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KAITLAN BASTON, MD, MSc, DFASAM Acting Commissioner

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In Re Licensure Violation:

AMENDED DIRECTED PLAN OF CORRECTION

Carewell Health Medical Center

(NJ Facility ID# 10704)

TO: Paige Dworak, FACHE, President and Chief Executive Officer

Carewell Health Medical Center

300 Central Avenue East Orange, NJ 07018

As you were notified by verbal order on February 21, 2024, effective immediately, the Department of Health (Department) is ordering an amended directed plan of correction to Carewell Health Medical Center ("the Medical Center" or "Carewell Health"). The Department is amending the Directed Plan of Correction (DPOC) issued to Carewell Health on February 1, 2024, to require Carewell Health to submit a plan for the transfer of any patients who require radiological and CT scan services to a local area hospital, including a plan for transport of such patients, and to require Carewell to increase the submission of staffing plans from weekly to daily. The requirements of the amended directed plan of correction are set forth in greater detail below.

By way of background, on February 1, 2024, the Department issued a DPOC requiring Carewell Health to file weekly staffing reports with the Department to demonstrate compliance with the requirements for staffing its radiology and computerized tomography (CT) scan departments, and the Medical Center was also required to participate in weekly status conference calls with the Department to discuss the staffing reports. The DPOC also required the Medical Center to immediately file the hospital's protocol for meeting patients' needs in a timely manner, as required by N.J.A.C. 8:43G-12.7(h).

These enforcement actions are being taken in accordance with the provisions set forth at N.J.A.C. 8:43E-2.4 (Plan of Correction) and 3.1 (Enforcement Remedies Available), after Staff from the Department's Health Facility Survey and Field Operations (HFS&FO or Survey) were on-site at Carewell Health and found significant deficiencies in the facility's ability to provide radiological services to patients in accordance with N.J.A.C. 8:43G-7A.3(a)(3) and N.J.A.C. 8:43G-12.7(w).

LICENSURE VIOLATIONS:

The Department has received credible evidence of deficient staffing practices at Carewell Health Medical Center, a stroke designated hospital. Due to lack of staffing for the CT scan and radiology departments, the Medical Center has failed to provide CT scan services at the Medical Center. The Medical Center has had ongoing staffing issues pertaining to CT services since December 25, 2023 and pertaining to X-ray services since January 24, 2024.

Pursuant to N.J.A.C. 8:43G-7A.3(a)(3), hospitals designated as primary stroke centers are required to provide "[n]euro-imaging services capability that is available 24 hours a day, seven days a week, such that imaging shall be performed within 25 minutes following order entry. Such studies shall be interpreted by a board-certified radiologist, board-certified neurologist or residents who interpret such studies as part of their training in an Accreditation Council of Graduate Medical Education-approved radiology training program with concurrence by a board-certified radiologist or board-certified neurologist within 20 minutes of study completion." Furthermore, N.J.A.C. 8:43G-7A.3(a)(3)(i) provides that "[n]euro-imaging services shall, at a minimum, include computerized tomography scanning or magnetic resonance imaging, as well as interpretation of the imaging."

Additionally, N.J.A.C. 8:43G-12.7(w) requires a hospital to provide radiology services for emergency needs in its the emergency department 24 hours a day. N.J.A.C. 8:43G-28.10(c) provides that, "[i]f 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."

Department surveyors have identified the following dates/shifts at the Medical Center with a lapse in radiology services for the CT and X-ray departments:

For the CT department: 12/25 (4PM-12AM); 12/30/23 (8PM-12AM); 1/5/24 (12PM-4PM); 1/6/24 (5PM-12AM); 1/8/24 (12AM-8AM); 1/9/24 (4PM-8PM); 1/14/24 (8PM-12AM); 1/16/24 (4P-12AM); 1/20/24 (4PM-12AM); 1/21/24 (8PM-12AM); and 1/28/24 (4PM-8PM). The CT department had a "lapse" in service 11 times from 12/25/23-1/30/24.

For the X-ray department: 1/1/24 (8AM-3PM); 1/9/24 (12AM-8AM); 1/16/24 (4PM-6PM); and 1/20/24 (4PM-8PM).

