



## OHIO DEPARTMENT OF HEALTH

246 North High Street  
Columbus, Ohio 43215

614/466-3543  
www.odh.ohio.gov

John R. Kasich/Governor

Richard Hodges/Director of Health

September 9, 2015

Heather Harrington, Administrator  
Preterm  
12000 Shaker Boulevard  
Cleveland, Ohio 44120

**Re: Preterm  
License Number: 0288AS  
Case Number: 15-BRE-0159  
Proposed Civil Penalty and Plan of Correction**

Dear Ms. Harrington:

You are notified that I propose to impose a civil money penalty in the amount of \$10,000 against Preterm, 12000 Shaker Boulevard, Cleveland, Ohio 44120, due to violations of Revised Code (R.C.) Chapter 3702 and Ohio Administrative Code 3701-83. This action is taken pursuant to R.C. 3702.32 and 3701-83-05.1(c)(2) and Ohio Admin. Code 3701-83-05.2, and in accordance with R.C. Chapter 119.

Representatives of the Ohio Department of Health conducted a licensure inspection at Preterm on April 30, 2015. A copy of the report is enclosed.

In addition, please submit a Plan of Correction on the enclosed Statement of Deficiencies Form, **within 10 calendar days of receipt of this letter and attain compliance no later than 30 calendar days from receipt of this notice.** The Plan of Correction should be submitted to Drema Phelps, Chief, Bureau of Community Health Care, 246 N. High St., 2nd Floor, Columbus, Ohio 43215.

You may request a hearing before me or my duly authorized representative concerning my proposal to impose a \$10,000 civil penalty against Preterm. Such request must be made in writing and received within 30 calendar days of receipt of this letter and should be directed to Heather Coglianese, Assistant Counsel, Ohio Department of Health, 246 N. High Street, 7th Floor, Columbus, Ohio 43215. A request is considered timely if it is received by the Department of Health via facsimile, hand delivery, or ordinary United States mail within 30 calendar days of the date of receipt of this letter.

At a hearing, you may appear in person or be represented by an attorney. You may present evidence and you may examine witnesses appearing for and against you. You also may present

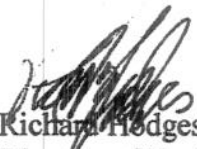
2 Preterm

your position, contentions, or arguments in writing, rather than appear in person for a hearing. If you are a corporation, you must be represented at the hearing by an attorney licensed to practice in Ohio. Please be advised that if you do not request a hearing within 30 calendar days, I will issue an order imposing the \$10,000 civil penalty.

If you have any questions regarding the POC, please contact the Bureau of Community Health Care at (614) 995-7466.

If you have any questions regarding the enforcement actions against your facility, please contact the Bureau of Regulatory Enforcement at (614) 644-6220.

Sincerely,

  
Richard Hodges, MPA  
Director of Health

Enclosure: 2KIS11

CMRR: 7010 1870 0000 7743 4405

c: Brian Dean, Interim Chief, Bureau of Regulatory Enforcement  
Heather Coglianesse, Senior Counsel, Office of General Counsel  
Drema Phelps, Chief, Bureau of Community Health Care  
Tamara Malkoff, Chief, Bureau of Licensure Operations

Ohio Dept Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>0288AS</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  <b>04/30/2015</b>
--	---	---	---

NAME OF PROVIDER OR SUPPLIER  <b>PRETERM</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>12000 SHAKER BOULEVARD CLEVELAND, OH 44120</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 DEFICIENCY)	(X5) COMPLETE DATE
C 000	<p>Initial Comments</p> <p>Licensure Compliance Inspection</p> <p>Administrator: Heather Harrington</p> <p>County: Cuyahoga</p> <p>Number of ORs: 5</p> <p>The following violation is issued as a result of the licensure compliance inspection completed on 04/30/15.</p>	C 000		
C 231	<p>O.A.C. 3701-83-19 (B) Drug Control &amp; Accountability</p> <p>The ASF shall:</p> <p>(1) Provide adequate space, equipment, and staff for storage and the administration of drugs in compliance with state and federal laws and regulations.</p> <p>(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.</p> <p>This Rule is not met as evidenced by: 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</p>	C 231		

Ohio Department of Health  
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE \_\_\_\_\_ TITLE \_\_\_\_\_ (X6) DATE \_\_\_\_\_

Ohio Dept Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>0288AS</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  <b>04/30/2015</b>
NAME OF PROVIDER OR SUPPLIER  <b>PRETERM</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>12000 SHAKER BOULEVARD CLEVELAND, OH 44120</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 DEFICIENCY)	(X5) COMPLETE DATE
C 231	<p>Continued From page 1</p> <p>12 months.</p> <p>Findings include:</p> <p>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.</p> <p>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.</p> <p>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</p>	C 231		

Ohio Dept Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>0288AS</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  <b>04/30/2015</b>
--	---	---	---

NAME OF PROVIDER OR SUPPLIER  <b>PRETERM</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>12000 SHAKER BOULEVARD CLEVELAND, OH 44120</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 DEFICIENCY)	(X5) COMPLETE DATE
C 231	<p>Continued From page 2</p> <p>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.</p> <p>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.</p>	C 231		