

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>390195</b>	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____	(X3) DATE SURVEY COMPLETED:  <b>08/24/2023</b>	
NAME OF PROVIDER OR SUPPLIER: <b>LANKENAU MEDICAL CENTER</b>  STATE LICENSE NUMBER: <b>120401</b>		STREET ADDRESS, CITY, STATE, ZIP CODE: <b>100 LANCASTER AVENUE WYNNEWOOD, PA 19096</b>		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE)	(X5) COMPLETE DATE
A 0000	<p>Continued from page 1</p> <p>This report is the result of an unannounced onsite complaint investigation (ACTS # 65724) initiated on August 23, 2023 and completed on August 24, 2023, at Lakenau Medical Center. It was determined the facility was not in compliance with the requirements of 42 CFR, Title 42, Part 482-Conditions of Participation for Hospitals.</p> <p>The identified non-compliance constituted a determination of Immediate Jeopardy (IJ) at 482.23 Nursing Services. The Immediate Jeopardy was called at 3:27 pm on August 23, 2023. The facility submitted an acceptable Immediate Jeopardy Removal Plan at 11:00 pm on August 23, 2023. The surveyor validated the Immediate Jeopardy Removal Plan was fully implemented by observation, education</p>	A 0000		

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A 0000	Continued from page 2  logs, and interviews. The Immediate Jeopardy was abated on-site at 11:00 am on August 24, 2023.	A 0000		
A 0385		A 0385		

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A 0385	Continued from page 3  482.23 NURSING SERVICES  The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.  This REQUIREMENT is not met as evidenced by:	A 0385	Plan for correcting each deficiency cited – Ensure Nursing Staff follow policy on Administration and Management of Medications: On 8/23/23 Nurse Managers and the Director of Nursing were provided with education by the Pharmacy Specialist for Regulatory Compliance, the Pharmacy Manager, and the System Director for Regulatory and Medical Staff Affairs on the policies for medication administration, wasting of controlled substances, controlled substance inventory discrepancy procedures, and controlled substances monitoring. The Nurse Manager's role in controlled substances monitoring was reviewed, including their role in the review of bar code scanning compliance, controlled substance discrepancies resolution and diversion follow-up process.  On 8/23/23 all nurses on duty at Lankenau Medical Center were educated by Nurse Managers, Assistant Nurse Managers and Educators on medication	Completion Date: <b>09/28/2023</b> Status: <b>APPROVED</b> Date: <b>10/03/2023</b>

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A 0385	Continued from page 4	A 0385	<p>administration, wasting of controlled substances, and controlled substance inventory discrepancy procedures. The education consisted of the Medication Wasting Computer-Based Training ("CBT"), with the addition of controlled substances discrepancy procedures and the policies for Medication Administration, Wasting of Controlled Substances, and the procedure for barcode scanning of medications. All other nurses will complete the education prior to the start of their next shift. The Vice President of Patient Care Services will monitor completion of the education using staff rosters and sign-in sheets to achieve 100% completion.</p> <p>This incident and removal plan was communicated on 8/23/2023 to the Lankenau Medical Center President, Main Line Health Chief Executive Officer, and the Chair of the Main Line Hospitals Quality, Safety and Equity Committee of the Board (the governing body). All resources necessary to meet the obligations of</p>	

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A 0385	Continued from page 5	A 0385	<p>the removal plan have been made available to the Lankenau Medical Center President and the Vice President of Patient Care Services. This incident and removal plan was also shared with the Main Line Hospitals Quality, Safety and Equity Committee of the Board. The employee involved was removed from the schedule after the event pending investigation. Root Cause Analysis (RCA) was held on August 24, 2023.</p> <p>Plan for improving the process that led to deficiency. Beginning 8/24/23, direct observation audits of controlled substance administration were conducted by nursing leaders and include the process for removal from the Pyxis, wasting of controlled substances, and medication administration. 30 observations per unit per week will be completed for 30 days and if the results are not 100% in compliance with policies, the observations will continue until 100% compliance is achieved and</p>	

