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

IN RE: Center for Ambulatory Surgery, LLC
d/b/a Center for Ambulatory Surgery, LLC
32 Imperial Avenue
Westport, CT 06880

SECOND CONSENT ORDER

WHEREAS, Center for Ambulatory Surgery, LLC of Westport, CT, located at 32 Imperial Avenue in Westport, Connecticut d/b/a Center for Ambulatory Surgery, LLC ("CAS"), has been issued license number 0292 to operate an outpatient surgical facility by the Connecticut Department of Public Health ("Department") pursuant to Chapter 368v of the General Statutes of Connecticut, as amended; and,

WHEREAS, the Facility Licensing and Investigations Section of the Department conducted announced inspections concluding on March 28, 2013 at the Facility for the purpose of a licensing renewal survey and to review implementation of the plan of correction for violation letters dated April 9, 2012 and June 21, 2012; and

WHEREAS, the Department, during the course of aforementioned inspections, identified violations of the Connecticut General Statutes and/or Regulations of Connecticut State Agencies and documented those violations in an amended violation letter dated June 4, 2012 (copy attached, Exhibit A); and

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

NOW THEREFORE, the FLIS of the Department acting herein and through Barbara Cass, R.N., Section Chief, and CAS, acting herein and through Joel B. Singer, M.D., Sole Owner of CAS, hereby stipulate and agree that CAS' license shall be placed on a period of probation for a period of two years under the following terms and conditions:

1. The First Amended Consent Order executed with the Department on September 12, 2012 (Exhibit B– copy attached) shall be superceded by this Second Consent Order.

2. Within fourteen (14) business days of the execution of this Second Consent Order, CAS shall contract with a Clinical Consulting Firm ("CCF") that has expertise in professional/clinical health care services specializing in outpatient surgical centers, evaluations of institutional systems, quality assessment reviews and expertise in the life safety code of health care facilities.

3. The Department must approve the CCF in writing prior to the execution of the contract between CAS the CCF. The Licensee shall incur all costs associated with the hiring and monitoring by the CCF.

4. CAS agrees not to begin its operation until after the CCF contract is approved and until it receives written approval that it is in compliance with the statutes and regulations regarding outpatient surgery centers, including but not limited to the provision that specifies the requirements for a clinical director.

5. The CCF shall, at a minimum, conduct onsite reviews of CAS and direct observation of CAS staffs' performance as further specified in paragraph five (5) of this Second Consent Order. The CCF Consultant shall consist of a credentialed healthcare professional(s) and with expertise in life safety codes necessary to address the issues identified in the amended violation letter dated June 4, 2013. The Life Safety Code includes but not limited to the Connecticut Public Health Code, Connecticut Fire Safety Code and NFPA 99 Health Care Facilities and other applicable codes, laws and regulations.

6. The CCF's review of CAS shall include, but not limited to, the following professional services and systems, and shall make written recommendations for improvements:

   a. Infection Control Program;
   b. Medical Record Documentation;
   c. Nursing Services;
   d. Nurse Staffing Levels;
   e. Nurse Supervisor Appointment;
   f. Nurse Staffing Training and Credentialing;
   g. Physician, CRNA, RN, and Scrub Technician Credentialing;
   h. Operating Room;
   i. Instrument Reprocessing;
   j. Instrument supplies;

k. Emergency Equipment;

l. Physical Plant Testing and Maintenance including but not limited to the fire alarm, the medical gas/vacuum systems, generator, electrical outlets, and electrical devices;

m. Medication Storage and Administration;

n. Government Body and Management;

o. Surgical Services; and

p. Quality Assessment and Performance Improvement Program.

7. The CCF and CAS shall enter into a written contract that includes the following requirements:

a. An initial on site review;

b. A minimum of four (4) hours every other week of direct observation of staff performance and to monitor the implementation of the issues in paragraph five (5) for the period of the Second Amended Consent Order or until sustained substantial compliance has been achieved as determined through onsite visits by the Department and review of all documentation and any information the Department deems relevant;

c. Provide consulting services as needed;

d. Review of staffs' credentialing and orientation files to ensure compliance with state and federal laws and/or regulations; and

e. The timeframes for the analysis and development of recommendations.

8. The initial onsite review by CCF must be scheduled within fourteen (14) days of the execution of the contract between CCF and CAS.

9. The CCF shall have seven (7) business days after the completion of the initial onsite review, to develop reports and provide the report with its written recommendations to the CAS and the Department. CCF monitoring reports shall be submitted biweekly. Neither CAS nor the Department shall be provided with the opportunity to review the reports prior to the release and both parties shall receive a copy of the report simultaneously. The reports shall identify methods utilized for the analysis, areas reviewed and process, findings and recommendations. CCF recommendations shall include, as applicable, areas that need to be addressed, continued onsite consulting initiatives, and number of onsite hours per consultant. If CAS disagrees with any CCF findings or recommendations, the CAS, the

CCF and the Department shall meet to discuss issues. CAS shall have the right to present information related to the CAS' areas of disagreement.

10. The Department shall have absolute and sole discretion to accept or reject the CCF recommendations should the parties not be able to reach mutual agreement.

11. CAS' Administrator and/or Medical Director, Nurse Supervisor and the CCF shall meet with the Department at monthly intervals during the period of the Second Consent Order.

12. Any records maintained by CAS in accordance with any state or federal law or regulation or as required by this Second Consent Order shall be made available to the Department upon request.

13. Effective immediately upon execution of this Second Consent Order, the Licensee shall inform the Department in writing within forty-eight (48) hours of the vacancy of staff employed as the clinical director/administrator, circulating nurse, nurse supervisor, and scrub technician. The Department shall approve in writing, and sent by facsimile or email to CAS, any staff designated or hired for these positions.

14. The Licensee shall ensure that all vendors to including but not be limited to suppliers or contracted services provided directly to the Licensee shall be paid in full within ninety (90) days of receipt of service or supplies unless there is any legitimate dispute with any vendor over payment amount, condition of supplies delivered or any failure of a vendor relating to service or services contracted for with a vendor. The Licensee shall submit copies of the bills or invoicesand copies of payment receipts monthly to the CCF, and the CCF shall report to the Department on the status of all vendor payments.

15. The Licensee shall ensure that all clinical staff and the CCF shall be paid in full within fourteen (14) business days of receipt of services or contractually agreed upon pay period. The Licensee shall submit copies of the bills and payment receipts biweekly to the CCF.

16. The Licensee shall submit a weekly report of all procedures conducted at CAS to the Department unless no procedures were conducted at the facility during the week.

17. The Licensee shall submit weekly logs of all instruments reprocessed and spore testing conducted by the Licensee to the Department unless no procedures were conducted at the facility during the week.

18. The Licensee shall submit a weekly infection control log to the Department.

19. Within thirty (30) days of the effective date of this Second Consent Order, CAS shall provide inservice education to all applicable staff regarding all policies and procedures. To the extent applicable staff is not available during the thirty (30) day period for inservice education, CAS shall develop a plan to ensure those staff members receive the inservice education as soon after the thirty (30) days as is possible. This inservice education shall also be provided, as applicable, at the time of employment and shall be repeated at appropriate intervals as determined by CAS. Documentation of inservice education shall be maintained for review by the Department for a period of three (3) years.

20. Within sixty (60) days of the effective date of this Second Consent Order, CAS shall establish a mechanism, whereby the CAS' Quality Assessment and Performance Improvement Program ("QAPI"), on an ongoing basis, reviews and evaluates the following:

a. Compliance with a comprehensive infection control program to minimize the risks of infections and communicable diseases;

    i. CAS shall incorporate into the QAPI, program indicators to analyze date and track quality pertinent to the specifications as outlined in this paragraph; and

    ii. Responsibility for the ongoing review and evaluation of the items identified in subparts (a) through (f) of this paragraph (19) shall be undertaken with continued oversight, including analyzing and tracking applicable quality indicators by the QAPI program;

b. Compliance with Registered Staffing, Training, Credentialing, and Staff Appointments;

c. Compliance with Physician and APRN Credentialing;

d. Compliance with Scrub Technician Staffing, Training, and Credentialing;

e. Compliance with Physical Plant Testing and Maintenance including but not limited to the fire alarm, the medical gas/vacuum systems, generator, electrical outlets and electrical devices; and

f. Compliance with Medical Record Documentation.

