State of New Jersey
DEPARTMENT OF HEALTH
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KAITLAN BASTON, MD, MSc, DFASAM
Commissioner

In Re Licensure Violation:	:	
	:	
Saddle Brook Endoscopic and Orthopedic Surgery Center	:	CURTAILMENT OF
	:	SURGICAL SERVICES ORDER
(NJ Facility ID# NJ31C0001037)	:	

TO: Dr. Sukdeb Datta,
Medical Director/Administrator
289 Market Street, Suite 2
Saddle Brook, New Jersey 07663

Dear Dr. Datta:

The Health Care Facilities Planning Act (N.J.S.A. 26:2H-1 et seq.) (the Act) provides a statutory scheme designed to ensure that all health care facilities are of the highest quality. Pursuant to the Act and N.J.A.C. 8:43E-1.1 et seq. (General Licensure Procedures and Standards Applicable to All Licensed Facilities), the Commissioner of Health is authorized to inspect all health care facilities and to enforce the Manual of Standards for Licensing of Ambulatory Care facilities set forth at N.J.A.C. 8:43A-1.1 et seq.

As you were notified through email and verbally on September 13, 2024, effective upon the facility's notification, the Department of Health (hereinafter, "the Department") ordered the curtailment of surgical services at Saddle Brook Endoscopic and Orthopedic Surgery Center (hereinafter "Saddle Brook "). This enforcement action was taken in accordance with the provisions set forth at N.J.A.C. 8:43E-3.1 (Enforcement Remedies available) and N.J.A.C. 8:43E-3.6 (Curtailment of Admissions) in response to serious deficiencies observed by Department staff at Saddle Brook during its re-licensure survey and federal recertification survey conducted from September 10, 2024, through September 12, 2024.

LICENSURE VIOLATIONS:

From September 10, 2024, through September 12, 2024, the Department conducted a state re-licensure survey in tandem with a federal recertification survey. During the survey, multiple issues were identified in the facility (see below).

N.J.A.C. 8:43A- 14.4(a)1 - Sterilization activities (decontamination and sterilization of surgical instruments), were not in accordance with AAMI, as follows:

1. Use of expired (2023) peel-packs (pouches used to contain instruments for sterilization) were identified as stated by SPD staff.

2. The sterilizer's (equipment used to sterilize surgical instruments) preventive maintenance was last completed in July 2022 and was due July 2023. The last reported service report in the facility log was November 2018. There was no documented evidence of a preventative maintenance record. Upon request, the facility failed to provide a service agreement with the vendor for the sterilizer and manufacturer's instructions for use of the sterilizer.

N.J.A.C. 8:43A: 5.2(a)2 and 3 - The Administrator failed to ensure managerial and operational activities of the center as evidenced by:

1. There was no evidence that a Quality Assurance Program or Plan for 2023 and 2024 was implemented.

2. Ventilation performance has not been checked for the past two years. For example, the decontamination room (where soiled surgical equipment is manually decontaminated before sterilization), a negative pressure room, was determined to have positive pressure during a tissue test by the surveyors. Upon request DON and Administrator were unable to provide evidence of an air balance report. Temperatures in all areas of the facility was not monitored.

3. The temperature in the Sterile Processing Department (SPD) Clean Workroom, was 98 degrees F, 52 degrees humidity on September 10, 2024, Day #1 of survey (per OSHA guidelines 68-76 F, 20-60 humidity). Building inspectors were on-site September 12, 2024 (Day #3) and it was observed that it was still 98 degrees, there was no air circulating in the clean workroom when the building inspector checked the vents.. Upon observation of the Pre-Op area outside of the Clean Workroom, the thermostat was observed to be OFF. An air balance report was requested from the DON and Administrator and none was provided as of end of survey.

4. Multiple contracts were expired: Pharmacy consultant, Infection Control consultant, Hospital Transfer Agreement with St. Joseph's medical Center.

5. CLIA waiver was expired.

N.J.A.C. 8:43A- 14.1(a), (b), and (c)- The facility failed to develop and implement an ongoing infection control program and plan for the facility.

1. There was no evidence of surgical site infection tracking for surgical cases for 2023 and 2024.

2. The DON was designated as the day-to-day IC lead even if there was no evidence of further education related to infection control surveillance, prevention.

3. The quality improvement program for infection prevention, was not done in 2023 or 2024.

4. The Infection Control consultant's (the Certified Infection Control [CIC] Professional) contract expired in 2023.

N.J.A.C. 8:43A:14.3(a)3 – The Facility failed to follow the Guidelines for Prevention of Surgical Site Infections (1999) (Infection Control and Hospital Epidemiology 1999; 20:247-278).

1. Infection prevention activities related to Surgical Site Infection (SSI) tracking was not done for 2023 and 2024 which was confirmed by the DON that the facility is not tracking surgical site infections.

N.J.A.C. 8:43A-15.2 (a) – The Facility failed to conduct drills of emergency plans on each shift at least quarterly.

1. There were no documented evidence that fire or disaster drills were conducted at least quarterly.

N.J.A.C. 8:43A-15.2(c) – The Facility failed to have Fire extinguishers examined annually and maintained in accordance with manufacturers' requirements, National Fire Protection Association (N.F.P.A.)10, as amended and supplemented, and N.J.A.C. 5:70, the New Jersey Uniform Fire Code.

