State of New Jersey
DEPARTMENT OF HEALTH
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Governor

TAHESHA L. WAY
Lt. Governor

KAITLAN BASTON, MD, MSc, DFASAM
Commissioner

In Re Licensure Violation:	:	
	:	
Clara Maass Medical Center	:	NOTICE OF ASSESSMENT OF
	:	
	:	PENALTIES
	:	
	:	
(NJ Facility ID# NJ10701)	:	
	:	

TO: Tamara Cunningham-Administrator
Clara Maass Medical Center
One Clara Maas Drive
Belleville, New Jersey 07109
tamara.cunningham@rwjbh.org

Dear Ms. Cunningham:

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 (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 of Health (Department) visited the Clara Maass Medical Center (the Facility) on October 25, 2023, for the purpose of conducting a complaint survey. The report of this visit, which is incorporated herein by reference, substantiated violations of the following:

A. *N.J.A.C. 8:43G 12.2(a). The emergency department shall have written policies and procedures for medical, trauma, and pediatric patients, that are reviewed at least once every three years, revised more frequently as needed, and implemented.*

The above regulation was violated when:

1.The Facility failed to ensure policies and procedures for Emergency Cart Equipment were developed and implemented; and

2. The Facility failed to ensure the "Code Record" in two medical records was completed accurately in accordance with the facility policy, (D2430 Emergency Dept/Trauma Services: Emergency Department Policy and Procedures).

B. *N.J.A.C. 8:43G-18.6 - Nursing care services related to pharmaceutical services*
(a) All medications administered by nursing personnel shall be administered in accordance with prescriber orders, medical staff policy, and all Federal and State laws and regulations.

The Facility violated the above regulation when it failed to ensure medications were administered in accordance with acceptable standards of practice, in three medical records involving medical errors. (D4155 Nursing Care Services Related to Pharmacy Services).

C. *N.J.A.C. 8:43G 23.2(a)(2) - Pharmacy policies and procedures*
"(a) The pharmacy and therapeutics committee, or its equivalent, shall review, approve, and ensure implementation of policies and procedures addressing at least the following areas:
...
2. Administration of drugs".

The Facility violated the above regulation when it:

1. Failed to ensure that medications identified as high alert were administered in accordance with the facility policies and procedures.

2. Failed to ensure that the order verification checks conducted in the pharmacy identified the administration of a high alert medication infusion at a rate higher than what was ordered.

3. Failed to ensure that safety measures to ensure safe medication administration were utilized, in accordance with the facility policies and procedures.

4. Failed to ensure that medication orders were written for the correct route of administration. (D5628 Pharmacy Policies and Procedures).

D. *N.J.A.C. 8:43G- 23.2 - Pharmacy policies and procedures.*
***"(a)** The pharmacy and therapeutics committee, or its equivalent, shall review, approve, and ensure implementation of policies and procedures addressing at least the following areas:*
...
(a)(7) Identification, reporting, reviewing, and monitoring of adverse drug reactions and medication errors;"

The facility violated the above regulation when it failed to ensure the implementation of policies and procedures that address the reporting and documentation of staff actions in response to medication errors. (D5643 Pharmacy: Policies and Procedures.).

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

A. N.J.A.C. 8:43G- 12.2(a) Emergency department policies and procedures.

1. The Department staff conducted an on-site interview of facility staff during a complaint survey on October 25, 2023. A review of the facility policy titled "Emergency Cart Equipment and Defibrillator-Daily Check checks and Maintenance, No. 2" states "All emergency carts and equipment must be checked once a day for proper operation, availability of supplies, and expiration dates of medications."

A review of the Monitor/Defibrillator/ Emergency/ Equipment checklist located on top of the Emergency Cart Equipment in Room 2 of the Emergency Department (ED) revealed that the facility failed to check the Broselow Pediatric Code Cart on eighteen different shifts on sixteen different days, as set forth below. The cart's drawers are color-coded and organized by patient length and weight ranges, and each drawer contains all necessary equipment for resuscitation of a patient in that specific length/weight range. The cart is used by professionals, during pediatric emergencies, to have quick access to properly sized medical supplies and dosage instructions for children up to approximately 12 years of age. on eighteen different shifts on fifteen different days, to wit:

A. 7:00 a.m. Shift on:
   1. June 12, 2023,
   2. October 2, 2023,
   3. October 5, 2023,
   4. October 10, 2023,
   5. October 11, 2023,
   6. October 13, 2023,
   7. October 14, 2023,
   8. October 16, 2023,
   9. October 18, 2023,
   10. October 19, 2023,
   11. October 21, 2023, and
   12. October 22, 2023 (N.J.A.C. 8:43G 12.2(a).).

