



State of New Jersey
DEPARTMENT OF HEALTH

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JUDITH M. PERSICILLI, RN, BSN, MA
Commissioner

IN RE: Licensure Violation) Notice of Directed Plan of Correction (DPOC)
NJ Facility ID # NJ 71702)
CMS # 310091)

TO: Lynn Righter-Shookla, AVP/Clinical Operations/Quality
Salem Medical Center
310 Woodstown Road
Salem, NJ 08079

Effective immediately, the Department of Health (Department) is ordering a Directed Plan of Correction (DPOC) requiring Salem Medical Center (the Hospital) to file weekly staffing reports with the Department to demonstrate compliance with the requirements for staffing its computerized tomography scan, laboratory and blood bank. This action is taken in accordance with the provisions set forth at N.J.A.C. 8:43E-2.4 in response to a record of deficiencies observed by Department staff in the Hospital.

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 Hospital Licensing Standards set forth at N.J.A.C. 8:43G-1.1 et seq.

LICENSURE VIOLATIONS:

During a complaint survey of Salem Medical Center on June 22, 2022, Department staff identified an immediate jeopardy at the facility for the failure to provide the required emergency medical services. Specifically, deficient practices were identified because of the facility's failure to provide computed tomography (CT) scan services, laboratory services and blood bank services. N.J.A.C. 8:43G-12.7(w) requires that radiology services for emergency needs shall be available to the emergency department 24 hours a day. N.J.A.C. 8:43G-12.7(x) requires that clinical laboratory services for emergency needs shall be available to the emergency department 24 hours a day. N.J.A.C. 8:43G-28.10(c) provides that, if provided by the hospital, computer tomography shall be available within one hour at all times, when deemed appropriate in the judgement of the radiologist, unless the machinery is temporarily disabled or in use. N.J.A.C. 8:8 sets forth requirements that blood banks must follow for the handling, processing, storage, distribution and administration of blood. Specifically, N.J.A.C. 8:8-2.3 (a) states that the blood bank shall have one or more supervisors who under the general direction of the blood bank director supervise all functions related to the collection, processing, testing, storage, and distribution of blood and blood components, and in the absence of the blood bank director are responsible for the proper performance of these procedures. N.J.A.C. 8:8-2.3 (d) specifies the requirements regarding personnel responsible for the collection, processing, compatibility testing, storage, or distribution of blood and blood components, including being adequate in number, educational background, training and experience, or a combination thereof, to assure competent performance of their assigned functions and ensure adherence to N.J.A.C. 8:8. The personnel shall have capabilities commensurate with their assigned functions, a thorough understanding of the procedures they perform, the necessary training or experience, and adequate

information concerning the application of pertinent provisions of the rules in N.J.A.C. 8:8 as related to their respective duties and responsibilities.

Additionally, personnel were not immediately available to all emergency department (ED) patients requiring these services. A notice of immediate jeopardy was issued to Salem Medical Center on June 22, 2022, with a request that the hospital submit a plan of removal for correcting the immediate jeopardy. The immediate jeopardy was removed on June 23, 2022, when Salem filed a removal plan that was accepted by the Department.

Review of the medical record for a patient revealed that on June 10, 2022, the patient arrived in the ED at 9:36 PM with complaints of abdominal cramping, nausea, vomiting, pounding headache, and pain to the forehead. The patient's pain was rated 10 out of 10. The patient was pregnant (unknown gestation) and had not had prenatal care for this pregnancy. The ED Physician documentation stated that there was a concern for a subarachnoid hemorrhage based on the patient's history, but that no CT available at this time. The notes stated further that the patient is attempting to find a ride as a transfer may take some time. At 9:00 PM the physician documented that the patient found a ride. The patient was discharged at 9:05 PM. The ED Nurse Documentation stated that the patient was discharged with advice to go to nearest hospital with CT capability. Review of the CT Staff Schedule with a staff member for June 10, 2022, revealed that there was no staff coverage from 7:00 PM - 7:00 AM shift. On June 22, 2022, the survey team interviewed an ED Physician for the hospital, who stated that there was a concern for subarachnoid hemorrhage and ectopic pregnancy due to the patient presenting with the worst headache (pain 10/10) and abdominal cramping. The physician stated further that "[t]here was (sic) no lab or CT services available on June 10, 2022. The patient was offered an ambulance which might take a significant delay, or the patient can find a ride to go to another facility with CT capability." During an interview, a hospital staff member stated that the patient's vital signs were stable, with no neurological deficits, and was not bleeding vaginally, thus it was safe for the patient to be discharged to go to another facility.

Review by survey staff of a second patient's medical record revealed that on June 10, 2022, the patient arrived at 11:55 PM, with complaints of leg swelling. On June 11, 2022, at 12:07 AM, the ED Physician documentation indicated "concerns for heart failure" and that lab work and Chest X-Ray was ordered. At 5:35 AM, the ED Physician documentation stated that "the labs are still pending results as they have to go to Vineland to be analyzed. The patient then requested to leave." The patient left against medical advice on June 11, 2022, at 5:46 AM. The survey team reviewed the ED Divert Log, which indicated that on June 10, 2022, the ED was on Total Care Divert from 9:00 – 12:00 due to "No Lab, No Blood Bank, No CT Scan."

The survey team also determined that the microbiologist on staff during the survey was not trained to handle and distribute blood to emergency room patients in accordance with the requirements of N.J.A.C. 8:8.

The inability of the facility to provide laboratory, CT services and blood labs for patients presenting with emergency medical needs places patients at risk for serious harm, injury, impairment or death.

In sum, in June 2022, the Department has identified numerous deficiencies. These violations pertain to the failure to provide appropriate staffing to care for patients using the emergency services at the Hospital.

DIRECTED PLAN OF CORRECTION:

The Department is, therefore, ordering the facility to file weekly staffing reports beginning no later than July 5, 2022, detailing how the facility met the basic staffing requirements set forth above for the prior week.

The Hospital should send weekly staffing reports demonstrating compliance with the staffing requirements of N.J.A.C. 8:43G to Health Facility Survey and Field Operations, via facsimile to (609) 943-3013, Attention: Kimberly Hansen, Acute Care Program Manager, or via email to Kimberly.Hansen@doh.nj.gov. The Hospital should send weekly staffing reports demonstrating compliance with the staffing requirements of N.J.A.C. 8:8-2.3 to Public Health and Environmental Laboratories, Robert R. Rees, Program Manager, Blood Bank Licensing and Regulatory Compliance, at Robert.Rees@doh.nj.gov.

These weekly reports shall include timely status updates regarding:

- Identified areas of non-compliance
- Corrective measures to address identified areas of non-compliance
- Status of corrective measures implementation

In addition, the Hospital is directed to maintain timely communication with the Department, including participation on weekly update calls, and additional calls as may be required by Department staff, including both the Hospital Administrator and the physician or other member of the Hospital's administrative staff responsible for emergency department services.

Please be advised that this DPOC shall remain in place until the facility is otherwise notified by a representative of this Department.

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) 984-8128.

Sincerely,



Gene Rosenblum, Director
Office of Program Compliance
Division of Certificate of Need and Licensing

DATE: June 30, 2022
FACSIMILE (856) 935-3175
E-MAIL lrighershockla@smc.health
REGULAR AND
CERTIFIED MAIL:
RETURN RECEIPT REQUESTED

Salem Medical Center
Notice of Directed Plan of Correction (Administrative Consultant)
June 30, 2022

Control # AX

- c. Stefanie Mozgai
Pamela Lebak
Kimberly Hansen
Robert Rees
Lisa King