1. The fire extinguishers not checked for a year and was last inspected on January 2023.

N.J.A.C. 8:43A-15.2(g) – The Facility failed to conduct testing of the emergency lighting which is required to be done at least monthly.

1. Not all emergency lights in the hallways are operational showing an absence of testing.

N.J.A.C. 8:43A-15.2(i) – The Facility failed conduct an annual inspection of the heating and ventilation system. The date of inspection, the results, and the inspector or agent conducting the inspection shall be documented.

1. There was no documented evidence of an annual inspection of the heating and ventilation system.

N.J.A.C. 8:43A-12.19 – The Facility failed to designate a consultant pharmacist who shall review all facility policies and procedures concerning the administration, control, and storage of medications at least semiannually.

1. The pharmacy consultant contract expired in 2023. There was no current active contract provided by facility.

N.J.A.C. 8:43A-17.4(a)13. The Facility failed to observe that all furnishings shall be clean and in good repair, and mechanical equipment shall be in good working order. Equipment shall be kept covered to protect from contamination and accessible for cleaning and inspection. Broken or worn items shall be repaired, replaced, or removed promptly.

and

N.J.A.C. 8:43A 4.1(a)2: The Facility failed to provide a safe physical plant equipped and staffed to maintain the facility and services.

1. Generator: The last time the Generator was provided with Preventative Maintenance was May 2019 (documented). A load test was last conducted in 2023. Upon observation, the battery terminal was corroded, the fault light was lit on the generator panel. There was no monthly run test or weekly visual test log for the generator. The facility does perform general anesthesia. This coming Tuesday per DON, they only have pain injections, no general anesthesia procedures. According to DON there was an event in 2023 where there was power failure and the generator did not kick in however, there were no patients in the facility at the time.

2. Radiology:
   a. C-Arm has not been checked since August 2022
   b. Staff do not wear dosimeters. There are no dosimeters in the facility available for staff at the current time. (Dosimeter badges are worn by facility staff during the use of the C-Arm. It detects and measures the amount of radiation exposure. The badges are sent out to a company that will provide a report of the radiation exposure).
   c. Testing for the Lead aprons was last completed August 2022; There were rips noted in the thyroid shield.
   d. No radiology technician. The anesthesiologist and surgeon/medical director are the ones operating the C-Arm during procedures. Review of the provider's files failed to contain training on C-arm.

N.J.A.C. 8:43A - 12.5(e) – The facility failed to comply with the proper monitoring of patients who have been administered an anesthetic agent for the purpose of creating conscious sedation shall be provided by an individual who is continuously present for the primary purpose of anesthesia monitoring, who is separate from the individual performing the operation. This individual shall be currently trained in Advanced Cardiac Life Support xxx;

1. Director of Anesthesiology Dr. Hagopian does not have a current ACLS certification in his file.

CURTAILMENT OF SURGICAL SERVICES:

The Department hereby orders the curtailment of surgical services at Saddle Brook effective end of business day, September 13, 2024, upon email and verbal notification to the facility.

Please be advised that N.J.A.C. 8:43E-3.4(a)(2) provides for a penalty of $250 per day from the date of admission to the date of discharge or lifting of the curtailment order for each patient provided surgical services in violation of this curtailment order.

FORMAL HEARING:

Saddle Brook is entitled to contest the curtailment by requesting a formal hearing at the Office of Administrative Law (OAL). Saddle Brook may request a hearing to challenge either the factual survey findings or the curtailment, or both. Saddle Brook must advise this Department within 30 days of the date of this letter if it requests an OAL hearing regarding the curtailment.

Please forward your OAL hearing request to:

Attention: OAL Hearing Requests
Office of Legal and Regulatory Compliance, New Jersey Department of Health
P.O. Box 360
Trenton, New Jersey 08625-0360

Corporations are not permitted to represent themselves in OAL proceedings. Therefore, if Saddle Brook is owned by a corporation, representation by counsel is required. In the event of an OAL hearing regarding the curtailment, Saddle Brook is further required to submit a written response to every charge as specified in this notice, which shall accompany its written request for a hearing.

Due to the emergent situation and the immediate and serious risk of harm posed to the patients, the Department will not hold the curtailment in abeyance during any appeal of the curtailment.

Failure to submit a written request for a hearing within 30 days from the date of this notice will render this a final agency decision. The final agency order shall thereafter have the same effect as a judgment of the court. The Department also reserves the right to pursue all other remedies available by law.

Thank you for your attention to this important matter and for your anticipated cooperation. Should you have any questions concerning this order, please contact Lisa King, Office of Program Compliance, at (609) 376-7751.

Sincerely,

Lisa King /jlm

Lisa King, Program Manager
Office of Program Compliance
Division of Certificate of Need and Licensing

LK:JLM:RSM/nj
DATE: September 17, 2024
E-MAIL (sdattamd@gmail.com)
REGULAR AND CERTIFIED MAIL
RETURN RECEIPT REQUESTED
Control # AX24027