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A 0385	Continued from page 6	A 0385	<p>maintained. The audits are performed based on patient orders for controlled substances. The nurse manager or designee reviews patients who are ordered controlled substances, to randomly select the medication administrations that will be observed.</p> <p>If the observed nurse is not at 100%, re-education of that staff member occurs at that time. Continued non-compliance will result in performance management.</p> <p>The nursing education on medication administration, wasting of controlled substances, and controlled substance inventory discrepancy procedures was added to annual CBT that will be launched to all MLH nursing staff on October 1, 2023, and will be due within 30 days of assignment. Those who do not meet this deadline will be subject to performance management.</p> <p>Completion date: All initial re-education was completed by 09/28/2023.</p>	

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A 0385	Continued from page 7	A 0385	<p>Monitoring and tracking procedures. The direct observation audit results are communicated to the Director of Nursing and Vice President for Patient Care Services, and deviation from practice results in coaching and performance management of the involved staff.</p> <p>After the units meet the 100% compliance on audits, the Nurse Manager will continue to audit the process – 10 patients per month for one year.</p> <p>The direct observation audit results are provided to the following groups: the Lankenau Medical Center President and Vice President of Patient Care Services on a daily basis for the first week and weekly thereafter; Clinical Operations Committee monthly; and the Main Line Hospitals Quality, Safety, and Equity Committee of the Board at regularly scheduled meetings until 100% compliance is achieved.</p> <p>Title of person responsible for implementing plan. Vice President, Patient Care Services</p>	

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A 0385	<p>Continued from page 8</p> <p>Based on the seriousness of the non-compliance and the effect on patient outcome, the facility failed to substantially comply with this condition.</p> <p>The facility failed to ensure nursing staff followed the facility's established policy regarding "Administration and Management of Medications" revision date January 2023 revealed "General Guidelines for Safe Preparation and Administration of All Medications ... A procedure in which two Practioners/Clinicians <i>independently</i> check each targeted component that requires verification when prescribing, dispensing, or administering a medication ... A. Right Time ...B. Right Medication ...C. Right Dosage ... D. Right Route ... E. Right Patient".</p> <p>The facility failed to ensure nursing staff followed the facility's policy "Automated Dispensing Cabinet 7:15" revision date October 2022 revealed, "Removing Medications ... Users are responsible for verifying the correct patient (via 2 identifiers), medication, dosage form, strength, dose (may be</p>	A 0385		



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A 0385	Continued from page 9  different from strength), and expiration date prior to administration ... For controlled substances, users are required to verify the physical inventory and enter it as a blind inventory count".  A discussion took place with the survey team and the facility's administrative staff (EMP1, EMP2, EMP3, EMP4 ) regarding the survey team's concerns related to Nursing Services on August 23, 2023, at approximately 3:27 pm.	A 0385		
A 0405		A 0405		

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A 0405	Continued from page 10  482.23(c)(1), (c)(1)(i) & (c)(2) ADMINISTRATION OF DRUGS  (1) Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice.  (i) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations.  (2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.  This REQUIREMENT is not met as evidenced by:	A 0405	Plan for correcting each deficiency cited – Ensure Nursing Staff follow policy on Administration and Management of Medication: On 8/23/23 Nurse Managers and the Director of Nursing were provided with education by the Pharmacy Specialist for Regulatory Compliance, the Pharmacy Manager, and the System Director for Regulatory and Medical Staff Affairs on the policies for medication administration, wasting of controlled substances, controlled substance inventory discrepancy procedures, and controlled substances monitoring. The Nurse Manager's role in controlled substances monitoring was reviewed, including their role in the review of bar code scanning compliance, controlled substance discrepancies resolution and diversion follow-up process.  On 8/23/23 all nurses on duty at Lankenau Medical Center were educated by Nurse Managers, Assistant Nurse Managers and	Completion Date: <b>09/28/2023</b> Status: <b>APPROVED</b> Date: <b>10/03/2023</b>

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A 0405	Continued from page 11	A 0405	<p>Educators on medication administration, wasting of controlled substances, and controlled substance inventory discrepancy procedures. The education consisted of the Medication Wasting Computer-Based Training ("CBT"), with the addition of controlled substances discrepancy procedures and the policies for Medication Administration, Wasting of Controlled Substances, and the procedure for barcode scanning of medications. All other nurses will complete the education prior to the start of their next shift. The Vice President of Patient Care Services will monitor completion of the education using staff rosters and sign-in sheets to achieve 100% completion.</p> <p>This incident and removal plan was communicated on 8/23/2023 to the Lankenau Medical Center President, Main Line Health Chief Executive Officer, and the Chair of the Main Line Hospitals Quality, Safety and Equity Committee of the Board (the governing body). All resources</p>	