21. CAS shall within fourteen (14) days of the effective date of this Consent Order submit the individual's name from the CCF assigned the responsibility to submit biweekly reports for the period of this Second Consent Order.

22. The Licensee shall pay a monetary penalty to the Department in the amount of seven thousand five hundred dollars ($7,500), by money order or bank check payable to the

Treasurer of the State of Connecticut. Three thousand dollars shall be paid at the time of execution of Second Consent Order. The remaining four thousand five hundred dollars shall be paid on or before September 15, 2013. The monetary penalty, any documentation and biweekly reports related to this Second Consent Order shall be submitted to:

Donna Ortelle, R.N., M.S.N., Public Health Services Manager
Facility Licensing and Investigations Section
Department of Public Health
410 Capitol Avenue, MS #12 FLIS
P.O. Box 340308
Hartford, CT 06134-0308

23. All parties agree that this Second Consent Order is an agreement with 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 CAS for violations of this Second 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, or any other administrative and judicial relief provided by law. This Second Consent Order may be admitted by the Department as evidence in any proceeding between the Department and CAS in which compliance with its terms or the statutes or regulations related to CAS' outpatient surgical center license is at issue, and all allegations in the Department's file shall be deemed true in any subsequent proceeding in which CAS' compliance with the statutes and regulations (state and federal) regarding the provision of care at outpatient surgery centers is at issue. CAS retains all of its rights under applicable law.

24. The execution of this Second Consent Order has no bearing on any criminal liability without the written consent of the Director of the Connecticut Medicaid Fraud Control Unit or the Bureau Chief of the Department of Criminal Justice's Statewide Prosecution Bureau.

25. If the Licensee has maintained substantial compliance with federal and state laws and regulations, the Department may rescind the probation.

26. CAS understands that this Second 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 CAS

of any other rights that it may have under the laws of the State of Connecticut or of the United States.

27. Should CAS not be able to maintain substantial compliance with the requirements of this Second Consent Order, the Department retains the right to issue charges including those identified in the Amended Violation Letter dated June 4, 2013.

28. CAS has consulted with its attorney prior to the execution of this Second Consent Order.

WITNESS WHEREOF, the parties hereto have caused this Second Consent Order to be executed by their respective officers and officials. I, Joel B. Singer, M.D., am licensed to practice medicine and surgery in Connecticut, and I am the sole owner of CAS. I am authorized to sign this Second Consent Order on behalf of CAS. I have read the above, and on behalf of CAS, I agree to the terms set forth therein. I further declare the execution of this Second Amended Consent Order to be my free act and deed.

CENTER FOR AMBULATORY SURGERY, LLC -

By: _____
Joel B. Singer, M.D., Sole Owner

Personally appeared the above named Joel B. Singer, M.D., on 31ST day of July, 2013, and made oath to the truth of the statements contained herein.

My Commission Expires: MARCH 31, 2015
(If Notary Public)

JASON S. STRIZVER
NOTARY PUBLIC
STATE OF CONNECTICUT
My Commission Expires
March 31, 2015

_____
Notary Public
Commissioner of the Superior Court

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

8/15, 2013

By: _____
Barbara Cass, R.N., Section Chief
Facility Licensing and Investigations Section

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Exhibit A

June 4, 2013

Joel Singer, M.D., Owner & Administrator
Center For Ambulatory Surgery
32 Imperial Avenue
Westport, CT 06880

Dear Dr. Singer:

This is the amended edition of the original violation letter dated April 25, 2013.

Unannounced visits were made to Center For Ambulatory Surgery commencing on March 21, 203 and concluding on March 28, 2013 by representatives of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting a certification survey, licensing renewal survey and revisit to review implementation of the plan of correction for the violation letters dated April 9, and June 21, 2012.

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 May 9, 2013 at 1 PM in the Facility Licensing and Investigations Section of the Department of Public Health, 410 Capitol Avenue, Second Floor, Hartford, Connecticut. Should you wish to retain legal representation, your attorney may accompany you to this meeting.

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.

Alternate remedies to violations identified in this letter may be discussed at the office conference. In addition, please be advised that the preparation of a Plan of Correction and/or its acceptance by the Department of Public Health does not limit the Department in terms of other legal remedies, including but not limited to, the issuance of a Statement of Charges or a Summary Suspension Order and it does not preclude resolution of this matter by means of a Consent Order.

Should you have any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,

Donna Ortelle, RN, MSN

Donna M. Ortelle, R.N., M.S.N.
Public Health Services Manager
Facility Licensing and Investigations Section

DMO:jpf

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

DATES OF VISIT: March 21, 22, 25 and 28, 2013

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-D56 (c) Ownership and Administration (1) and/or (d) Chief Executive Officer (3) and/or (e) Professional Staff (1)(c) and/or (4)(D).

1. Based on review of facility polices, review of facility documentation, and interviews, the facility failed to provide documentation that the Governing Body ensured that the facility's Quality Assurance/Performance Improvement Program was implemented and/or maintained by the facility. The findings include:
    a. Review of the Quality Assurance Committee minutes dated 9/24/12 identified that the committee developed a protocol to review the autoclave log. The facility failed to provide documentation to reflect that this QA project was implemented when a review of the Biological Monitoring (BI) log sheet identified that from 2/14/13 to 3/21/13, the Attest biological indicator (to monitor the effectiveness of the steam sterilization) was run through the autoclave, placed in the incubator in the morning, and removed the same day to be read. Interview with Scrub Tech #1 on 3/21/13 at 8:30am identified that he/she runs the BI with every load, removes the vial, crushes the vial, places the vial in the incubator in the morning and "reads it" before the end of the day. Further interview with Scrub Tech #1 failed to identify that a facility policy or manufacture directions on using the BI. The Nursing Supervisor provided a printout on 3/22/13 which identified that the BI is incubated for 48 hours for visual color change readout. The Protocol for Cleaning and Steam Sterilization of Surgical Instruments directed in part, a biologic indicator such as Prospore2 is placed in the autoclave with every load and biologic testing is done with an incubator and recorded. The facility had a conflicting policy posted in the instrument processing area titled "Autoclave Procedures" which directed the biological test be read after four hours.

    In addition, during the survey on 3/21/13, Surgical Tech #1 was unable to provide a log to track the sterilization of items packaged and sterilized at the facility. Observation of the instrument packages and of the Autoclave Daily Test Log failed to track the instruments and load should there be a recall of instruments due to spore growth identified by spore testing.

    In addition, observation on 3/21/13 at approximately 8:40 am identified the inside of the autoclave (bottom) with rusty discolorations. Two large lipo packs were stored in a drawer containing instruments on a tray in a peel pack and were noted with condensation and a small amount of water within the pack. In addition, surgical packs containing instruments had water stains with rust discolorations. Review of the Autoclave Daily

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

Test Log and interview with Scrub Tech #1 on 3/21/13 at approximately 8:40am identified that since he/she started working at the facility on 2/14/13, he/she had never cleaned the autoclave and there is no documentation in the log that the autoclave had been cleaned during this period. Scrub Tech #1 further identified that he/she did not have manufacturer ' s guidelines to direct him/her on when or how to clean the autoclave and/or when testing was required.

The Protocol for Cleaning and Steam Sterilization of Surgical Instruments directed that the autoclave is cleansed and drained weekly. The use and care manual for the sterilizer directs weekly cleaning and inspection of the chamber, cleaned with Omni-Cleaner and distilled water. Interview with MD #1 on 3/25/13 at 8:00 AM identified that he/she thought that staff was cleaning the autoclave weekly.

b. Review of the Quality Assurance Committee minutes dated 12/17/12 identified that the Nurse Supervisor and/or designee would conduct quarterly reviews of all fire safety policies and procedures to ensure 100% compliance. The facility failed to provide documentation to reflect that this QA project was implemented when during the survey, it was identified that the facility's fire alarm system had not been functioning since 10/29/12. Interview with MD #6 on 3/28/13 identified that he was unaware that the fire alarm was not functioning. In addition, review of facility documentation identified that the fire alarm signal was not transmitted during the drill which is required.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D56 (d) Chief Executive Officer (3) and/or (e) Professional Staff (1)(c) and/or (i) General (4) and/or (5).

