

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

IN RE: Opticare Eye Health Centers, Inc.
 d/b/a Waterbury Outpatient Surgical Center
 87 Grandview Avenue
 Waterbury, CT 06708

STIPULATED AGREEMENT

WHEREAS, Opticare Eye Health Centers, Inc. (hereinafter the "Licensee"), has been issued License No.0071 to operate an Ambulatory Surgical Center known as Waterbury Outpatient Surgical Center, (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 May 16, 2007 and concluding on November 19, 2007; 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 December 4, 2007 (Exhibit A – copy attached); and

WHEREAS, the execution of this Stipulated Agreement does not constitute any admission or adjudication of any violation of the Connecticut General Statutes and/or Regulations of Connecticut State Agencies; and

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

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

1. Effective upon the execution of this Stipulated Agreement, the Licensee, through its Governing Body, Administrator and Director of Nursing Services, shall:
 - a. Review policies and procedures regarding the decontamination, cleaning, maintenance, handling, storage and sterilization of surgical instruments;
 - b. Ensure compliance with manufacturers' written instructions regarding the proper use, care and maintenance of surgical instruments.
2. The Licensee shall maintain its existing Quality Assurance Program (QAP) to review patient care issues, including those identified in the December 4, 2007 violation letter. Minutes of the QAP meetings shall be kept for a minimum of three (3) years and made available for review upon request of the Department
3. 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 Stipulated Agreement. The name of the designated individual shall be provided to the Department.
4. In accordance with Connecticut General Statute Sections 19a-494 (4) and 19a-494 (7) the Commissioner of the Department of Public Health hereby issues a reprimand to the Licensee to comply with all statutory and regulatory requirements pertaining to the operation of an Ambulatory Surgical Center.
5. The Licensee shall pay a monetary penalty to the Department in the amount of Two Thousand Dollars (\$2,000.00), by money order or bank check payable to the Treasurer of the State of Connecticut and mailed to the Department within two (2) weeks of the effective date of this Stipulated Agreement. The money penalty shall be directed to:

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

6. All parties agree that this Stipulated Agreement 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 the Licensee for violations of the Stipulated Agreement 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 the imposition of civil penalties or any other administrative and judicial relief provided by law. This Stipulated Agreement may be admitted by the Department as evidence in any proceeding between the Department and the Licensee in which compliance with its terms is at issue. The Licensee retains all of its rights under applicable law.
7. 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.
8. The terms of this Stipulated Agreement shall remain in effect for a period of two (2) years from the effective date of this document unless otherwise specified in this document.
9. The Licensee understands that this Stipulated Agreement 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.
10. The Licensee had the opportunity to consult with an attorney prior to the execution of this Stipulated Agreement.

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

OPTICARE EYE HEALTH CENTERS, INC

4/14/08
Date

By: *David Pierson*
David Pierson, President

STATE OF ~~CONNECTICUT~~ New Jersey

County of Camden ss April, 14 2008

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

My Commission Expires: July 23, 2012 *Eleanor Ann Carnuccio*
(If Notary Public) Notary Public
Justice of the Peace
Town Clerk
Commissioner of the Superior Court

ELEANOR ANN CARNUCCIO
Notary Public of New Jersey
My Commission Expires July 23, 2012

STATE OF CONNECTICUT,
DEPARTMENT OF PUBLIC HEALTH

4/21/08
Date

By: *Jean D. Leavitt*
Jean D. Leavitt, R.N., M.S., Section Chief
Facility Licensing and Investigations
Section



STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

EXHIBIT A
PAGE 1 OF 3

December 4, 2007

Nancy Noll, Administrator
Waterbury Outpatient Surgical Center
87 Grandview Avenue
Waterbury, CT 06708

Dear Ms. Noll:

An unannounced visit was made to Waterbury Outpatient Surgical Center on May 16, 2007 by a representative of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting an investigation and a certification inspection.

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.

You may wish to dispute the violations and you may be provided with the opportunity to be heard. If the violations are not responded to by December 18, 2007 or if a request for a meeting is not made by the stipulated date, the violations shall be deemed admitted.

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

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

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

Respectfully,

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

ESA:lsj

- c. Director of Nurses
Medical Director
President
C #6519



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: May 16, 2007

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT
STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES
WERE IDENTIFIED

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D56 Licensing of Outpatient Surgical Facilities (c) Ownership & Administration (1) and/or (d) Chief Executive Officer (3) and/or (i) General (5).

1. Based on staff interviews the facility failed to assure that patients were properly monitored during the administration of anesthesia. Findings include:
 - a. Person #1 stated that there were occasions when the anesthesiologist left the patient unattended during the administration of anesthesia to check on other patients. The Director of Nurses and LPN #1 stated that the anesthesiologist did, on occasion, leave the patient while under anesthesia, if a patient in the post or pre op areas developed a non emergent problem such as elevated blood pressure, nausea and vomiting. On 11/19/07 at 1:30 pm, the Anesthesiologist stated that as long as the patient in the operating room was stable, the patient was awake and the scrub tech and the surgeon were present, the anesthesiologist could step out to check on other patients if necessary. The patient was monitored with equipment and a nurse and the physician were always present. Since the surgical center was a small area, the anesthesiologist was only a matter of feet away from the operating room and was still able to see the patient. According to standards of the American Society of Anesthesiologists (last amended 10/25/05), because of the rapid changes in patient status during anesthesia, qualified anesthesia personnel shall be continuously present to monitor the patient and provide anesthesia care. In the event that an emergency requires the temporary absence of the person primarily responsible for the anesthetic, the best judgement of the anesthesiologist will be exercised in comparing the emergency with the anesthetized patient's condition and in the selection of the person left responsible for the anesthetic during the temporary absence. Facility policy regarding standards for basic anesthetic monitoring states that qualified personnel shall be present in the room throughout the conduct of all regional anesthetics and monitored anesthesia care and straight local anesthesia.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D56 Licensing of Outpatient Surgical Facilities (c) Ownership & Administration (1) and/or (e) Professional Staff (9)(A) and/or (c).

2. Based on clinical record review and staff interviews, the facility failed to follow their policy regarding the re-use of single use instruments. Findings include:
 - a. On 11/16/07 at 10:45 am, the Administrator stated that on 10/5/06, she received a letter from Person #1 who complained that the facility was re-using surgical instruments that

FACILITY: Waterbury Outpatient Surgical Center

Page 3 of 3
EXHIBIT A

DATE OF VISIT: May 16, 2007

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT
STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES
WERE IDENTIFIED

were identified as single use only. The Administrator conferred with the Director of Nurses and directed that the practice of re-use of single use instruments immediately cease. On 11/16/07 at 11:35 am, the Director of Nurses stated that the facility's re-use of single use instruments had been a common practice since 1986. Single use items included the 25 gauge retinal forceps and the crescent knife. Facility policy states that all disposable surgical items are single use items as per the manufacturer's guidelines. If any disposable are multiple use, it is per the manufacturer's guidelines. On 11/16/07 at 10:30 am, a representative of single use instruments stated that the company he represented did not recommend the re-use of any single use surgical instruments for any reason. All packaging of single use instruments were clearly labeled as single use as well as the insert information that accompanied the instruments.