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A 0405	Continued from page 12	A 0405	<p>necessary to meet the obligations of the removal plan have been made available to the Lankenau Medical Center President and the Vice President of Patient Care Services. This incident and removal plan and was also shared with the Main Line Hospitals Quality, Safety and Equity Committee of the Board. The employee involved was removed from the schedule after the event pending investigation. Root Cause Analysis (RCA) was held on August 24, 2023.</p> <p>Plan for improving the process that led to deficiency. Beginning 8/24/23, direct observation audits of controlled substance administration were conducted by nursing leaders and include the process for removal from the Pyxis, wasting of controlled substances, and medication administration. 30 observations per unit per week will be completed for 30 days and if the results are not 100% in compliance with policies, the observations will continue until</p>	

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A 0405	Continued from page 13	A 0405	<p>100% compliance is achieved and maintained. The audits are performed based on patient orders for controlled substances. The nurse manager or designee reviews patients who are ordered controlled substances, to randomly select the medication administrations that will be observed.</p> <p>If the observed nurse is not at 100%, re-education of that staff member occurs at that time. Continued non-compliance will result in performance management.</p> <p>The nursing education on medication administration, wasting of controlled substances, and controlled substance inventory discrepancy procedures was added to annual CBT that will be launched to all MLH nursing staff on October 1, 2023, and will be due within 30 days of assignment. Those who do not meet this deadline will be subject to performance management.</p> <p>Completion date: All initial re-education was</p>	

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A 0405	Continued from page 14	A 0405	<p>completed by 09/28/2023.</p> <p>Monitoring and tracking procedures. The direct observation audit results are communicated to the Director of Nursing and Vice President for Patient Care Services, and deviation from practice results in coaching and performance management of the involved staff.</p> <p>After the units meet the 100% compliance on audits, the Nurse Manager will continue to audit the process – 10 patients per month for one year.</p> <p>The direct observation audit results are provided to the following groups: the Lankenau Medical Center President and Vice President of Patient Care Services on a daily basis for the first week and weekly thereafter; Clinical Operations Committee monthly; and the Main Line Hospitals Quality, Safety, and Equity Committee of the Board at regularly scheduled meetings until 100% compliance is achieved.</p> <p>Title of person responsible for</p>	

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A 0405	<p>Continued from page 16</p> <p>Based on review of facility documents, medical records (MR), and staff interview (EMP), it was determined the facility failed to ensure medication orders were administered in accordance with the approved policies and procedures for MR1.</p> <p>Findings include:</p> <p>On August 23, 2023, review of facility policy "Administration and Management of Medication " revision date January 2023 revealed General Guidelines for Safe Preparation and Administration of All Medications ... A procedure in which two Practioners/Clinicians <i>independently</i> check each targeted component that requires verification when prescribing, dispensing, or administering a medication ... A. Right Time ...B. Right Medication ...C. Right Dosage ... D. Right Route ... E. Right Patient".</p> <p>On August 23, 2023, review of facility policy "Wasting of Controlled Substances - Nursing" revision date June 2023 revealed, "Controlled substances that are prescribed in excess of what is</p>	A 0405		