2. Based on observation and interview, the facility failed to ensure that defibrillator checks were conducted to ensure proper function. The finding includes:
   a. Observation during tour of the facility on 3/21/13 at approximately 9:15 AM identified a defibrillator in the post anesthesia care unit (PACU). Review of the paper printout identified a date stamp of 1/9/13. Review of the defibrillator machine and interview with the Nursing Supervisor on 3/21/13 at 12:45 PM identified that he/she does not check the defibrillator. Upon inquiry on 3/22/13, the Nursing Supervisor tested the defibrillator and the paper printout was functioning and printed the correct date.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D56 (c) Ownership and Administration (1) and/or (4)(D) and/or (d) Chief Executive Officer (3) and/or (e) Professional Staff (1)(c).

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

3. Based on review of personnel files, review of facility policy and Medical Staff By-Laws, and interview, the facility failed to ensure that the credentialing process was completed for 6 of 6 physicians, MD's #1, #2, #3, #4, #5 and #6 in accordance with facility policy. The findings include:
   a. Review of staff files for MD's #1, #2, #3, #4, #5, and #6 on 3/21/13 lacked documentation to reflect that the credentialing process had been completed. The files lacked a Practitioner Peer Reference Form. Review of the Medical Staff Credentialing Program policy (last revised 6/15/10) identified that all applicants will receive a packet to include in part, a practitioner peer reference sample form. Completed applications will be forwarded to the Medical Advisory Committee for recommendation.
   In addition, MD's #1, #2, #3, #4, and #5 credentialing files contained controlled substance registration certificates (DEA) with an address listed from another city and/or site. The certificate identified that it is not transferable on change of ownership, control, location, or business activity, and it is not valid after the expiration date.
   b. MD's #1, #2, #3, #4, and #5 were granted temporary privileges to practice anesthesiology on 7/12/12 for 180 days. The physicians were not granted appointments until 12/10/12 to 2/28/13, more than 120 days. Review of the facility's Bylaws identified that the duration of temporary privileges will not exceed 120 days.
   c. Review of MD #6's credentialing file failed to contain documentation to reflect physician privileges in a hospital licensed in CT to perform the duty or procedure which will be done at the surgi center. Interview with the Independent Nurse Consultant (INC) on 3/28/13 identified that MD #6's credentialing file was lacking this information.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D56 (c) Ownership and Administration (1) and/or (d) Chief Executive Officer (3) and/or (e) Professional Staff (1)(c) and/or (g) Nursing Staff (3) and/or (i) General (5).

4. Based on review of clinical records, review of facility policies, and interview, the facility failed to ensure that at least two Registered Nurses were present for two of two patients (Patients # 11, 22) who underwent surgical procedures on 12/20/2012. The findings include:

   a. Patient #11 was admitted to the facility on 12/20/12 to undergo a bilateral Breast Augmentation. Review of the clinical record identified that the Nurse Supervisor provided preoperative, intraoperative, and postoperative services to Patient #11. Interview with the Nurse Supervisor on 3/22/13 at 2:00 PM identified that she was the only Registered Nurse in the surgery center on 12/20/12. The Nurse Supervisor identified that she was unaware of any regulations that required two RNs to be present in the surgery center during procedures and that she had been the only RN under those circumstance on four to five other occasions since her employment at the center nine months earlier.

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

b. Patient #22 was admitted to the facility on 12/20/12 to undergo a fat transfer to the face. Review of nursing documentation identified that the Nursing Supervisor was the only Registered Nurse (RN) working at the facility during this procedure. Interview with the Nursing Supervisor on 3/22/13 at 2pm identified that he/she was the only RN at the facility on this date and there were approximately four other occasions when he/she was the only RN at the facility when there was surgery at the facility over the last nine months.

c. Patient #11's intraoperative record dated 12/20/12 identified that the patient's procedure began at 9:45 AM and ended at 12:10 PM. Documentation in Patient #22's clinical record dated 12/20/12 identified that the Nursing Supervisor administered Keflex 500 mg. preoperatively to Patient #22 at 11:30 AM. Review of staffing identified that the Nursing Supervisor was the only RN scheduled on 12/20/12 and therefore would have had to leave the OR during the procedure for Patient #11 to administer the preoperative medication to Patient #22.

d. Documentation in Patient #11's clinical record dated 12/20/12 identified that Patient #11's procedure ended at 12:00 PM and that the patient was discharged at 1:00 PM. Review of Patient #22's intraoperative record dated 12/20/12 identified that Patient #22 entered the OR at 12:50 PM. Based on the staffing levels at the facility, the Nurse Supervisor would have needed to address the nursing needs of both Patient #11 and Patient #22 concurrently during the pre/intra/and postoperative periods.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D56 (c) Ownership and Administration (1) and/or (d) Chief Executive Officer (3) and/or (e) Professional Staff (1)(c) and/or (4)(D)((g)and/or (h) and/or (f) Records and Reports (3) and/or (i) General (5).

5. Based on review of clinical records, review of facility policies, and interview, the facility failed to ensure that medications were administered for 9 of 22 patients (Patients #3, #4, #6, #7, #8, #12, #13, #17, #22) and/or that preoperative testing was completed for 4 of 22 patients (Patients #3, #4, #6, #7) in accordance with physician orders. The findings include:
    a. Patient #3 was admitted to the facility on 12/6/12 to undergo an abdominoplasty. Physician orders dated 12/6/12 directed the oral administration of Keflex two hundred and fifty milligrams (250 mg.) preoperatively. Review of the "Day of Surgery" form dated 12/6/12 identified that Nurse Supervisor administered Keflex five hundred mg. (500 mg.) to Patient #3 at 8:00 AM. In addition, the clinical record lacked documentation to reflect that a preoperative pregnancy test was completed.
    b. Patient #4 was admitted to the facility on 12/27/12 to undergo a bilateral breast

augmentation. Physician orders dated 12/27/12 directed the oral administration of Keflex two hundred and fifty milligrams (250 mg.) preoperatively. Review of the "Day of Surgery" form dated 12/27/12 identified that Nurse Supervisor administered Keflex five hundred mg. (500 mg.) to Patient #4 at 10:00 AM.

In addition, physician orders dated 12/27/12 directed that a Blood Urea Nitrogen (BUN) test be obtained preoperatively. Review of Patient #4's clinical record identified that although a BUN was obtained preoperatively, the blood work was obtained on 10/20/12, more than two months prior to the surgery. Interview with the Nurse Supervisor at the time of the review identified that the blood work should have been obtained closer to the surgery date in order to be useful to the surgeon.

c. Patient #13 was admitted to the facility on 12/17/12 to undergo a bilateral breast augmentation. Physician orders dated 12/17/12 directed the oral administration of Keflex two hundred and fifty milligrams (250 mg.) and Zofran four mg. (4 mg.) preoperatively. Review of the "Day of Surgery" form dated 12/17/12 identified that no preoperative medications were administered. Interview with the Nurse Supervisor on 3/22/13 at 2:00 PM identified that although she could not be certain, it was likely that Patient #13 had forgotten to bring the medications to the facility as preoperative medication administered in the facility is prescribed in advance of the scheduled procedure and the patients are supposed to bring the medication in with them on the day of surgery. The clinical record further lacked documentation to reflect the reason the medications were not administered.

d. Patient #12 was admitted to the facility on 12/6/12 to undergo a bilateral breast augmentation secondary to asymmetry after a previous breast augmentation. Physician orders dated 1/24/13 directed the oral administration of Cephalexin two hundred and fifty milligrams (250 mg.) preoperatively. Review of the "Day of Surgery" form dated 12/6/12 identified that the Nurse Supervisor administered Keflex five hundred mg. (500 mg.) to Patient #12 at 8:00 AM.

e. Patient #17 was admitted to the facility on 3/13/13 to undergo drainage of a left breast hematoma. Review of the "Day of Surgery" form dated 3/13/13 identified that the Nurse Supervisor administered Ibuprophen eight hundred mg. (800 mg.) preoperatively at 12:00 PM. Review of the clinical record lacked documentation to reflect that a physician's order was written to administer the Ibuprophen to Patient #17.

