal electrocardiogram (ECG) replaced the dislodged internal electrode. Review of the record and interview with the evening shift nurse, RN #3 revealed that she did not know why an amnioinfusion was administered to Patient #1 and could not recall why the amnioinfusion was discontinued. Review of the Amnioinfusion Policy identified that the FHR, uterine activity and amnioinfusion flow rate would be monitored continuously and the Registered Nurse would monitor the maternal and fetal response during the procedure. Review of the EFM Policy identified that FHR assessment should be made immediately prior to, during and following any medical intervention. Review of the Amnioinfusion Policy also indicated that the OB/CNM would document the procedure in the Progress Notes. Review of the Patient #1's Progress Notes lacked OB/CNM documentation of the amnioinfusion procedure. The hospital lacked evidence that the patient was monitored according to the EFM and Amnioinfusion Policies.

\*The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2)(3), and/or (c) Medical staff (2)(B) and/or (D) and/or (4)(B), and/or (d) Medical

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records (3), and/or (i) General (7).

Based on record reviews and interviews, for one patient receiving Pitocin, the hospital lacked evidence that the OB physician was immediately available for active labor and delivery as per policy. The findings include:

5. Patient #1 was admitted to the LDRP unit on 10/9/05 and had Pitocin augmentation. Interview with RN #3 identified that MD #2 indicated he would be back to evaluate Patient #1 in 2 hours on 10/9/05 (after examining the patient at 8 PM), however, RN #3 did not recall MD #2 returning. Review of the record revealed MD #2 returned at 2:20 AM. Interview with RN #2 indicated that at 2:04 AM she turned off the Pitocin, increased the intravenous (IV) fluid, administered oxygen and called for the CNM and OB physician when the patient's EFM exhibited decelerations and the baby's heart rate did not recover after pushing. Review of the Detail Notes Log revealed RN #2 made 3 calls for the CNM and/or MD to the bedside between 2:04 AM and 2:11 AM. Review of the record indicated CNM #1 arrived at 2:12 AM and MD #2 arrived at 2:20 AM. Record review also revealed the infant was a spontaneous vaginal delivery (SVD) at 2:28 AM through meconium stained amniotic fluid (MSAF) with nuchal cord x 2 noted. The Cervical Ripening and Induction Augmentation of Labor Policy identified that a physician who has privileges to perform cesarean deliveries must be immediately available to the LDRP during the course of treatment. Subsequently, a new LDRP Policy dated 10/12/05 identified the supervising OB/GYN physician would be immediately available during active labor and delivery. Review of the record and interviews with hospital staff lacked evidence that the OB physician was immediately available for Patient #1's active labor and delivery as per policy.

\*The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical records (3), and/or (e) Nursing service (1), and/or (i) General (7).

Based on record reviews and interviews, the hospital failed to monitor the patient receiving Pitocin according to the Cervical Ripening and Induction Augmentation Policy. The findings include:

6. Patient #1's Detail Notes Log dated 10/09/05 identified a blood pressure (BP) of 144/59 and a pulse (P) of 62 at 11:57 PM. Review of the Detail Notes Log dated 10/10/05 at 12:31 AM identified the Pitocin was increased to 5mU/min. The next BP (125/80) was recorded at 3:24 AM on the Log, more than 3 hours after the last BP recording and almost one hour after the delivery time of 2:28 AM. Review of the Cervical Ripening and Induction Augmentation of Labor Policy identified that the patient's blood pressure and pulse for Inpatient Induction/Augmentation of labor with Pitocin would be monitored every 30 minutes with dosage increase and hourly when the dose was not increased. The hospital failed to monitor the patient as per Cervical Ripening and Induction Augmentation Protocol.

\*The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2)(3) and/or (e) Nursing service (1), and/or (i) General (7).

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Based on record reviews and interviews, for one infant requiring neonatal cardiopulmonary resuscitation, the hospital failed to provide the necessary intubation equipment during resuscitation. The findings include:

