PRINTED: 02/18/2015
FORM APPROVED

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA630003541	A. BUILDING: ______ B. WING ______	C 12/30/2014

NAME OF PROVIDER OR SUPPLIER: PLANNED PARENTHOOD OF THOUSAND OAK

STREET ADDRESS, CITY, STATE, ZIP CODE: 1200 W HILLCREST DR STE 100, THOUSAND OAKS, CA 91360

(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
D 000	Initial Comments The following represents the findings of the California Department of Health during a entity reported incident investigation. Complaint No.CA00420949 Representing the Department of Public Health Surveyor ID 2780 The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.	D 000	2015 MAR -6 PM 4:22 VENTURA DISTRICT OFFICE	
D 070	T22 DIV5 CH7 ART4-75030(a)(1) Basic Services--Policies and Procedures (1) Description of the types and scope of services which the clinic will provide. This Statute is not met as evidenced by: Based on interview and record review the facility failed to implement it's written policy and procedure for scope of services when an abortion procedure was initiated on Client A whose pregnancy was beyond the gestational age of the clinics established limits. Findings: Review of the clinic's policy in the "Manual of Medical Standards and Guidelines", dated 12/14/12, revised 6/12, page 5 subhead "Client Selection" #2 indicates "...is pregnant and is not more than the gestational age limit of the affiliate program". This clinic was approved for abortion services up to 16 weeks gestation.	D 070	The majority of corrective actions outlined in this document occurred immediately following the incident. This was shared with the DPH surveyor when on site. Safeguards are now in place to ensure the deficient practice does not recur. PPSBVSLO's medical standards and guidelines are being updated (performed on an annual basis). The policy and procedure portion regarding our ability to perform procedures to 16 weeks gestational age remains unchanged.	

Licensing and Certification Division

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Ramia Aleqxes MD
TITLE: Medical Director
(X6) DATE: 3-6-15

Rec'd 3-11-15 KK

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D 070	Continued From page 1 Review of client A's medical record on 12/18/14, revealed the following: Client A was seen on 11/11/14 for a surgical abortion. The procedure was started and the physician, realizing the gestational age was greater than 16 weeks, stopped the procedure. Client A was transported to a nearby hospital for completion of the procedure. During an interview with the physician assistant (PA) on 12/18/14, at 1:45 p.m., the PA indicated she had performed the ultrasound on Client A prior to the procedure. The PA also indicated this was her first time using this particular ultrasound machine (Brand S). According to the PA, all of the other ultrasound machines in this and the other two associated clinics were a different brand (Brand G). Further investigation revealed prior to the ultrasound being performed, the patient services representative routinely enters the clients stated last menstrual period date, into the (Brand S) ultrasound machine. This results in the Brand S ultrasound machine printing out two dates. The first line date is the calculated gestational age according to the patients stated last menstrual period. The second line date is the actual ultrasound calculated gestational age according to the ultrasound image. However, when using the G brand ultrasound there is only the first line date which with the G brand ultrasound is the actual ultrasound calculated gestational age. The PA indicated she requested assistance from the nurse practitioner (NP) with the ultrasound because "She wasn't getting a clear picture". During an interview with the NP on 12/18/14, at 5:10 p.m., the NP indicated she took another ultrasound and after reviewing the image she	D 070	The following corrective actions took place immediately following this incident: 1) A debriefing with the clinic staff took place immediately following the incident. Attachment I shows the incident as the first agenda time on a staff meeting that had already been scheduled to take place that day after clinic. 2) Three days later, a clinical debriefing took place with the staff and was lead by the medical Director (also the surgeon). During this meeting the incident was reviewed, outcomes discussed and Attachment II outlines the corrective actions to be implemented which would prevent a similar incident from occurring again. The emergency was handled appropriately with all staff carrying out their roles effectively. 3) On December 2, 2014 a Root Cause Analysis was performed by our Manager of Quality and Risk. Attachment III outlines the analysis followed by corrective action to be taken. Follow up on the recommendations were made on January 2, 2015 with most tasks completed. The remaining action item is the purchase of an ultrasound machine (same as Brand G) which was ordered on 2/19/15. We anticipate arrival within the next 2-3 weeks. Brand S machine was removed from abortion services on 11/21/14.	11/18/14 11/21/14 12/2/14 1/2/15

Date is 11/18 not 11/11

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D 070	Continued From page 2 stated she "Wasn't seeing the classic landmarks for the gestational age". The NP approached the MD to ask "If the image was OK ?" According to the NP when she was discussing the ultrasound image with the MD, she relayed to the MD,in error, the gestational age was the first line age printed on the ultrasound image, 13 weeks 1 day (which was actually the age calculated by the clients stated last menstrual period). The actual ultrasound calculated gestational age prints out on the second line when using the Brand S. In this case the actual ultrasound calculated gestational age was actually 21 weeks and 1 day. During a concurrent review of the ultrasound results and an interview with the MD on 12/18/14, at 6 p.m.,The MD indicated prior to the procedure, when asked to look at the ultrasound, she was "only looking at the image" and was responding as to whether or not the image was "clear". The MD confirmed that two dates showed up on the ultrasound Brand S machine and the Brand S machine is the only ultrasound machine used which has a different system of printing out the gestational age.	D 070	4) As part of this incident review, it was determined that the PA appropriately consulted with the more experienced clinician. Both appropriately consulted with the physician. 5) On the day of the incident, the Medical Director (surgeon) appropriately was in communication with the receiving hospital physician before the patient arrived. Follow up with the same local physician took place the following day to obtain information on the patient outcome and current patient status. 6) In an effort to ensure that no other patients were effected by this incident, an audit was conducted on all patients receiving abortion service that same day. All tissue examinations matched gestational age obtained on ultrasound and were appropriately documented in EHR. As stated above, the ultrasound Brand S was removed service. Attachment IV. Quarterly gestational age audit added to QM Plan effective January 2015.	11/18/14 11/18/14 11/19/14 2/20/15