Interview with the Nurse Supervisor on 3/22/13 at 2:00 PM identified that she had been calling in prescriptions for Keflex 500 mg. for most prospective patients. The Nurse Supervisor stated that the discrepancy between the preprinted physician orders and what was being called in for the patients was noted by the facility's Independent Nurse Consultant (INC). The Nurse Supervisor stated that the preprinted orders were

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

subsequently changed to reflect the 500 mg. dosage of Keflex requested by the surgeon, MD #6, to be ordered preoperatively.

f. Patient #6 underwent lower lid blepharoplasty on 1/31/13. The Nursing documentation identified that the patient received Hydrocodone 17.5 milligrams at 1:45 PM. Review of the physician orders failed to identify an order for the medication.
Additionally, the medical record failed to identify that a pregnancy test was conducted prior to surgery in accordance with facility policy.
Further review of the physician orders failed to identify discharge orders. The Medical Records Policy, not dated, directed that the contents of the medical record include all orders for treatment, medications signed by the prescriber and orders for screening tests and their results. The anesthesiologist is responsible for documentation the patient's suitability for discharge.

g. Patient #7 underwent a breast augmentation and mastoplexy on 2/21/13. The nursing documentation identified that the patient received Zofran 8mg by mouth at 10:15 AM and Keflex 600 mg by mouth at 10:15 AM. Review of the physician orders failed to identify an order for the medications.
Additionally, the nursing documentation identified that a urine pregnancy test was performed prior to surgery lacking a physician order. The Medical Records Policy, not dated, directed that the contents of the medical record include all orders for treatment, medications signed by the prescriber.

h. Patient #8 underwent an abdominolplasty and penniculectomy on 2/27/13. Review of the medical record failed to identify a discharge order and sponge and instrument for the second and final counts. The Medical Records Policy, not dated, directed that the circulating nurse shall complete the operating room record.

i. Patient #22 underwent a fat transfer to the face on 12/20/13. Review of the physician orders directed valium 5 mg. Review of the medical record failed to identify that valium was administered. The Medical Records Policy, not dated, directed a record of medications administered, including the name and strength of the drug, date and time of administration, dosage administered, method of administration, and signature of the person who administered the drug.
Additionally, the nursing documentation identified that a urine pregnancy test was performed prior to surgery lacking a physician order. The Medical Records Policy, not dated, directed that the contents of the medical record include all orders for treatment, medications signed by the prescriber.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D56 (d) Chief Executive Officer (3) and/or (e) Professional Staff (1)(c) and/or (4)(D)(h) and/or (f) Recors and Reports (3) and/or (i) General (5).

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

6. Based on review of clinical records, review of facility policies, and interview, the facility failed to ensure that clinical records were complete and/or accurate for 10 of 22 patients (Patients # 6, #7, #8, #10, #11, #12, #14, #18, #21, and #22) in accordance with facility policies. The findings include:
    a. Patient #11 was admitted to the facility on 12 20/13 to undergo a bilateral Breast Augmentation Review of the Post Anesthesia Care Unit (PACU) record lacked documentation to reflect the amount of fluids received in the OR and/or PACU and/or how they were administered.
    b. Patient #6 was admitted to the facility on 1/31/13 to undergo bilateral breast augmentation. Review of the clinical record lacked documentation to reflect that preprocedure orders for Patient #6 were dated, timed, and/or signed by the surgeon.
    c. Patient #7 was admitted to the facility on 2/21/13 to undergo bilateral breast augmentation. Review of the clinical record lacked documentation to reflect that preprocedure orders for Patient #7 were dated, timed, and/or signed by the surgeon.
    d. Patient #8 was admitted to the facility on 2/15/13 to undergo a lower eye blepharoplasty. Review of the clinical record lacked documentation to reflect that preprocedure orders for Patient #8 were dated, timed, and/or signed by the surgeon. In addition, review of the operative report of Patient #8 dated 2/14/13 lacked documentation to reflect preoperative preparation of the skin and/or what solution was used for the preparation of the surgical areas/areas.
    e. Patient #10 was admitted to the facility on 3/7/13 to undergo liposuction. Review of the clinical record lacked documentation to reflect that preprocedure orders for Patient #10 were dated, timed, and/or signed by the surgeon. In addition, review of the operative report of Patient #10 dated 3/1/13 lacked documentation to reflect preoperative preparation of the skin and/or what solution was used for the preparation of the surgical areas/areas.
    f. Patient #12 was admitted to the facility on 1/24/13 to undergo bilatereal breast augmentation. Review of the operative report of Patient #12 dated 1/24/13 lacked documentation to reflect preoperative preparation of the skin and/or what solution was used for the preparation of the surgical areas/areas.
    g. Patient #14 was admitted to the facility on 1/21/13 to undergo a labiaplasty. Review of the operative report dated 1/21/13 identified that excision of excess tissue was performed on the right labia. The clinical record lacked documentation to reflect pathology and/or disposition of the excised tissue. Interview with the Nurse Supervisor on 3/21/13 at 2:00 PM identified that there was "no hard and fast rule" but that she believed that a sample of most tissue excised during a procedures was sent to pathology for review.

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

h. Patient #18 was admitted to the facility on 3/14/13 to undergo liposuction for unilateral gynecomastia. Review of the clinical record lacked documentation to reflect that pre-procedure orders for Patient #18 were dated, timed, and/or signed by the surgeon.

i. Patient #21 was admitted to the facility on 3/11/13 to undergo an abdominalplasty. Review of the clinical record lacked documentation to reflect that pre-procedure orders for Patient #21 were dated, timed, and/or signed by the surgeon.

j. Patient #22 was admitted to the facility on 12/20/12 to undergo a fat transfer to the face. Review of the clinical record lacked documentation to reflect that pre-procedure orders for Patient #22 were dated, timed, and/or signed by the surgeon. In addition, review of the operative report was initially dated 12/4/12. The number "4" of the date was crossed off, a "20" was added below it, and the circled initials "CE" were added. Review of the facility's staff list identified that the initials belonged to the receptionist and not a licensed staff member.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D56 (d) Chief Executive Officer (3) and/or (e) Professional Staff (1)(c) and/or (4)(D)(g) and/or (i) General (5).

7. Based on observation, review of facility documentation and interview, the facility failed to store medications to prevent contamination and/or the facility failed to ensure that medications were not outdated and/or for 8 of 22 patients (Patients #3, #4, #6, #7, #12, #13, #17, and #22), the facility failed to ensure that there were physician orders for medications administered. The finding includes:

   a. Observation on 3/21/13 at 9 AM of the medication refrigerator in the post anesthesia care unit (PACU) identified it to be unlocked with a lock hanging from the door. The refrigerator contained medications including a container with a hand written label "BLT", succinylcholine vials, and rocuronium vials. The freezer compartment contained metal rollers, ice packs and a specimen jar with tissue floating in a liquid labeled with a patient ' s name, nasal cartilage, and dated 12/13/06.
   Although the Infection Control Checklist, Assessing the Environment completed for 1/2013, 2/2013, and 3/2013 by the Nursing Supervisor identified that medications which require refrigeration are maintained in an environment free from potential contact with specimens, food and other sources of contamination, the specimen/medications were not appropriately stored.

   b. Observation during tour of the PACU on 3/21/13 at approximately 9 AM identified a malignant hyperthermia cart containing supplies and medications. Four of the four sodium bicarbonate injectable syringes had expired 3/1/13. Interview with the Nursing Supervisor on 3/21/13 at 1:30 PM identified that he/she checks the bin on surgery days but was not aware that this medication had expired. Interview with the Pharmacy

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

Consultant on 3/22/13 identified that during his/her last inspection, February 2013, he/she recommended that the sodium bicarbonate medication be changed out before expiring.

Although the Infection Control Checklist, Assessing the Environment completed for 1/2013, 2/2013, and 3/2013 by the Nursing Supervisor identified that expiration dates are clearly labeled and outdated products are not available, expired medications were still available for potential use.

c. Patient #6 underwent lower lid blepharoplasty on 1/31/13. The Nursing documentation identified that the patient received Hydrocodone 17.5 milligrams at 1:45 PM. Review of the physician orders failed to identify an order for the medication.

