Approved BSPRINTED: 07/06/2012 FORM APPROVED 11-28-12

Ohio Dept Health STATEMENT OF DEFICIENCIES (X3) DATE SURVEY (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION OMPLETED IDENTIFICATION NUMBER: A. BUILDING of HEALTH B. WING 0288AS 07/02/2012 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE MINE 23 P 12: 191 12000 SHAKER BOULEVARD **PRETERM** CLEVELAND, OH 44120 (X4) ID SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLETE (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE PREFIX **PREFIX** REGULATORY OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DATE TAG DEFICIENCY) C 000 Initial Comments C 000 DL/AA

C 119

Administrator: Chrisse France County: Cuyahoga Number of Operating Rooms: Four procedure rooms Services Provided: Surgical & Medical Abortions The following violation is a result of the complaint

Complaint Inspection #OH00065769

C 119 O.A.C. 3701-83-08 (A) Professional Standards

investigation completed on 07/02/12.

Each HCF shall utilize personnel that have appropriate training and qualifications for the services that they provide. Any staff member who functions in a professional capacity shall meet the standards applicable to that profession. including but not limited to possessing a current Ohio license, registration, or certification, if required by law, and working within his or her scope of practice.

Copies of current Ohio licenses, registrations and certifications shall be kept in the employee's personnel files or the provider of the HCF shall have an established system to verify and document the possession of current Ohio licenses, registrations, or other certifications required by law. Nurse licenses shall be copied in accordance with paragraph (E) of rule 4723-7-07 of the Administrative Code.

Each staff member has appropriate training and qualifications for The services They provide. Employees who function in a professional capacity meet the standards applicable to their profession including but not limited to possessing a current Ohio license, registration or certification if required by law, and work within his/her scope of practice. Copies of current licenses, registrations and cortifications shall be kept in the employees personnel file.

Ohio Department of Health

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

executive director

Ohio Dept Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MUL ¹ A. BUILDI	TIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED		
		0288AS		B. WING		07/02/2012
DRETERM 12000 S			12000 SH	DRESS, CITY, AKER BOL ND, OH 44		,
(X4) ID PREFIX TAG C 119	SUMMARY STA (EACH DEFICIENCY REGULATORY OR LETTE PROBLEM CONTINUED TO PARTIE AND THIS Rule is not me Based on interview this facility failed to documentation for a in order to verify quipotential to affect a ultrasound services has performed 2,40 1, 2012. Findings include: The medical record on 07/02/12 at apport that ultrasounds we on 05/18/12 by Staff was completed on 0 personnel file for St 07/02/12 and reveal ultrasound technicial requires the technic of and ability to perform an ultrasound of an ability to perform an ultrasound 07/02/12 at 2:45 PM skills demonstrated to shipperform an ultrasound of Staff #3. Staff # 2, 3, 5 and 6 technicians who we per telephone intervolution of 7/02/12 in the interview there regarding the training the training of the staff was completed or 7/02/12 in the interview there regarding the training the training of the staff was completed or 7/02/12 in the interview there regarding the training the traini	et as evidenced by: and personnel recor ensure training ultrasound staff was a alifications. This had alifications. This had alifications this facility. This from this facility. This for patient #1 was re- for patient #1 was re- foximately 1:00 PM re-	ccevela s FULL strion) d review retained the retained the re is facility January eviewed evealed facility sound The on for an ion cnowledge raining ability to taff B on raining or nel file asound and #4 of N stated mpletion			complete complete date
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Ohio Dept Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIE IDENTIFICATION NU		MBER:		TIPLE CONSTRUCTION		(X3) DATE SURVEY COMPLETED	
		I DENTIL TOX THOM NO	WIDEK.	A. BUILDING B. WING			
	0288AS			07/0:	2/2012		
NAME OF F	PROVIDER OR SUPPLIER		l		STATE, ZIP CODE		
PRETERM			CLEVELA	AKER BOU ND, OH 44			
(X4) ID PREFIX TAG	(EACH DEFICIENCY	TEMENT OF DEFICIENCIE MUST BE PRECEDED BY SC IDENTIFYING INFORMA	FULL	ID PREFIX TAG	PROVIDER'S PLAN OF C (EACH CORRECTIVE ACTIC CROSS-REFERENCED TO TH DEFICIENCY	ON SHOULD BE IE APPROPRIATE	(X5) COMPLETE DATE
C 119	The personnel files documentation of a technician, however training was completed demonstrated to shaperform an ultrasour. The personnel files descriptions for ultra application for empleand years attended however, no evident training was included. At 3:20 PM Staff B state DON and the Documentation of the Staff B was not able office. Staff B state skills/competency cavailable at this time sure the four other uthrough training but documentation in or	for Staff # 2, 3, 5 an job description for ur, lacked evidence the ted or that any skills ow knowledge of the ind. for Staff #1 and 4 in asound technician are loyment included the for the study of ultrace of successful content in the personnel filestated he/she had specific problem.	altrasound hat any sewere eability to cluded job and the eschool isound, inpletion of le. booke to cluded job and the eschool isound, inpletion of le. booke to cluded job and the eschool isound, inpletion of le. booke to cluded job and the eschool isound, inpletion of le. booke to cluded job and the eschool isound, inpletion of le.	C 119			

