State of New Jersey
DEPARTMENT OF HEALTH
PO BOX 358
TRENTON, N.J. 08625-0358
www.nj.gov/health

PHILIP D. MURPHY
Governor

TAHESHA L. WAY
Lt. Governor

JEFFREY A. BROWN
Acting Commissioner

In Re Licensure Violation:	:	
	:	
Jersey City Medical Center	:	NOTICE OF ASSESSMENT OF
	:	
	:	PENALTIES
	:	
(NJ Facility ID# NJ10904)	:	
	:	

TO:

Joanne Reich, Administrator
Jersey City Medical Center
355 Grand Street
Jersey City, NJ 07302
Joanne.Reich@rwjbh.org

Dear Ms. Reich,

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 N.J.A.C. 8:43E-1.1 et seq., General Licensure Procedures and Standards Applicable to All Licensed Facilities, the Commissioner of the Department of Health (the "Department") 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:

Staff from the Department visited the Jersey City Medical Center (the Facility) on February 27, 2024, February 28, 2024, and February 29, 2024, for the purpose of a conducting a complaint survey. The report of this visit, which is incorporated herein by reference, substantiated violations of N.J.A.C. 8:43G-23.2(a)(5) and N.J.A.C. 13:39-10.3(c).

N.J.A.C. 8:43G-23.2(a)(5) provides that the pharmacy and therapeutics committee, or its equivalent, shall review, approve, and ensure implementation of policies and procedures addressing at least the following areas: Storage and distribution of drugs, including, at least, dispensing devices (if used in the hospital), emergency drugs and kits, and control and accountability of controlled substances in accordance with applicable laws and regulations.

N.J.A.C. 13:39-10.3(c)(2) and (5) of the New Jersey State Board of Pharmacy Regulations provide that the pharmacist-in-charge shall be responsible for:

> 2) Ensuring that there are written policies and procedures, which are reviewed and approved by the pharmacist-in-charge for system operation, safety, security, accuracy, and access, patient confidentiality and prevention of unauthorized access and malfunction, and ensuring compliance with such policies and procedures;
> ...
> 5) Assigning, discontinuing or changing personnel access to the automated medication system.

The facts substantiating the violations of these rules are set forth below.

On February 27, 2024, at 12:35 p.m., the Director of Pharmacy stated during an interview that the pharmacy staff did not have access to the corporate drug diversion software "Med Assist," and that pharmacy staff performed randomized audits to ensure the accountability of Controlled Dangerous Substance (CDS) inventory and usage in patient care areas.

On February 28, 2024, at 9:50 a.m., the Director of Pharmacy stated that Pyxis consoles located in procedural areas are not profiled by the pharmacy department, and all medications stored inside could be removed with an override.

On February 28, 2024, at 9:45 a.m., the Director of Pharmacy stated that S25, a former pharmacy staff member in charge of monitoring CDS reports daily, no longer worked in the facility, and since S25 left, the department reviewed CDS accountability reports for the processes completed within the pharmacy department, such as monitoring the narcotic safe transactions. Regarding the monitoring of CDS usage in patient care areas, the Director of Pharmacy stated that he/she monitored CDS overridable drug reports from patient care areas "randomly."

On February 28, 2024, at 10:45 a.m., the Director of Pharmacy stated that while the pharmacy staff completed CDS usage monitoring, the facility did not maintain documentation of the CDS monitoring. The Facility was unable to provide evidence that the pharmacy staff was monitoring the CDS distribution, administration, and waste within the facility.

On February 28, 2024, at 1:55 p.m., S16, the Information Technology (IT) Pharmacist, introduced by the Director of Pharmacy as a staff member responsible for monitoring some of the CDS accountability reports, stated that while CDS reports should be monitored on a routine basis, he/she had not completed report monitoring in January or February of 2024. S16 also confirmed that the pharmacy staff did not have documentation to ensure monitoring of CDS usage in the Facility was completed on a routine basis.