The Medical Records Policy, not dated, directed that the contents of the medical record include all orders for treatment, medications signed by the prescriber and orders for screening tests and their results.

d. Patient #7 underwent a breast augmentation and mastoplexy on 2/21/13. The nursing documentation identified that the patient received Zofran 8mg by mouth at 10:15 AM and Keflex 600 mg by mouth at 10:15 AM. Review of the physician orders failed to identify an order for the medications.

The Medical Records Policy, not dated, directed that the contents of the medical record include all orders for treatment, medications signed by the prescriber.

e. Patient #22 underwent a fat transfer to the face on 12/20/13. Review of the physician orders directed valium 5 mg. Review of the medical record failed to identify that valium was administered. The Medical Records Policy, not dated, directed a record of medications administered, including the name and strength of the drug, date and time of administration, dosage administered, method of administration, and signature of the person who administered the drug.

f. Patient #3 was admitted to the facility on 12/6/12 to undergo an abdominoplasty. Physician orders dated 12/6/12 directed the oral administration of Keflex two hundred and fifty milligrams (250 mg.) preoperatively. Review of the "Day of Surgery" form dated 12/6/12 identified that Nurse Supervisor administered Keflex five hundred mg. (500 mg.) to Patient #3 at 8:00 AM.

g. Patient #4 was admitted to the facility on 12/27/12 to undergo a bilateral breast augmentation. Physician orders dated 12/27/12 directed the oral administration of Keflex two hundred and fifty milligrams (250 mg.) preoperatively. Review of the "Day of Surgery" form dated 12/27/12 identified that Nurse Supervisor administered Keflex five hundred mg. (500 mg.) to Patient #4 at 10:00 AM.

h. Patient #13 was admitted to the facility on 12/17/12 to undergo a bilateral breast augmentation. Physician orders dated 12/17/12 directed the oral administration of

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

Keflex two hundred and fifty milligrams (250 mg.) and Zofran four mg. (4 mg.) preoperatively. Review of the "Day of Surgery" form dated 12/17/12 identified that no preoperative medications were administered. Interview with the Nurse Supervisor on 3/22/13 at 2:00 PM identified that although she could not be certain, it was likely that Patient #13 had forgotten to bring the medications to the facility as preoperative medication administered in the facility is prescribed in advance of the scheduled procedure and the patients are supposed to bring the medication in with them on the day of surgery. The clinical record further lacked documentation to reflect the reason the medications were not administered.

i. Patient #12 was admitted to the facility on 12/6/12 to undergo a bilateral breast augmentation secondary to asymmetry after a previous breast augmentation. Physician orders dated 1/24/13 directed the oral administration of Cephalexin two hundred and fifty milligrams (250 mg.) preoperatively. Review of the "Day of Surgery" form dated 12/6/12 identified that the Nurse Supervisor administered Keflex five hundred mg. (500 mg.) to Patient #12 at 8:00 AM.

j. Patient #17 was admitted to the facility on 3/13/13 to undergo drainage of a left breast hematoma. Review of the "Day of Surgery" form dated 3/13/13 identified that the Nurse Supervisor administered Ibuprophen eight hundred mg. (800 mg.) preoperatively at 12:00 PM. Review of the clinical record lacked documentation to reflect that a physician's order was written to administer the Ibuprophen to Patient #17.

Interview with the Nurse Supervisor on 3/22/13 at 2:00 PM identified that she had been calling in prescriptions for Keflex 500 mg. for most prospective patients. The Nurse Supervisor stated that the discrepancy between the preprinted physician orders and what was being called in for the patients was noted by the facility's Independent Nurse Consultant (INC). The Nurse Supervisor stated that the preprinted orders were subsequently changed to reflect the 500 mg. dosage of Keflex requested by the surgeon, MD #6, to be ordered preoperatively.

The Medical Records Policy, not dated, directed that the contents of the medical record include all orders for treatment, medications signed by the prescriber.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D56 (c) Ownership and Administration (1) and/or (d) Chief Executive Officer (3) and/or (e) Professional Staff (1)(c) and/or (4)(D)(f) and/or (7)(B)(p) and/or (i) General (5).

8. Based on observation, review of facility documentation, review of facility policy, and interviews, the facility failed to maintain an infection control program that seeks to minimize infections and communicable diseases. The finding includes:

a. Observation on 3/21/13 at 8:15am identified that the Bowie-Dick test cards (test for

residual air in autoclave sterilizing machine) had expired 1/13. Review of the Autoclave Daily Test Log identified that the Bowie-Dick test was conducted on the facility's autoclave on 15 occasions since 1/13. Interview with Scrub Tech #1 on 3/21/13 at 8:15 AM identified that he/she didn't realize the test cards were expired and further identified that there were no more test cards available (except the expired ones).

Review of the Autoclave Procedures, posted in the instrument processing area titled "at the start of each surgery day" and the Protocol for cleaning and steam sterilization of surgical instruments (not dated) directed that the Bowie-Dick Test be performed at the beginning of each surgical day. Interview with MD #6 on 3/25/13 identified that the facility's autoclave was a gravity displacement type and does not require a Bowie Dick Test.

b. Review of the Biological Monitoring (BI) log sheet identified that from 2/14/13 to 3/21/13, the Attest biological indicator (to monitor the effectiveness of the steam sterilization) was run through the autoclave, placed in the incubator in the morning, and removed the same day to be read. Interview with Scrub Tech #1 on 3/21/13 at 8:30 AM identified that he/she runs the BI with every load, removes the vial, crushes the vial, places the vial in the incubator in the morning and" reads it" before the end of the day. Further interview with Scrub Tech #1 failed to identify that a facility policy or manufacture directions on using the BI. The Nursing Supervisor provided a printout on 3/22/13 which identified that the BI is incubated for 48 hours for visual color change readout.

The Protocol for Cleaning and Steam Sterilization of Surgical Instruments directed in part, a biologic indicator such as Prospore2 is placed in the autoclave with every load and biologic testing is done with an incubator and recorded. The facility had a conflicting policy posted in the instrument processing area titled" Autoclave Procedures" which directed the biological test be read after four hours.

c. During the survey on 3/21/13, Surgical Tech #1 was unable to provide a log to track the sterilization of items packaged and sterilized at the facility. Observation of the instrument packages and of the Autoclave Daily Test Log failed to track the instruments and load should there be a recall of instruments due to spore growth identified by spore testing.

d. Observation on 3/21/13 at approximately 8:40 AM identified the inside of the autoclave (bottom) with rusty discolorations. Two large lipo packs were stored in a drawer containing instruments on a tray in a peel pack and were noted with condensation and a small amount of water within the pack. In addition, surgical packs containing instruments had water stains with rust discolorations. Review of the Autoclave Daily Test Log and interview with Scrub Tech #1 on 3/21/13 at approximately 8:40 AM

identified that since he/she started working at the facility on 2/14/13, he/she had never cleaned the autoclave and there is no documentation in the log that the autoclave had been cleaned during this period. Scrub Tech #1 further identified that he/she did not have manufacturer's guidelines to direct him/her on when or how to clean the autoclave and/or when testing was required.

The Protocol for Cleaning and Steam Sterilization of Surgical Instruments directed that the autoclave is cleansed and drained weekly. The use and care manual for the sterilizer directs weekly cleaning and inspection of the chamber, cleaned with Omni-Cleaner and distilled water. Interview with MD #1 on 3/25/13 at 8 AM identified that he/she thought that staff was cleaning the autoclave weekly.

e. Observation on 3/21/13 at 9:30 AM identified Scrub Tech #1 cleaning surgical instruments after a surgical procedure. Scrub Tech #1 identified on 3/21/13 that he/she pours one capful of the enzymatic detergent into a basin of hot water to soak and clean the instruments. The basin held approximately one gallon of liquid. The cap was quarter sized and approximately one half inch high.

The label on the enzymatic detergent bottle directed 1 to 2 ounces of enzymatic to one gallon of water. Interview with Scrub Tech #1 identified that he/she did not know how much the cap measured and did not have a measuring cup for use at the facility.

f. Observation on 3/21/13 at 9:30 AM identified two wire bushes and one nylon brush which were used to clean instruments and were noted to be flattened and worn out. Interview with Scrub Tech #1 on 3/21/13 identified that there were no additional supplies of brushes at the facility.