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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE)	(X5) COMPLETE DATE
A 0405	Continued from page 17  used are to be wasted or destroyed in front of a witness. The administering nurse should ensure the controlled substance is sealed and intact and then opened in the presence of the witnessing nurse. Both nurses verify the controlled substance label, that the volume or amount being wasted matches the documentation, that the controlled substance being wasted physically matches the medication in the documentation, and that the wasting occurs in a manner that makes the controlled substance irretrievable ... The witnessing nurse observes the administering nurse open the medication, draw up or cut the correct dose to assure the controlled substance has not been substituted or unadulterated".  Review of facility policy "Automated Dispensing Cabinet 7:15" revision date October 2022 revealed, "Removing Medications ... Users are responsible for verifying the correct patient (via 2 identifiers), medication, dosage form, strength, dose (may be different from strength), and expiration date prior to administration ... For controlled substances,	A 0405		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>390195</b>	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____	(X3) DATE SURVEY COMPLETED:  <b>08/24/2023</b>	
NAME OF PROVIDER OR SUPPLIER: <b>LANKENAU MEDICAL CENTER</b>  STATE LICENSE NUMBER: <b>120401</b>		STREET ADDRESS, CITY, STATE, ZIP CODE: <b>100 LANCASTER AVENUE WYNNEWOOD, PA 19096</b>		
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A 0405	<p>Continued from page 18</p> <p>users are required to verify the physical inventory and enter it as a blind inventory count".</p> <p>Review of MR1 on August 23, 2023 revealed, "HYDROmorphone (DILAUDID) injection 1.5 mg ...every 3 hours prn ordered on 8/11/23 @ 0349" ordered by provider.</p> <p>Frrther review of MR1 on August 23, 2023 revealed, the patient was found unresponsive with pulse and required administration of Narcan, was resuscitated and transferred to the Intensive Care Unit (ICU).</p> <p>Interview with EMP3 on August 23, 2023 at 12:30 PM, revealed "the nurse (EMP13) came forward and admitted to giving the wrong dose" of Hydromorphone (Dilaudid) to the patient involved.</p> <p>Interview with EMP1 on August 23, 2023 at 12: 40 PM confirmed "the nurse (EMP13) admitted to giving the wrong dose of Dilaudid to the patient ". Further revealed " the nurse officially came off the schedule on 8/16/23, but she hasn ' t worked since</p>	A 0405		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>390195</b>	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____	(X3) DATE SURVEY COMPLETED:  <b>08/24/2023</b>	
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A 0405	Continued from page 19  8/11/23".  Interview with EMP2 on August 23, 2023 at 1:00 PM revealed, "it was a nurse (EMP13) medication error that resulted in an overdose" for the patient.  Interview on August 23, 2023 at 3:10 PM with EMP7 confirmed, "Dilaudid vials comes in three different strengths. The nurse involved pulled 2 vials of Hydromorphone which were 2 mg each instead of one vial. The vials come in 1mg and 2 mgm. She gave 3mgm of Dilaudid instead of the ordered 1.5 mgm".  Review of the pharmacy Pyxis audit report provided by the pharmacy manager (EMP6) shows the nurse did waste 0.5mg each time. First dosage of (2)-2mg vials pulled from Pyxis drawer on 8/11/23 at 1334 with a 0.5 mg waste at 13:36. Second dosage of (2)-2mg vials pulled from Pyxis on 8/11/23 at 1739, 0.5mg wasted at 1740. Medication count started at 15 of the 2mg Hydromorphone drawer on 8/11/23 prior to the withdrawal of the medication. The nurse involved listed a count of 13 vials for the	A 0405		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>390195</b>	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____	(X3) DATE SURVEY COMPLETED:  <b>08/24/2023</b>
NAME OF PROVIDER OR SUPPLIER: <b>LANKENAU MEDICAL CENTER</b>		STREET ADDRESS, CITY, STATE, ZIP CODE: <b>100 LANCASTER AVENUE WYNNEWOOD, PA 19096</b>		
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A 0405	Continued from page 20  verified inventory (blind count) count in Pyxis drawer on 8/15/23 after her withdrawal of the med. Without any other withdrawal noted since 8/11/23 at 1739, report shows Discrepancy/Resolution with actual count of 11, "wrong count" noted- " user miscounted pocket contents". Interview with EMP2 on August 23, 2023 at 4:31 PM revealed "I don't think she (the nurse involved- EMP13) scanned the vials".  Interview with EMP2 on August 23, 2023 at 8:38 PM confirmed, "the nurse (EMP13) involved didn't follow the policy in place, when following the Pyxis instructions for giving medication. She didn't scan the meds, that's why the "guardrails" failed". Cross Reference: Nursing Services 482.23	A 0405		



# Certified End Page

**LANKENAU MEDICAL CENTER**  
**STATE LICENSE NUMBER: 120401**  
**SURVEY EXIT DATE: 08/24/2023**

**I Certify This Document to be a True and Correct Statement of Deficiencies and Approved Facility Plan of Correction for the Above-Identified Facility Survey**

Handwritten signature of Jeane Parisi in black ink.

*Jeane Parisi*  
*Deputy Secretary for Quality Assurance*

Handwritten signature of Debra L. Bogen MD in black ink.

*Debra L. Bogen, MD, FAAP*  
*Acting Secretary of Health*



THIS IS A CERTIFICATION PAGE

**PLEASE DO NOT DETACH**

THIS PAGE IS NOW PART OF THIS SURVEY