On February 28, 2024, at 10:55 a.m., the Director of Pharmacy stated that the facility did not have a current updated policy that outlined the process used to monitor the CDS usage in patient care areas to ensure accountability, but showed a "Pyxis Controlled Substance Minimum Monitoring Standards" policy, dated 6/15, which the facility followed. The Director could not provide documentation that the monitoring required by this policy was completed.

On February 28, 2024, review of the facility's investigation, including DEA Form-106 and the Pyxis Reconciliation Report for S24, identified that S24 removed approximately 304 vials of Fentanyl 100 micrograms/ 2 milliliters from the Pyxis

consoles over the course of 9 working shifts between 1/22/24 and 2/14/24: on 1/29/24 at 10:13 a.m., two vials were removed; on 1/30/24 at 10:04 a.m., two vials were removed; on 2/1/24 at 9:37 a.m., two vials were removed; on 2/9/24 at 7:11 a.m., two vials were removed; on 2/12/24 at 8:38 a.m., two vials removed; and on 2/14/24 at 5:06 p.m., four vials removed. This discovery was identified by the nurses who reported the suspicious behavior and was not identified by the routine audit of CDS usage. The Facility failed to ensure the accountability of CDS.

On February 28, 2024, at 1:25 p.m., the Director of Pharmacy stated there was no routine audit of CDS usage in the procedural areas, which was not in accordance with Facility policy.

On February 28, 2024, at 12:20 p.m., six of eleven medical records reviewed lacked documentation of a physician's order for Fentanyl, though Fentanyl was missing.

A review of the Pyxis Console Access Reports for S25, S26, and S27 indicated that the three RNs could access the Pyxis consoles, and CDS stored inside, in 29 areas. The Director of Pharmacy stated that the Facility had neither policies nor procedures that addressed the limitation of staff access to the Pyxis consoles, and the CDS stored inside, as required by State regulations.

On February 27, 2024, at 9:45 a.m., the Vice President of Quality, Safety, and Regulatory confirmed the that the Facility identified and reported an incidence of potential drug diversion on 2/15/24; however, the Facility failed to report the incident of CDS theft or loss discovered to the New Jersey Board of Pharmacy and NJ Drug Control Unit as required by facility policy. The facility reported the event to these agencies on 2/27/24, after the documentation was requested.

During an interview on February 27, 2024, at 10:40 a.m., S7, an RN Nurse Educator, stated that when a CDS needs to be wasted, a second RN is required as a witness, and the waste documentation should be completed immediately after the medication is removed from Pyxis. On 2/28/24, the Pyxis "Dispense to Reconciliation Report" for S24, dated 1/22/24 to 2/14/24, was reviewed, indicating that 72 of 135 incidences of Fentanyl wasting were completed more than one hour after the medication was removed from the Pyxis console. The late wasting of the

Fentanyl occurred from 1.04 hours up to 9.41 hours after the removal of the medication from the Pyxis console.

On February 28, 2024, at 1:40 p.m., Director of Pharmacy confirmed that the Facility did not have a policy that addressed the maintenance of the Pyxis patient list, as required by State regulations.

In summary, the Facility failed to: ensure the implementation of policies and procedures that address the monitoring of, and accountability for, CDS; the development and implementation of policies and procedures that address the limitation of staff access to the Pyxis automated dispensing cabinet and the CDS inside; the implementation of policies and procedures that address the reporting of CDS loss or diversion to required agencies; the implementation of policies and procedures that address the wasting of CDS; and the development and implementation of policies and procedures that address the maintenance of the patient list in Pyxis, and the accessibility of medications stored inside. See N.J.A.C. 8:43G-23.2(a)5. Furthermore, the pharmacist-in-charge failed to ensure that there were written policies and procedures, which must be reviewed and approved by pharmacist-in-charge, for system operation, safety, security, accuracy, and access, patient confidentiality and prevention of unauthorized access and malfunction, as well as assigning, discontinuing or changing personnel access to the automated medication system. See N.J.A.C. 13:39-10.3 (c)(2) and (5).