The Protocol for Cleaning and Steam Sterilization of Surgical Instruments (not dated) directed to clean instruments with a stiff brush to remove any dried blood or organic or non-organic material.

g. Review of staff files for MD's #1, #2, #3, #4, #5, #6, RN #1, Nursing Supervisor, Scrub Tech #1, and Scrub Tech #2 failed to identify that staff received any infection control inservicing. Additionally, Scrub Tech #1's first day of work was on 2/14/13. Scrub Tech #1's file lacked documentation that he/she received orientation to his/her duties.

9. Based on observation and interview, the facility failed to ensure that the facility provided and sanitary environment for the provision of surgical services. The finding includes:

   a. Observation during tour on 3/21/13 at 7:55 AM identified used mop heads stored on the floor of the utility closet. Interview with Scrub Tech #1 at this time identified that the used mop heads should be stored in a bag while waiting for the vendor to pick up.

   b. Observation on 3/21/13 at 7:35 AM of the staff dressing room identified scrub outfits hung in a closet, Tide and Snap detergent and a jug of Chlorax bleach stored on a shelf

above a washer and dryer. Interview with the Receptionist on 3/22/13 at approximately 11 AM identified that a contracted agency launders the scrubs but when there are procedures more than twice per week, there are not enough scrubs. The Receptionist further noted that he/she launders the scrubs with Tide Detergent and has been doing so for the last three months. Patient blankets are also laundered by Receptionist. Although staff at the facility laundered the scrubs when the supplies ran out, the scrubs were not laundered with an appropriate detergent to ensure adequate sanitation.

c. Observation on 3/21/13 at 9:05 AM in the PACU identified a patient recline chair and the bilateral arms had tape on edges rendering it difficult to thoroughly clean the chair. Although the Infection Control Checklist, Assessing the Environment completed for 1/2013, 2/2013, and 3/2013 by the Nursing Supervisor identified that recovery room beds, exam chairs are intact (no cracks or tears in the vinyl), this checklist was not accurate.

d. Observation on 3/21/13 at approximately 9:30 AM in the surgical hallway identified an eyewash station. The eyewash solution was dated 6/6/12. Interview with the Nurse Supervisor and MD #6 on 3/21/13 at 9:30 AM identified that the solution was normal saline and it is mixed quarterly or monthly.

e. Observation on 3/21/13 at 9 AM in the PACU identified two bottles of alcohol based hand sanitizers that had expired in 11/2011 and 11/2012.

f. Observation on 3/21/13 at 9 AM of the medication refrigerator in the post anesthesia care unit (PACU) identified it to be unlocked with a lock hanging from the door. The refrigerator contained medications including a container with a hand written label "BLT", succinylcholine vials, and rocuronium vials. The freezer compartment contained metal rollers, ice packs and a specimen jar with tissue floating in a liquid labeled with a patient's name, nasal cartilage, and dated 12/13/06.

10. Based on review of personnel files, review of facility policies, and interview, the facility failed to ensure that a qualified individual was designated as the Infection Control Nurse. The findings include:

a. During a review of the facility's infection control program on 3/22/13, the facility was unable to provide documentation and/or evidence of a designated Infection Control Nurse (ICN). Interview with RN #1 on 3/22/13 at 2:00 PM identified that although she was designated as the facility supervisor, she was not the designated Infection Control Nurse as she did not have any formal training in Infection Control. RN #1 stated that she did not participate in monitoring of infection rates beyond making postoperative calls to patients the day after a procedure. RN #1 stated that if a patient had a concern with a potential infection subsequent to that call, the patient would call the surgeon

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

directly on his cell phone but that she would not have that information. RN #1 stated that she does not have the responsibility for monitoring sterilization of OR equipment/instruments and was unaware of any formal infection control program. Interview with MD #6 on 2/22/13 at 3:00 PM identified that his last Infection Control Nurse had retired but was unable to state when that retirement told place and/or provide any documentation of any visits by his last reported designated Infection Control Nurse. MD #6 stated that had not been able to hire an Infection Control Nurse. Review of the Infection Control meeting minutes dated 6/29/12, 9/24/12, 12/17/12, and 3/4/12 lacked documentation to reflect that a designated Infection Control Nurse participated in any of the meetings.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D56 (d) Chief Executive Officer (3) and/or (i) General (2) and/or (3).

11. Based on review for 10 of 10 staff files, the facility failed to ensure that staff received infection control training or inservicing. The findings include:
    a. Review of staff files for MD's #1, #2, #3, #4, #5, #6, RN #1, Nursing Supervisor, Scrub Tech #1, and Scrub Tech #2 failed to identify that staff received any infection control inservicing. Additionally, Scrub Tech #1's first day of work was on 2/14/13. Scrub Tech #1's file lacked documentation that he/she received orientation to his/her duties.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D56 (d) Chief Executive Officer (3) and/or (e) Professional Staff (1)(c) and/or (f) Recors and Reports (3).

12. Based on review of 2 of 22 medical records, Patients #6, #8 and review of facility policy, the facility failed to obtain a written order for discharge. The findings include:
    a. Patient #6 underwent lower lid blepharoplasty on 1/31/13. Review of the physician's order failed to identify discharge orders.
    b. Patient #8 underwent an abdominolplasty and penniculectomy on 2/27/13. Review of the medical record failed to identify a discharge order.

    The Medical Records Policy, not dated, directed that the contents of the medical record include all orders for treatment, medications signed by the prescriber and orders for screening tests and their results. The anesthesiologist is responsible for documentation the patient's suitability for discharge.

DATES OF VISIT: March 21, 22, 25 and 28, 2013

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

The Following were violations of the Regulations of Connecticut State Agencies Section 19-13-D56 (b) Physical Standards B. (1)(b)(1)(b)(c)(d),(5), (I) Air Conditioning and Ventilation Systems (J) Electrical Requirements (1) Lighting (4) Emergency Electrical Service (5) Details (K) Fire Alarm Systems, Section 19-13-D56 (i) General (5).

13. The following are violations based on observation, staff interview, and/or subsequent document reviews during an inspection on /3/28/13:
    a. The surveyor was not provided with documentation by MD #6 to indicate that the battery backup emergency lights were tested for thirty (30) seconds a month and ninety (90) minutes annually as required by the Connecticut Fire Safety Code 21.2.9.1 and 7.9. MD #6 stated that he does the testing but he does not document when the testing is done. This is a repeat citation from inspection conducted on 05/02/11;
    b. The facility did not ensure that nonflammable medical gas systems and equipment used for the administration of inhalation therapy and for resuscitative purposes was in compliance with the NFPA 99: "Heath Care Facilities" and the Connecticut Fire Safety Code:
        i. The surveyor accompanied by the Nurse Supervisor observed that the warning system for the gases was in alarm indicating that changeover to the reserve oxygen tank had occurred; i.e., visual alarm activated, the audible alarm was silent and when facility was between cases in the Operating Room the facility did connect the additional reserve tank to the system.
        ii. The surveyor accompanied by the Nurse Supervisor observed that the facility did not ensure that nonflammable medical gas systems and equipment used for the administration of inhalation therapy and for resuscitative purposes was in compliance with NFPA 99: Heath Care Facilities; i.e., "H" and "E" type cylinders in the Oxygen Room were not rendered stable either by being individually secured against a wall by a chain or provided with a base designed to render the cylinders stable. This is a repeat citation from inspection conducted on 05/02/11.
    c. The facility did not ensure that piped in medical gas systems are in compliance with NFPA 99, NFPA 70 and Public Act No. 02-92:
        i. The surveyor was not provided with documentation by MD #6 to indicate that the facility had established a maintenance program in accordance with the manufacturer's recommendations for the medical gas system as required in NFPA 99 "Heath Care Facilities" Section 4-5.5.2.3 (c); i.e., annual preventive maintenance, quality assurance testing and certification of the medical gas piping system by a qualified contractor was last conducted by Med Flo on 05/04/11. This is a repeat citation from inspection conducted on 05/02/11.
        ii. The surveyor was not provided with documentation by MD #6 to indicate that after repairs to the medical gas system, installation of the new Power Max for the vacuum