B. 7:00 p.m. Shift on
   1. October 9, 2023,
   2. October 13, 2023,
   3. October 15, 2023,
   4. October 16, 2023,
   5. October 17, 2023, and
   6. October 18, 2023. (N.J.A.C. 8:43G 12.2(a).).

Further, the facility policy lacked evidence of a contents list of emergency supplies for the Broselow Pediatric Code Cart. The policy also failed to address the procedure for the Emergency Department (ED) technician's responsibility of restocking the code cart and ensuring the Broselow Pediatric Code Carts were checked and contained the emergency medical supplies needed for pediatric emergencies.

On Octboer 23, 2023, in the Peds Observation ED, the Broselow Pediatric Code Cart was opened and inspected in the presence of S1 and S14, an ED RN (Registered Nurse). The top drawer contained medications used for a pediatric code, with a contents list that was supplied and checked by pharmacy. The code cart was missing intubation supplies in six of the eight color coded drawers.
The facility failed to ensure the Broselow Pediatric Code Carts were checked and contained the emergency supplies needed for pediatric emergencies, in accordance with facility policy. The facility thus failed to ensure policies and procedures for Emergency Cart Equipment were developed and implemented, in violation of N.J.A.C. 8:43G 12.2(a).

2. On October 23, 2023, a review of two code records of a patient showed the code records to be incomplete as they were lacking evidence of a documented cardiac rhythm entry at certain times on June 10, 2023.

This failure to enter the required data on the code records is evidence that the Facility failed to ensure the Code Record was complete and accurate, in accordance with facility policy, in violation of N.J.A.C. 8:43G-12.2(a).

B. N.J.A.C. 8:43G-18.6 - Nursing care services related to pharmaceutical services

On October 25, 2023, a review of records, staff interviews and review of New Jersey Board of Nursing Statutes, revealed that the facility failed to ensure medications were administered in accordance with acceptable standards of practice, in three medical records involving medical errors, in violation of N.J.A.C. 8:43G-18.6(a). Specifically, it was identified that a patient received an improper dose of Alteplase, an anticoagulant, and the nurse overrode a high dose alert on the infusion of the pump. It was also identified that the infusion of Cardene, a blood pressure medication, was not administered to another patient in accordance with the physician's order. A third patient received insulin instead of Heparin and was then transferred to ICU for close observation. In addition, documentation was incomplete in the electronic medical record, including a two-nurse verification of a high alert medication.

The Facility also failed to ensure medications were administered in accordance with Facility policy by verifying the drug name prior to administration, in violation of N.J.A.C. 8:43G-18.6,

C. N.J.A.C. 8:43G 23.2(a)(2) - Pharmacy policies and procedures

Based on the medical records, it was determined that four patients (P1,P3,P4 and P10), the Facility failed to ensure that: 1) medications identified as high alert were administered in accordance with facility policies and procedures; 2) the order verification checks conducted in the pharmacy identified the administration of a high alert medication infusion at a rate higher than what is ordered; 3) safety measures were implemented to ensure safe medication administration, in accordance with facility policies and procedures; and 4) medication orders were written for the correct route of administration.

The infusion errors and failures to follow facility policy for high alert medications placed patients at risk for serious injury, serious harm, serious impairment or death. In fact, an Immediate Jeopardy (IJ) situation was issued to the Facility for failure to follow regulations on pharmaceutical services. The facility also failed to minimize medication errors by failing to ensure the correct route of administration was ordered. These failures violated N.J.A.C. 8:43G-23.2(a)(2).

D. N.J.A.C. 8:43G 23.2(a)(7) - Pharmacy policies and procedures

Based on medical record review, facility documents, and staff interviews, it was determined that the facility failed to ensure the implementation of policies and procedures that address the reporting and documentation of staff actions in response to medication errors.

P1's medical record lacked documentation that a physician examined the patient after he/she was administered Alteplase at a rate that was ten times higher than what was ordered. The "Progress Note-Physician" found in P1's medical record, dated October 19, 2023, at 2:05 PM, states, "October 19: Patient seen examined. Waiting for the OR (operating room). No acute events overnight." The physician did not document the medication administration error involving the Alteplase infusion in P1's medical record. The Facility's incident report for P1, dated October 19, 2023, also lacked documentation of the physician's findings.

On October 24, 2023, Facility staff confirmed that P1's medical record lacked documentation that P1 was notified regarding the medication error. The facility failed to notify P1 regarding the medication administration error that occurred while he/she was an inpatient as required by facility policy and in violation of N.J.A.C. 8:43G 23.2(a)(7).