MONETARY PENALTIES:

N.J.A.C. 8:43E-3.4(a)(8) provides that the Department may assess a monetary penalty of $1,000 each day noncompliance is found where there are multiple deficiencies related to patient care or physical plant standards throughout a facility. The Department is assessing a $1,000 per day penalty for the facility's failure to comply with the requirements of N.J.A.C. 8:43G-23.2(a) and N.J.A.C. 13:39-10.3(c)(2) and (5), from January 22, 2024 (date S5 was first documented to have taken Fentanyl vials) to May 30, 2024 (completion date of education for staff) or $1,000 x 129= $129,000. These violations of the proper creation and administration of policies and noncompliance by the pharmacist-in-charge can result in a serious risk of harm to residents and staff, as well as the public at large, especially when dealing with a substance as lethal as Fentanyl.

The total penalty for these violations is $129,000, for violations of N.J.A.C. 8:43G-23.2(a)(5), N.J.A.C. 13:39-10.3 (c)(2), and N.J.A.C. 13:39-10.3 (c)(5).

The total amount of this penalty is required to be paid within 30 days of receipt of this letter by certified check or money order made payable to the "Treasurer of the State of New Jersey" and forwarded to Office of Program Compliance, New Jersey Department of Health, P.O. Box 358, Trenton, New Jersey 08625-0358, Attention: Lisa King. **On all future correspondence related to this Notice, please refer to Control AX24037.**

INFORMAL DISPUTE RESOLUTION (IDR):

N.J.A.C. 8:43E-2.3 provides facilities the option to challenge factual survey findings by requesting Informal Dispute Resolution with Department representatives. Facilities wishing to challenge only the assessment of penalties are not entitled to IDR review, but such facilities may request a formal hearing at the Office of Administrative Law as set forth herein below. Please note that the facility's rights to IDR and administrative hearings are not mutually exclusive and both may be invoked simultaneously. IDR requests **must be made in writing within ten (10) business days from receipt of this letter** and must state whether the facility opts for a telephone conference, or review of facility documentation only. The request must include an original and ten (10) copies of the following:

1. The written survey findings;

2. A list of each specific deficiency the facility is contesting;

3. A specific explanation of why each contested deficiency should be removed; and

4. Any relevant supporting documentation.

Any supporting documentation or other papers submitted later than 10 business days prior to the scheduled IDR may not be considered at the discretion of the IDR panel.

Send the above-referenced information to:

Nadine Jackman
Office of Program Compliance
New Jersey Department of Health
P.O. Box 358
Trenton, New Jersey 08625-0358

The IDR review will be conducted by professional Department staff who do not participate in the survey process. **Requesting IDR does not delay the imposition of any enforcement remedies.**

FORMAL HEARING:
The Jersey City Medical Center is entitled to challenge the assessment of penalties pursuant to N.J.S.A. 26:2H-13, by requesting a formal hearing at the Office of Administrative Law (OAL). The Jersey City Medical Center may request a hearing to challenge the factual survey findings and/or the assessed penalties. The Jersey City Medical Center must advise this Department within 30 days of the date of this letter if it requests an OAL hearing regarding the findings and/or penalty.

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

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.

Corporations are not permitted to represent themselves in OAL proceedings. Therefore, if the Jersey City Medical Center is owned by a corporation, representation by counsel is required. In the event of an OAL hearing, the Jersey City Medical Center is required to submit a written response to each and every

charge as specified in this notice, which shall accompany its written request for a hearing.

Finally, be advised that Department staff will monitor compliance to determine whether corrective measures are implemented by the Jersey City Medical Center. Failure to comply with the regulations set forth herein and any other applicable requirements, as set forth in pertinent rules and regulations, may result in the imposition of additional penalties. 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 Nadine Jackman, Office of Program Compliance, at Nadine.Jackman@doh.nj.gov.

Sincerely,

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

LK:JI:nj
DATE: May 19, 2025
E-MAIL: joanne.reich@rwjbh, margaret.ames@rwjbh.org
REGULAR AND CERTIFIED MAIL, RETURN RECEIPT REQUESTED
Control# AX24037