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

system, that the medical gas system was repaired, inspected and tested as required by NFPA 99 "Heath Care Facilities" Section 4-5.4 Performance Criteria and Testing and Public Act No. 02-92 an act ensuring the proper installation and maintenance of Medical Gas and Vacuum systems.

d. The surveyor was not provided with documentation by MD #1 to indicate that generator was inspected weekly and exercised under load for thirty (30) minutes per month in accordance with NFPA 99 "Heath Care Facilities" Section 3.4.4.1, and NFPA 110 "Standard for Emergency and Standby Power Systems", Chapter 6; i.e., documentation provided indicated that the facility generator was not inspected weekly and load testing was not conducted 06/12, 08/12 (unit off no fuel), 09/12(unit off no fuel), 013, 02/13 and 03/13 (Northeast Generator). The facility's required generator log was not maintained; i.e., last entry was 03/12. This is a repeat citation from insopection conducted in 5/02/11;

e. The surveyor was not provided with documentation by MD #1 to indicate that the smoke detection system was being inspected and tested on a semi-annual basis as required in the Connecticut fire Safety Code, NFPA 21.3.4 and 9.6.1.8 and NFPA 72 and as part of the facility's preventive maintenance program; i.e., documentation provided indicated that the required functional testing of the system was conducted by Advanced Electrical Systems on 06/13/11; the report dated 06/01/12 lacked an accurate inventory of alarm-initiating devices and circuit information; alarm notification appliances and circuit information, supervisory signal-initiating devices and circuit information, and initiating and supervisory device tests and inspections. Also semi-annual visual inspection and battery testing due 12/11 and 12/12 were not conducted. This is a repeat citation from inspection conducted on 05/02/11;

f. The facility did not ensure that where a required fire alarm system is out of service for more than 4 hours in a 24-hour period, the authority having jurisdiction is notified, and the building is evacuated or an approved fire watch is provided for all parties left unprotected by the shutdown until the fire alarm system has been returned to service as required by the Connecticut Fire Safety Code and NFPA 101 "Life Safety Code" 9.6.1.8;

g. During a tour of the basement, the surveyor while accompanied by MD #6, observed that the components of the fire alarm control panel were water damaged and that the system was inoperable. Interview with MD #6 indicated that the basement level of the facility was flooded on 10/29/13 and all mechanical items in the basement; i.e., fire alarm control panel, phone system, Med Gas Vacuum System, hot water heater, elevator etc., were "fried". MD #6 did not provide documentation to indicate that the Authority Having Jurisdiction (local fire marshal) was notified and that an approved fire watch was implemented when the facility was occupied. Subsequently the local fire marshal was informed of the alarm being out of service from 10/29/12 till the survey date of 03/28/13 and he directed the building owner to repair the fire alarm system and ordered a fire watch conducted by the local fire

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

department during hours of procedures until the alarm was repaired and fully functional;

h. The surveyor was not provided with documentation by MD #6 to indicate that fire drills were held at unexpected times under varying conditions at least quarterly on each shift and that drills included the transmission of a fire alarm signal as required by the Connecticut Fire Safety Code and NFPA 101 Section 21.7.1.2; i.e., documentation was not provided to indicate that fire drills were conducted on the first shift in the second quarter of 2012 and on the first shift in the fourth quarter of 2012. Documentation for the drill conducted on 01/10/13 did not indicate that a fire alarm signal was transmitted. This is a repeat citation from inspection conducted on 05/02/11;

i. The surveyor was not provided with documentation by the Nurse Supervisor to indicate that electrical receptacle outlets in patient care areas are inspected annually as required by the Connecticut Fire Safety code and NFPA 99 "Health Care Facilities", Section 3-3.3.3, and as part of the facility's preventive maintenance program; i.e., documentation provided indicated that electrical receptacle outlets in patient areas were tested 02/12 by Medicanix and not tested again till 03/22/13 by Medical Arts Support Corporation, exceeding the twelve month requirement for testing;

j. The surveyor was not provided with documentation that electrical devices in patient care areas are inspected annually as required in the Connecticut Fire Safety Code and NFPA 99 Section 7-6.2.1.2; i.e., documentation provided indicated that patient care electrical devices were tested 02/12 by Medicanix and not tested again till 03/22/13 by Medical Arts Support Corporation, exceeding the twelve month requirement for testing;

k. The surveyor was not provided with documentation by MD #6 to indicate that the facility maintains a permanent file of instruction and maintenance manuals for all patient care appliances as required in NFPA 99 "Health Care Facilities" section 7.6.3; i.e., instruction and maintenance manuals for all patient care appliances within the facility were not available;

l. The surveyor was not provided with documentation by MD #6 to indicate that the patient care appliances within the facility were inspected and/or maintenance as required in manufacture's instruction and maintenance manuals and NFPA 99 "Health Care Facilities" section 7.6.3 i.e., no inspection and maintenance logs maintained for manufacture's inspection and/or testing of patient care appliances.

m. The surveyor was not provided with documentation by MD #6 to indicate that the facility's emergency generator was functional at all times and operating as required in NFPA 99 "Health Care Facilities" Section 3-4.1.1.8; i.e., documentation provided by Northeast Generator Company dated 08/31/12 and 09/1012 indicated that the facility's emergency generator was off due to no fuel and/or fuel line to emergency generator "actually not submerged once tank gets below 1/3 full", no fuel available to emergency generator.

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

Additional documentation indicated that on 10/16/12 that city Oil filled the fuel tank that supplies the generator. Also documentation provided indicated that Northeast Generator Company conducted a load test of the emergency generator on 10/22/12.

n. The surveyor was not provided with documentation by MD #6 to indicate that the emergency generator's fuel supple storage tank was equipped with a low fuel sensing switch as required by NFPA 110 "Standard for Emergency and Standby Power Systems 3-4.2 Fuel Supply".

o. The surveyor was not provided with documentation by Nurse Supervisor to indicate that all employees are in-serviced on hire and annually as to their duties during a fire emergency as required by the Connecticut Fire Safety Code, NFPA 101 "Life Safety Code" 21.7.1 and annually as required in NFPA 99 "Health Care Facilities" 11-5.3.8; i.e., information not available for recent hires including OR Nurse/ PACU nurse who started on the day of the survey, 03/28/13.

p. The surveyor was not provided with documentation by the Nurse Supervisor to indicate that one or more specific responses of the emergency preparedness plan were held at least semi-annually as required by the referenced LSC and NFPA 99 "Health Care Facilities" Section 11-5.3.9; i.e., emergency preparedness drills were not conducted during 2011, 2012 and to date in 2013.

q. The surveyor was not provided with documentation by MD #6 to indicate that the facility followed state and local building codes and the 2003 International Building Code Chapter 1 section 105.1 requirements for permits; i.e., any owner or authorized agent who intends to construct, enlarge, alter, repair, move, demolish, or change the occupancy of a building or structure, or to erect, install, enlarge, alter, repair, remove, convert or replace any electrical, gas, mechanical or plumbing system, the installation of which is regulated by this code, or to cause any such work to be done, shall first make application to the building official and obtain the required permit. Copies of the required permits for the installation of the "Power Max" which was recently installed to the Gas and Vacuum System collection system that was located at the basement were not available for the mechanical, electrical and structural work performed by the contractors;

r. The surveyor was not provided with documentation by MD #6 to indicated that the Air Conditioning, Heating and Ventilating Systems met the required temperature and humidity levels, General Pressure Relationships and Ventilation of Certain Out-Patient Surgical Areas, and Filter Efficiencies for Central Ventilation and Air Conditioning Systems in Out-Patient Surgery Facilities; i.e., temperature, relative humidity, air changes per hour for required rooms and filter efficiencies conducted by a qualified contractor were not available;

s. The required clinical sink at the Recovery Room was not functional; i.e., water supply to the sink was off.