Ohio Department of Health

Attachment1

Sono/Screening Orientation/Competency Checklist

Orientee's name			
Preceptor's initials, signatures			
		٠.	
Preceptor to initial box when orientee observed, comp *needs more practice +see notes	leted, independe	nt of task	
	Observed	Completed	Independent
Sono/Screening Preparation:	Objetved	Completed	macponatin
Turns on sono machine			
Sets up lab area			
Screening materials			
Stock			
Run controls			
Obtains patient chart & additional pages (pages 3, 6 for all patients) (pages 15A for 4 – 16 weeks, 15B and 15C for >17 weeks)	7	· 🗀	
Computer Documentation			
In/out times			
Initials			
Pregnancy dates			
Rh NEG (as needed)			
Applies necessary alerts if indicated (i.e. Rhogam, inhaler, allergy)			
Calls Patient, Introduces Self			
Explains Procedures			

	Observed	Completed	Independent
Medical Screening & Documentation			
Height/weight			
Vital signs			
Asks appropriate questions per page 5			
Aware of Preterm's screening criteria			
Labwork			
Performs proper technique for fingerstick			
Obtains blood sample for point of care testing (i.e. Hgb, Rh, UHCG)			
Documentation			
Performs Ultrasound Exam			
Directs patient to lie down on exam table			
Applies sono gel to lower abdomen			
Identifies normal pelvic anatomy (uterus, ovaries, cervix, vagina, fallopian tubes if visible, urinary bladder, adnexas, bowel)			
If applicable, identifies congenital anomaly i.e. bicornuate or didelphic uterus (or verbal demonstration)			
Identifies pelvic pathology (ovarian cysts, fibroids with location, cervical and vaginal cysts if applicable)			
Obtains appropriate 1 Δ pregnancy images with measurements			
Gestational sac (yolk sac, fetal pole if visible, hyperechoic ring)			
CRL (crown-rump length)			
If applicable, identifies abnormalities (i.e. molar pregnancies, fetal demise, pseudo sac, blighted ovum, miscarriage, ectopic)			
If applicable, identifies twin gestation			
Documentation with image attached			

	Observed	Completed	Independent
Obtains appropriate 2Δ pregnancy images with measurement			
BPD (biparietal diameter)			
FL (femur length)			
Placental location			
If applicable, identifies twin gestation			
Documentation with image attached			
Transvaginal ultrasound			
Explains exam			
Instructs patient to empty bladder (urine sample if necessary)			
Assists patient into proper position			
Prepares vaginal probe			
Inserts vaginal probe			
Locates uterus, pregnancy, measures appropriately			
Mifeprex follow-up			
Vital signs			
Questions per follow-up page			
Obtains image of uterus & documents findings			
M.D. to review & sign			
Record in follow-up book			
Places Completed Chart in Appropriate Area			

	Observed	Completed	Independent
Special Circumstances			
Unable to locate pregnancy			
Image empty uterus & adnexas			
Document & attach image			
Too early/ectopic warnings handout			
Identifies ectopic (extrauterine) pregnancy			
Presence of pseudo sac?			
Location			
Document & attach image			
Gives copy to patient			
Instructs patient to go to ER immediately & documents			
Notes:			
have completed the above orientation and feel I can	work independen	tly doing sono	/screening.
Name	Date		· · · · · · · · · · · · · · · · · · ·

Attachment 2

Sono/Screening Annual Review Checklist

Employee's name			•	
Observer's initials, signatures				
Observer to initial box when employee observed, com *needs more practice +see notes	pleted, independ	ent of task		
	Observed	Completed	Independent	Initials
Sono/Screening Preparation:	··			
Turns on sono machine				
Sets up lab area				
Screening materials				
Stock	Ū.			
Run controls				
Obtains patient chart & additional pages (pages 3, 6 for all patients) (pages 15A for 4 – 16 weeks, 15B and 15C for >17 weeks)				
Computer Documentation				
In/out times				
Initials				
Pregnancy dates				
Rh NEG (as needed)				
Applies necessary alerts if indicated (i.e. Rhogam, inhaler, allergy)				
Calls Patient, Introduces Self				
Explains Procedures				

