Ohio Dept Health

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 0288AS | A. BUILDING: ODH/OHAL COMMUNITY HEALTH CARE B. WING | 04/30/2015 |

2015 SEP 22 PM 12:10

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| PRETERM | 12000 SHAKER BOULEVARD CLEVELAND, OH 44120 |

| (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 DEFICIENCY) | (X5) COMPLETE DATE |
|---|---|---|---|---|
| C 000 | Initial Comments<br><br>Licensure Compliance Inspection<br><br>Administrator: Heather Harrington<br><br>County: Cuyahoga<br><br>Number of ORs: 5<br><br>The following violation is issued as a result of the licensure compliance inspection completed on 04/30/15. | C 000 | C231- Preterm has already addressed this issue and come into full compliance by evidence of the fact that Staff B immediately re-educated Staff D as to the nature of her labeling error at the time of the survey and immediately re-labeled the 19 syringes in question. As is stated in the summary of deficiencies, no patients were ever administered any medication from the syringes in question and no patients were harmed. In addition, Preterm only purchases Fentanyl in pre-mixed 50 mcg/mL vials from which syringes are directly drawn, making it virtually impossible to administer the wrong dose, even had the labeling error not been corrected. | 5/15/15 |
| C 231 | O.A.C. 3701-83-19 (B) Drug Control & Accountability<br><br>The ASF shall:<br><br>(1) Provide adequate space, equipment, and staff for storage and the administration of drugs in compliance with state and federal laws and regulations.<br><br>(2) Establish and implement a program for the control and accountability of drug products throughout the facility and maintain a list of medications that are always available.<br><br>This Rule is not met as evidenced by:<br>Based on observation and staff interview, the facility failed to ensure a Schedule II narcotic anesthesia drug was labeled with the correct dose. This involved nineteen syringes of the medication which were pre-drawn and labeled by a licensed staff member of the facility. This could potentially affect all patients who were administered the medication. The facility performed a total of 5264 procedures in the past | C 231 | | |

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| C 231 | Continued From page 1<br>12 months.<br><br>Findings include:<br><br>On 04/30/15 at 10:55 AM, Staff B was observed counting the facility's supply of narcotic medications for accountability. The narcotic log revealed the facility should have nineteen Fentanyl 100 mcg/2 ml (microgram/milliliter) containers of this medication. Observation revealed nineteen syringes with 2 ml each of clear solution. The label on each syringe was observed with the name of the medication (Fentanyl), dated 04/27/15, times varying between 1:07 PM and 1:10 PM, Staff D's initials, and the dosage of 1 mcg/ml. The dosage on the labels were handwritten in ink.<br><br>When questioned as to the labels, and the solution in the syringes, Staff B stated each syringe contained 2 ml of Fentanyl in the dosage of 50 mcg per milliliter. Staff B stated according to the labels on the syringes, Staff D (registered nurse) drew up the Fentanyl into each syringe, and mis-labeled the dosage of the medication on each of the nineteen syringes. Staff B stated the dosage should not be 1 mcg/ml but should be labeled as 50 mcg/ml. Staff B stated he/she would call Staff D to correct the dosage of the labels. Staff B confirmed the incorrectly labeled syringes of narcotic medication could result in potential harm to patients if administered.<br><br>On 04/30/15 at 5:00 PM, Staff B stated that no patients have received medication from the incorrectly labeled syringes. Staff B stated the facility does not have a policy for pre-drawing medications. Staff B stated he/she spoke with the Ohio State Board of Pharmacy regarding the practice of facility staff pre-drawing medications | C 231 | C231- The labeling error in question did not affect the actual dosage in the 19 syringes. These 19 syringes contained the correct and standard dosage of 50mcg/mL, including the correct and standard healthcare-wide concentration (50mcg/mL) and correct amount of volume (2mL). This was a labelling error only, not a dosing error. Further, although Preterm did not recieve the legally required notification of this violation until 137 days after the survey, Preterm proactively instituted a policy of having a second nurse validate both the filling and labeling of pre-drawn medications. (See Attachment A- the Narcotic Record in use prior to the survey; Attachment B- the Narcotic Record updated 5/15/15, showing the addition of the pre-drawn medication validation; | |

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| C 231 | Continued From page 2<br>and labeling the syringes. When questioned as to why Fentanyl medication is pre-drawn into the syringes, Staff B replied "It helps facilitate the flow of patients." Staff B confirmed this narcotic medication is used by the Certified Registered Nurse Anesthetist (CRNA) to sedate patients during a procedure.<br><br>On 04/30/15 at 5:00 PM, Staff C stated the incorrectly labeled syringes of narcotic medication could result in harm to the patients, and stated this is a serious matter. | C 231 | C231- Attachment C- several Narcotic Records, with patient names redacted, showing our sustained compliance. Although Preterm already had in place a rigorous program for the control and accountability of drugs throughout the facility, Preterm voluntarily strengthened the program months before recieving written notice of this issue from the Ohio Department of Health. | |

# State Form: Revisit Report

| (Y1) Provider / Supplier / CLIA / Identification Number | (Y2) Multiple Construction | (Y3) Date of Revisit |
|---|---|---|
| 0288AS | A. Building<br>B. Wing Desk Audit | 11/20/2015 |

| Name of Facility | Street Address, City, State, Zip Code |
|---|---|
| PRETERM | 12000 SHAKER BOULEVARD<br>CLEVELAND, OH 44120 |

This report is completed by a State surveyor to show those deficiencies previously reported that have been corrected and the date such corrective action was accomplished. Each deficiency should be fully identified using either the regulation or LSC provision number and the identification prefix code previously shown on the State Survey Report (prefix codes shown to the left of each requirement on the survey report form).

| (Y4) Item | (Y5) Date Correction Completed | (Y4) Item | (Y5) Date Correction Completed | (Y4) Item | (Y5) Date Correction Completed |
|---|---|---|---|---|---|
| ID Prefix C0231<br>Reg. # O.A.C. 3701-83-19 (B)<br>LSC | 11/20/2015 | ID Prefix<br>Reg. #<br>LSC | | ID Prefix<br>Reg. #<br>LSC | |
| ID Prefix<br>Reg. #<br>LSC | | ID Prefix<br>Reg. #<br>LSC | | ID Prefix<br>Reg. #<br>LSC | |
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|---|---|---|---|---|
| Reviewed By ✓ State Agency | Reviewed By | Date: 11/21/16 | Signature of Surveyor: | Date: 11/20/15 |
| Reviewed By CMS RO | Reviewed By | Date: | Signature of Surveyor | Date: |

| | |
|---|---|
| Followup to Survey Completed on: 4/30/2015 | Check for any Uncorrected Deficiencies. Was a Summary of Uncorrected Deficiencies (CMS-2567) Sent to the Facility? YES NO |