7. Review of Patient #2's medical record indicated that Patient #2, a male infant was born at 2:28 AM on 10/10/05. The infant weighed 3320 grams and had Apgar scores of 1/0/0 at 1, 5 and 10 minutes. A Labor and Delivery Record identified the patient's heart rate was 95 and respirations were 0. The condition was noted as unstable with a disposition to the Neonatal Intensive Care Unit (NICU). Patient #2's Final Autopsy Report dated 10/12/2005 identified meconium aspiration syndrome leading to extensive intraalveolar pulmonary hemorrhage and severe hypoxia complicated by anoxic brain injury, acute myocardial infarction, acute tubular necrosis and multisystem organ failure as the cause of death. Review of the record and interview with Neonatal Physician Assistant (NPA) #1 indicated the newborn was delivered through thick MSAF, was depressed at birth, hypotonic and was not breathing with a heart rate < 100. Review of the Resuscitation Note dated 10/10/05 and interview with NPA #1 identified a meconium aspirator was not available for intubation and suction. Interview with the labor nurse, RN #3, revealed the labor nurse was responsible for the delivery equipment in the patient's room and she had never seen a meconium aspirator used in her past experience. Review of hospital information identified that the meconium aspirator utilized at the hospital was the "KURTIS Meconium Suction Device" that included an ETT. Review of the Neonatal Code Cart List identified 2 meconium aspirator endotracheal tubes (3.0 & 3.5 mm, 1 each) were to be stocked on the neonatal carts. Review of the Cardiopulmonary Resuscitation Policy indicated that the neonatal carts would be stocked/restocked by staff in those areas and to refer to unit policies for specific guidelines and responsibilities. Review of hospital information identified the LDRP "Check-off Sheets for Resuscitation Cart" were completed for 10/9/05 & 10/10/05. However, review of hospital information and interviews with hospital staff revealed the hospital lacked LDRP unit specific policies for neonatal cart check procedures that would include stocking and restocking responsibilities as noted in the Cardiopulmonary Resuscitation Policy under "Equipment".

\*The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2), and/or (c) Medical staff (2)(B)and/or (D) and/or (4)(A), and/or (d) Medical records (3)and/or(4)and/or(7), and/or (e) Nursing service (1), and/or (i) General (7).

Based on record reviews and interviews, for one patient receiving cardiopulmonary resuscitation, the hospital failed to document the resuscitation according to hospital policy. The findings include:

8. Although review of the record and interviews with hospital staff identified Patient #2's cardiopulmonary resuscitation began at the time of delivery, 2:28 AM on 10/10/05, the Neonatal Resuscitation Record indicated the resuscitation interventions began at 2:36 AM. Record review and interviews with hospital staff revealed the Neonatal Resuscitation Record and/or Progress Note lacked timed interventions for the first 8 minutes of resuscitation proceedings. Review of

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the Cardiopulmonary Resuscitation Policy identified that the Nurse Recorder was responsible for recording resuscitation proceedings and the Assistant Director of Nursing was identified as the recorder. The hospital failed to record neonatal cardiopulmonary resuscitation as per hospital policy.

\*The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2), and/or (c) Medical staff (2)(B) and/or (D) and/or (4)(A), and/or (d) Medical records (3) and/or (4) and/or (7), and/or (e) Nursing service (1), and/or (i) General (7).

Based on record reviews and interviews, the hospital failed to complete the medical record within thirty days after discharge for one patient. The findings include:

9. Patient #1 was admitted to the hospital's LDRP unit for labor on 10/9/05 and delivered Patient #2 on 10/10/05. The patient was discharged home on 10/10/05. Review of Patient #1's medical record identified the record lacked the discharge summary. The hospital failed to complete the patient's discharge summary within thirty days.

\*The following is a violation of the General Statutes of Connecticut Sections 19a-127n, as amended by section 123 of public act 03-278 and the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (1)(A) and/or (2), and/or (i) General (7).

Based on record review, interviews with hospital staff and review of hospital information, the hospital staff failed to complete a comprehensive adverse event report. The findings include:

10. Patient #1, a pregnant 27 year old, Gravida 1 Para 0 at 41 2/7 weeks gestation, was admitted to the hospital on 10/9/05 at 12:27 PM for evaluation of contractions and cramping. Review of the record indicated that after fourteen hours of labor, a male newborn, Patient #2 was delivered on 10/10/05 at 2:28 AM through thick meconium and neonatal resuscitation was performed. Review of Patient #2's medical record indicated the infant weighed 3320 grams and had Apgar scores of 1/0/0 at 1, 5 and 10 minutes. A Labor and Delivery Record identified the patient's heart rate was 95 and respirations were 0. Patient #2's Final Autopsy Report dated 10/12/2005 identified meconium aspiration syndrome leading to extensive intraalveolar pulmonary hemorrhage and severe hypoxia complicated by anoxic brain injury, acute myocardial infarction, acute tubular necrosis and multisystem organ failure as the cause of death. The hospital's corrective action plan failed to fully identify strategies to reduce the risk of similar adverse events occurring in the future, as well as, failed to develop and implement measures to evaluate the effectiveness of such strategies. Although, the adverse event report identified, in part, strategies including education and counseling of the CNM and increased attention to review of fetal monitoring, the plan failed to address issues related to practitioner assessment, monitoring, documentation and availability of equipment as outlined above.