Exhibit B

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

IN RE: Center for Ambulatory Surgery, LLC
d/b/a Center for Ambulatory Surgery, LLC
32 Imperial Avenue
Westport, CT 06880

FIRST AMENDED CONSENT ORDER

WHEREAS, Center for Ambulatory Surgery, LLC of Westport, CT, located at 32 Imperial Avenue in Westport, Connecticut d/b/a Center for Ambulatory Surgery, LLC ("CAS"), has been issued license number 0292 to operate an outpatient surgical facility by the Connecticut Department of Public Health ("Department") pursuant to Chapter 368v of the General Statutes of Connecticut, as amended; and,

WHEREAS, the Facility Licensing and Investigations Section of the Department conducted an announced inspection at CAS for the purpose of reviewing implementation of the plan of correction for the violation letter dated October 7, 2011, a complaint investigation, and to conduct a monitoring visit; and,

WHEREAS, the Department, during the course of aforementioned inspections identified violations of the Connecticut General Statutes and/or Regulations of Connecticut State Agencies in - violation letters dated April 9, 2012 and June 21, 2012 (copy attached, Exhibits A and B); and

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

NOW THEREFORE, the FLIS of the Department acting herein and through Barbara Cass, R.N., Section Chief, and CAS, acting herein and through Joel B. Singer, M.D., Sole Owner of CAS, hereby stipulate and agree as follows:

1. The Consent Order executed with the Department on May 24, 2011 (Exhibit C – copy attached) shall be made part of this First Amended Consent Order.

2. Within thirty (30) days of the execution of this First Amended Consent Order, CAS shall contract with a Clinical Consulting Firm ("CCF") that has expertise in professional/clinical health care services specializing in outpatient surgical centers, evaluations of institutional systems and quality assessment reviews.

3. The Department must approve the CCF prior to the execution of the contract between CAS the CCF. The Licensee shall incur the cost of the CCF and any other costs necessary to comply with the terms of this First Amended Consent Order.

4. The CCF shall, at a minimum, conduct onsite reviews of CAS and direct observation of CAS staffs' performance as further specified in paragraph five (5) of this First Amended Consent Order. The CCF consultant shall consist of a credentialed healthcare professional(s) necessary to address the issues identified in the violation letters dated April 19, 2012 and June 21, 2012.

5. The CCF's review of CAS shall include, but not limited to, the following professional services and systems, and shall make written recommendations for improvements:
   a. Infection Control Program;
   b. Medical Record Documentation;
   c. Nursing Services;
   d. Nurse Staffing Levels;
   e. Nurse Supervisor Appointment;
   f. Nurse Staffing Training and Credentialing;
   g. Physician and APRN Credentialing;
   h. Operating Room;
   i. Instrument Reprocessing;
   j. Instrument supplies;
   k. Medication Storage;
   l. Government Body and Management;
   m. Surgical Services; and
   n. Quality Assessment and Performance Improvement Program.

6. The CCF and CAS shall enter into a written contract that includes the following requirements:

a. A minimum of four (4) hours per month of direct observation of staffs' performance for the period of the First Amended Consent Order;
b. Provide consulting services as needed;
c. Review of staffs' credentialing and orientation files to ensure compliance with state and federal laws and/or regulations; and,
d. The timeframes for the analysis and development of recommendations.

7. The initial onsite review by CCF must take place within thirty (30) days of the execution of the contract between CCF and CAS.

8. The CCF shall have fourteen (14) days after the completion of the initial onsite review, to develop reports and provide the report with its written recommendations to the CAS and the Department. Reports shall be submitted monthly. Neither party shall be provided with the opportunity to review the reports prior to the release and both parties shall receive a copy of the report simultaneously. The reports shall identify methods utilized for the analysis, areas reviewed and process, findings and recommendations. CCF recommendations shall include, as applicable, areas that need to be addressed, continued onsite consulting initiatives, and number of onsite hours per consultant. If CAS disagrees with any CCF findings or recommendations, the CAS, the CCF and the Department shall meet to discuss issues. CAS shall have the right to present information related to the CAS' areas of disagreement.

9. The Department shall have absolute and sole discretion to accept or reject the CCF recommendations should the parties not be able to reach mutual agreement.

10. CAS' Administrator and/or Nurse Supervisor and the Medical Director shall meet with the Department at quarterly intervals during the period of the First Amended Consent Order.

11. Any records maintained by CAS in accordance with any state or federal law or regulation or as required by this First Amended Consent Order shall be made available to the Department upon request.

12. Within thirty (30) days of the effective date of this First Amended Consent Order, CAS shall provide inservice education to all applicable staff regarding all policies and procedures. To the extent applicable staff is not available during the thirty (30) day period for inservice education, CAS shall develop a plan to ensure those staff members receive the inservice education as soon after the thirty (30) days as is possible. This inservice

education shall also be provided, as applicable, at the time of employment and shall be repeated at appropriate intervals as determined by CAS. Documentation of inservice education shall be maintained for review by the Department for a period of three (3) years.

13. Within ninety (90) days of the effective date of this First Amended Consent Order, CAS shall establish a mechanism, whereby the CAS' Quality Assessment and Performance Improvement Program ("QAPI"), on an ongoing basis, reviews and evaluates the following:

    a. Compliance with a comprehensive infection control program to minimize the risks of infections and communicable diseases;

        i. CAS shall incorporate into the QAPI, program indicators to analyze date and track quality pertinent to the specifications as outlined in this paragraph; and

        ii. Responsibility for the ongoing review and evaluation of the items identified in subparts (a) through (d) of this paragraph (13) shall be undertaken with continued oversight, including analyzing and tracking applicable quality indicators by the QAPI program;

    b. Compliance with Registered Staffing, Training, Credentialing, and Staff Appointments;

    c. Compliance with Physician and APRN Credentialing; and

    d. Compliance with Medical Record Documentation.

14. CAS shall within thirty (30) days of the effective date of this First Amended Consent Order submit the individual's name from the CCF assigned the responsibility to submit monthly reports for the period of this First Amended Consent Order.

15. Monthly reports related to this First Amended Consent Order shall be submitted to:

    Donna Ortelle, R.N., M.S.N., Supervising Nurse Consultant
    Facility Licensing and Investigations Section
    Department of Public Health
    410 Capitol Avenue, MS #12 FLIS
    P.O. Box 340308
    Hartford, CT 06134-0308

16. All parties agree that this First Amended Consent Order is an agreement with 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 CAS for violations of this First Amended 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, or any other administrative and judicial relief provided by law. This

First Amended Consent Order may be admitted by the Department as evidence in any proceeding between the Department and CAS in which compliance with its terms or the statutes or regulations related to CAS' outpatient surgical center license is at issue. CAS retains all of its rights under applicable law. The allegations contained in Exhibit A shall be deemed true in any subsequent proceeding in which the licensees compliance with this First Amended Consent Order or the statutes and regulations governing physicians and outpatient surgical facilities are at issue.

17. The execution of this document has no bearing on any criminal liability without the written consent of the Director of the Connecticut Medicaid Fraud Control Unit or the Bureau Chief of the Department of Criminal Justice's Statewide Prosecution Bureau.

18. The terms of this First Amended 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.

19. CAS understands that this First Amended 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 CAS of any other rights that it may have under the laws of the State of Connecticut or of the United States.

20. Should CAS not be able to maintain substantial compliance with the requirements of this First Amended Consent Order, the Department retains the right to issue charges including those identified in the Violation Letter dated May 23, 2011.

21. CAS had consulted with its attorney prior to the execution of this First Amended Consent Order.

WITNESS WHEREOF, the parties hereto have caused this First Amended Consent Order to be executed by their respective officers and officials. I, Joel B. Singer, M.D., am licensed to practice medicine and surgery in Connecticut, and I am the sole owner of CAS. I am authorized to sign this First Amended Consent Order on behalf of CAS. I have read the above First Amended Consent Order, and on behalf of CAS, I agree to the terms set forth therein. I further declare the execution of this First Amended Consent Order to be my free act and deed.

CENTER FOR AMBULATORY SURGERY, LLC -

By: Joel B. Singer MD
Joel B. Singer, M.D., Sole Owner

Personally appeared the above named Joel B. Singer, M.D., on 29th day of August, 2012, and made oath to the truth of the statements contained herein.

My Commission Expires: 10-31-12
(If Notary Public)

Notary Public
Commissioner of the Superior Court

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

9-12-12 2012 By: Barbara Cass

Barbara Cass, R.N., Section Chief
Facility Licensing and Investigations Section