Surveyors determined that no CT technicians were scheduled for: 2/2/24 (4PM-12AM); 2/3/24 (4PM-12AM); 2/4/24 (8AM-4PM, 4PM-12AM); 2/9/24 (4PM-12AM); and 2/10/24 (4PM-12AM).

Surveyors determined that no X-ray technicians were scheduled for 2/3/24 (8AM-4PM; 4PM-12AM); and 2/10/24 (8AM-4PM; 4PM-12AM).

Surveyors reported that the Radiology Director stated that the contingency plan to address the immediate gaps in the schedule is to "try to convince agency tech or staff tech to pick up the shifts."

The surveyors determined that the CT Department currently has six CT technicians (employment status not identified) with one currently on a leave of absence, and no agency CT technicians.

The surveyors determined that the X-ray Department currently has eight X-ray technicians to cover the radiology and emergency departments. The staff schedule for 1/14/24-2/10/24 did not identify any agency X-ray technicians. Four agency X-ray technicians were identified on the 12/17/23-1/13/24 schedule.

The survey team also substantiated that the Medical Center does not have a protocol to meet the needs of the patients in a timely manner, as required by N.J.A.C. 8:43G-12.7(h). N.J.A.C. 8:43G-12.7(h) requires a hospital to implement a protocol for meeting the needs of patients in a timely manner, such as augmenting staff and notifying or diverting ambulances when a specified volume of patients in the emergency department is reached, or patient waiting time before initial evaluation by qualified medical personnel exceeds four hours.

On February 14, 2024, Department Survey staff were on-site at Carewell Health and found additional gaps in radiology staff coverage. Specifically, the surveyors found that there is no CT coverage for 2/16/24 from 4 pm to 12 am and no X-ray coverage for 2/18/24 from 8 am to 12 am. The Surveyors also identified an immediate jeopardy when placement of a Central Venous Line in a patient was not confirmed via X-ray prior to use for the administration of medication. The delay in obtaining the confirmation of the placement was due to lack of X-ray staff. In addition, Survey staff has confirmed that Carewell Health had no Xray coverage from 8:00 p.m. through 12:00 a.m. on the evening of February 19, 2024.

AMENDED DIRECTED PLAN OF CORRECTION:

As you were notified in the verbal order on February 21, 2024, the Department is ordering Carewell Health to submit a written plan for the transfer of any patients who require radiological and CT scan services to a local area hospital, including a plan for transport of such patients. The plan must include a mechanism for alerting the area hospital in advance of the gap in radiological services at Carewell. The amended DPOC also requires Carewell Health to have appropriate medical transportation on-site, twenty-four hours a day for one week, for any patient requiring CT or radiological services. At the conclusion of one week, the Department will re-evaluate this requirement.

The Medical Center shall send the transportation plan by February 23, 2024, to Health Facility Survey and Field Operations, via facsimile to (609) 943-3013, Attention: Kimberly Hansen, Acute Care Program Manager, and via email to Kimberly.Hansen@doh.nj.gov; gene.rosenblum@doh.nj.gov; and lisa.king@doh.nj.gov.

The Department is also ordering the facility to file daily staffing reports beginning no later than February 23, 2024, detailing how the facility will meet the basic staffing requirements set forth

above for the day the staffing report is filed, and how the Medical Center met the staffing report requirements for the previous day. The staffing plan must include staffing for all shifts and back-up coverage for any radiology and CT scan staff who call out.

The Hospital shall send the daily 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.

These daily 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 CT and emergency department services.

Please be advised that this amended DPOC and the initial DPOC issued on February 1, 2024, shall remain in place until the facility is otherwise notified by a representative of this Department.

Please also be advised that you may be subject to other enforcement remedies in addition to this order.

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

rue Rosallin

DATE: February 21, 2024 FACSIMILE 973-989-3122

E-MAIL: paige.dworak@carewellhealth.org and clay.mcclain@carewellhealth.org

REGULAR AND CERTIFIED MAIL:

RETURN RECEIPT REQUESTED Control # AX24005

c. Stefanie Mozgai Pamela Lebak Kimberly Hansen Michael Kennedy Gene Rosenblum Lisa King