MONETARY PENALTIES:

Pursuant to N.J.A.C. 8:43E-3.4 (a)(8), where there are multiple deficiencies related to patient care or physical plant standards throughout a facility, and/or such violations represent a direct risk that a patient's physical or mental health will be compromised, or where an actual violation of a resident's or patient's rights is found, a penalty of $ 1,000 per violation may be assessed for each day noncompliance is found. The Department is assessing a $1000 per day penalty for the facility's failure to comply with the requirements of N.J.A.C. 8:43G 12.2(a), specifically, $1000 x 15 different days= $15,000. The facility's failure to ensure that the Broselow Pediatric Code Carts are checked every shift to determine adequacy of supplies and medicine in accordance with the facility policy poses a direct risk that a patient's health will be compromised. An inadequately stocked Code Cart will result to injury or death of a patient, if the supplies needed are not available to save the coding patient. Whether a Code Cart is sufficiently stocked or not could only be determined by checking the "Monitor/Defibrillator/Emergency Cart/Equipment Checklist" and comparing the contents of the cart with the list. The facility failed to check the Monitor/Defibrillator/Emergency Cart Checklist on fifteen different days, which resulted to Code Carts not being checked as to the sufficiency of medical supplies, that in the event of a code, may have saved the lives of coding patients.

N.J.A.C. 8:43E-3.4(a)7 provides that, for violations of licensure regulations related to patient care or physical plant standards that represent a risk to the health, safety, or welfare of patients or residents of a facility or the general public, $500 per violation may be assessed where such deficiencies are isolated or occasional and do not represent a pattern or widespread practice throughout the facility. The Department is assessing a $500 penalty per violation for failure to ensure that the "Code Records" in two medical records were completed accurately in accordance with the facility policy, in violation of N.J.A.C. 8:43G-

12.2(a). Thus, the penalty assessed is $500 x 2 violations=$1,000. Correctly entered information in a "Code Record" will save lives as it would help medical professionals in diagnosing and treating patients.

N.J.A.C. 8:43E-3.4(a)10 provides that for violations resulting in either actual harm to a patient or resident, or in an immediate and serious risk of harm, $2,500 per violation may be assessed for each day noncompliance is found. The Department is assessing a $2,500.00 penalty per patient for the facility's failure to comply with N.J.A.C 8:43G-18.6(a). Thus, the penalty assessed is $2,500 x 3 patients = $7,500. The facility's failure to ensure medications were administered in accordance with acceptable standards of practice, for three patients' medical records involving medical errors, may have resulted in either actual harm to a patient or resident or an immediate and serious risk of harm. The improper administration of medicine can cause serious injury to the patients or may even result in their deaths if the wrong dosage or incorrect medicine is administered.

Likewise, the Department is also imposing a $2,500 per violation penalty for violations of N.J.A.C. 8:43G-23.2(a)(2), for the failure to ensure, for four patients, that: 1) medications identified as high alert were administered in accordance with facility policies and procedures; 2) the order verification checks conducted in the pharmacy identified the administration of a high alert medication infusion at a rate higher than what was ordered; 3) safety measures were implemented to ensure safe medication administration, in accordance with facility policies and procedures; and 4) medication orders were written for the correct route of administration. Specifically, the penalty assessed is $2,500 per violation x 4 patients = $10,000. Medication errors may result to actual harm to a patient or resident or in an immediate and serious risk of harm or death to a patient if they receive a wrong medicine or dosage of medicine.

Finally, pursuant to N.J.A.C. 8:43E-3.4 (a)(8), a $1000 assessment is issued to the facility based on its violation of N.J.A.C. 8:43G-23.2(a)(7) (Pharmacy Administration), when the doctor failed to record a medication error and the facility failed to notify a patient regarding the medication administration error that occurred while he/she was an inpatient as required by facility policy. These failures represent a direct risk that a patient's physical or mental health will be compromised and violate the patient's rights.

Therefore, the total penalty for these violations is $34,500 under N.J.A.C. 8:43G 12.2(a), N.J.A.C. 8:43G 18.6(a), N.J.A.C. 8:43G 23.2(a)(2) and N.J.A.C. 8:43G 23.2(a)(7).

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 086250358, Attention: Lisa King. On all future correspondence related to this Notice, please refer to **Control AX24040**.

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 facility is entitled to contest 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 facility may request a hearing to challenge any or all of the following: the factual findings and/or the assessed penalties. The facility must advise this Department within 30 days of the date of this letter if it requests an OAL hearing.

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 the facility is owned by a corporation, representation by counsel is required. In the event of an OAL hearing regarding the penalty, the facility is further 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.

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. If you have any questions regarding this Notice of Assessment, please contact Nadine Jackman, Office of Program Compliance, at Nadine.Jackman@doh.nj.gov.

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

GR:RSM:nj
DATE: March 24, 2025
E-MAIL: tamara.cunningham@rwjbh.org
REGULAR AND CERTIFIED MAIL, RETURN RECEIPT REQUESTED
Control# AX24040