	Observed	Completed	Independent	Initials
Medical Screening & Documentation				
Height/weight				
Vital signs				
Asks appropriate questions per page 5				
Aware of Preterm's screening criteria				
Labwork		.•		
Performs proper technique for fingerstick				
Obtains blood sample for point of care testing (i.e. Hgb, Rh, UHCG)				
Documentation				
Performs Ultrasound Exam				
Directs patient to lie down on exam table				
Applies sono gel to lower abdomen				·
Identifies normal pelvic anatomy (uterus, ovaries, cervix, vagina, fallopian tubes if visible, urinary bladder, adnexas, bowel)				
If applicable, identifies congenital anomaly i.e. bicornuate or didelphic uterus (or verbal demonstration)				
Identifies pelvic pathology (ovarian cysts, fibroids with location, cervical and vaginal cysts if applicable)				
Obtains appropriate 1\Delta pregnancy images with measurements				
Gestational sac (yolk sac, fetal pole if visible, hyperechoic ring)				
CRL (crown-rump length)				
If applicable, identifies abnormalities (i.e. molar pregnancies, fetal demise, pseudo sac, blighted ovum, miscarriage, ectopic)				
If applicable, identifies twin gestation				
Documentation with image attached				

	Observed	Completed	Independent	Initials
Obtains appropriate 2\Delta pregnancy images with measurement				
BPD (biparietal diameter)				
FL (femur length)				
Placental location				
If applicable, identifies twin gestation				
Documentation with image attached				
Transvaginal ultrasound		•		
Explains exam				
Instructs patient to empty bladder (urine sample if necessary)				
Assists patient into proper position				
Prepares vaginal probe				
Inserts vaginal probe				- '
Locates uterus, pregnancy, measures appropriately				
Mifeprex follow-up				
Vital signs				
Questions per follow-up page				
Obtains image of uterus & documents findings				
M.D. to review & sign				·
Record in follow-up book				
Places Completed Chart in Appropriate Area				

	Observed	Completed	Independent	Initials
pecial Circumstances	**			
Unable to locate pregnancy				
Image empty uterus & adnexas				
Document & attach image				
Too early/ectopic warnings handout				
Identifies ectopic (extrauterine) pregnancy				
Presence of pseudo sac?				
Location				
Document & attach image				
Gives copy to patient				
Instructs patient to go to ER immediately & documents				
otes:				
		<u></u>		
nave completed the above observation and feel I can	work independe	ently doing sono	o/screening.	
ame	·	Date	·	



State	Form:	Revisit	Report
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(Y1)	Provider / Supplier / CLIA / Identification Number
	0288AS

(Y2) Multiple Construction A. Building

B. Wing

(Y3) Date of Revisit 11/28/2012

Name of Facility

PRETERM

Street Address, City, State, Zip Code

12000 SHAKER BOULEVARD 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	(Y4) Item	(Y5)	Date	(Y4)	Item	(Y5)	Date
ID Prefix Reg. # LSC	O.A.C. 3701-83-08 (A)	Correction Completed 11/28/2012	Reg. #		Correction Completed		Reg.#		
ID Prefix Reg. # LSC		Correction Completed	ID Prefix Reg. # LSC		Correction Completed		Reg. #		
Reg. #			Reg. #		Correction Completed		Reg. #	·	
ID Prefix Reg. # LSC		Correction Completed	ID Prefix Reg. #				Reg. #		
ID Prefix Reg. # LSC		Correction Completed	ID Prefix Reg. #		Correction Completed		Reg.#		Correction Completed
Reviewed I State Agen Reviewed I	ncy	u	Date: \ る \ろ Date:	Signature of Sur Signature of Sur	veyor:	en	eeTla	Dat	11/20/12
Followup	to Survey Completed o	n:		Check for any Uncor Uncorrected Defic					S NO

STATE FORM: REVISIT REPORT (5/99)

Event ID: 70D612

POC REVIEW

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Provider Name:	PRE	2 ter	m		cc	N: <i>C</i>	1288	AS	-		_		
Facility Phone #:_					Surve	ey Exit D	ate:	7-2-	12				
POC Reviewed By	: 35	laggi			Date	Approve	ed:	11-2	8-12				
Desk Audit: 4								-					
2567 signed and d	Co	mpleted											
	Tag # C 119	Tag#	Tag#	Tag #	Tag#	Tag #	Tag#	Tag #	Tag #	Tag#	Tag#	Tag #	Tag
Correction date within timeframe?	CIT										<u> </u>		
If POC refers to creating new policies/procedures, is a copy included?													
Does the plan address all of the deficient practice?	~												
Does the plan address who will monitor for compliance?	~												
Waiver/Variance requested?													
COMMENTS:						1	1						
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	Tag#	Tag#	Tag#	Tag#	Tag #	Tag#	Tag#	Tag#	Tag#	Tag#	Tag#	Tag#	Tag #
Correction date within timeframe?													
If POC refers to creating new policies/procedures, is a copy included?			•										
Does the plan address all of the deficient practice?													
Does the plan address who will monitor for compliance?													-
Waiver/Variance requested?							<u> </u>		<u> </u>	<u> </u>	<u> </u>		1

	Tag#	Tag#	Tag#	Tag#	Tag#	Tag#	Tag#	Tag#	Tag #	Tag#	Tag#	Tag#	Tag#
						<u> </u>					-		
Correction date within timeframe?													
If POC refers to creating new policies/procedures, is a													
copy included? Does the plan address all of the deficient													
practice? Does the plan address who will monitor for compliance?													
Waiver/Variance requested?								<u> </u>					<u></u>