IN RE: Licensure Violation Cease and Desist Order
   NJ Facility ID # NJ 11103

TO: Janet L. Ready, President
    Penn Medicine Princeton Medical Center
    1 Plainsboro Road
    Plainsboro, NJ 08536

This letter will confirm our October 22, 2018, telephone conversation with you, James Demetriades, and Certificate of Need, Office of Program Compliance, staff from the Department of Health (the “Department”), wherein you were informed that, effective immediately, the Department ordered Penn Medicine Princeton Medical Center (the “Hospital”) to cease and desist the use of rooms D.2158 (also referred to as “OR 12”) and D.2160 (also referred to as “OR 14”) as operating rooms. You confirmed that the hospital has ceased using these two rooms as operating rooms.

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:

The Hospital applied to the Department to convert room D.2158, a cystoscopy room, and room D.2160, a multi-purpose procedure room, into new operating rooms. Department staff conducted an approval survey on February 20, 2018, but the rooms at that time did not meet required standards for approval. On March 23, 2018, the Hospital submitted a Plan of Correction specifying that the rooms “have not been utilized for patient care, treatment or services since October 5, 2017 when construction began for the conversion project and will remain closed indefinitely until which point the project is reevaluated for scope of work and licensure.” The Department accepted this Plan of Correction on April 9, 2018.
Penn Medicine Princeton Medical Center
Cease and Desist Order
November 2, 2018

Staff from the Department’s Health Facility Survey and Field Operations (HFS&FO) were on-site at the Hospital on October 19, 2018 for a complaint investigation regarding use of an unapproved operating room. Survey staff substantiated through operating room logs provided by the Hospital and staff interviews that both rooms D.2158 and D.2160 have been used for operations without prior departmental approval. Furthermore, the surveyors observed the rooms and found that the ceilings in the rooms had not been replaced and the room ventilation had not been brought into compliance with FGI and ASHRE standards. Therefore, the Hospital did not implement the corrective action required to address the findings from the approval survey, and the rooms should have remained out of service as operating rooms pursuant to the approved Plan of Correction.

The Hospital applied to the Department seeking a waiver of the minimum square footage requirement for proposed new OR 14, advising the Department that it would only be used for lower acuity surgical procedures that required less surgical equipment. The Hospital also requested a waiver regarding the monolithic ceiling requirements, setting forth an alternative ceiling proposal. Despite neither waiver request having been approved, the Hospital utilized the rooms for operative procedures as evidenced by the operations log. These violations pertain to the care of patients using the services at the Hospital.

CEASE AND DESIST ORDER:

The Department has, therefore, ordered the Hospital to cease and desist the use of rooms D.2158 and D.2160 as operating rooms. This DPOC shall remain in place until the Hospital is otherwise notified by a representative of this Department.

Finally, be advised that Department staff will monitor the Hospital’s compliance with this notice to determine whether corrective measures are implemented by the Hospital in a timely fashion. Failure to comply with these and any other applicable requirements, as set forth in pertinent rules and regulations, may result in the imposition of penalties. The Department also reserves the right to pursue any and 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) 984-8128.

Sincerely,

[Signature]
Gene Rosenblum, Director
Office of Program Compliance
Division of Certificate of Need and Licensing
Penn Medicine Princeton Medical Center
Cease and Desist Order
November 2, 2018

GR:jlm

DATE: November 2, 2018
FACSIMILE (609) 853-7101
E-MAIL jready@princetonhc.org
REGULAR AND
CERTIFIED MAIL: 7009 1680 0002 1239 4222
RETURN RECEIPT REQUESTED
Control # AX 18018

c. Alison Gibson
   Stefanie Mozgai
   Lisa King
   Jean Markey