

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA140000241	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 12/08/2016
--	--	--	---

NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD - ANTIOCH	STREET ADDRESS, CITY, STATE, ZIP CODE 1104 BUCHANAN ROAD, SUITE C10 ANTIOCH, CA 94509
---	---

(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 001	<p>Initial Comments</p> <p>The following represents the finding of the California Department of Public Health during the investigation of a complaint.</p> <p>Complaint Number: CA00425037</p> <p>Representing the Department: HFEN 25206 and HFES 25205.</p> <p>The inspection was limited to the specific complaint investigated and does not represent the findings of a full inspection of the facility.</p> <p>Three deficiencies were written as a result of the investigation.</p> <p>The following definitions are included for clarity.</p> <p>Transvaginal ultrasound: a type of ultrasound used by doctors to examine female reproductive organs by inserting a probe into the vagina.</p> <p>Complete Abortion: the complete expulsion or extraction from its mother of a fetus or embryo; complete expulsion of any other product of gestation.</p> <p>Incomplete Abortion: an abortion that was partially successful. The pregnancy has ended-no fetus will develop, but the body has only expelled part of the tissue and products of pregnancy.</p> <p>D&C: also known as dilation and curettage, is a surgical procedure often performed after a first-trimester miscarriage. In a D&C, dilation refers to opening the cervix; curettage refers to removing the contents of the uterus.</p> <p>Invasive procedure is a medical procedure in</p>	D 001	N/A – definitions and background only.	
-------	--	-------	--	--

Licensing and Certification Division
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Handwritten signature and date:
CAY
2/18/17

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA140000241	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 12/08/2016
--	--	--	---

NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD - ANTIOCH	STREET ADDRESS, CITY, STATE, ZIP CODE 1104 BUCHANAN ROAD, SUITE C10 ANTIOCH, CA 94509
---	---

(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 001	<p>Continued From page 1</p> <p>which the body is "invaded" or entered by a needle, tube, device or scope. Examples of invasive procedures are needle prick for a blood test, inserting a tube, device or scope.</p> <p>Medical Board of California (MBC): the state agency that licenses medical doctors, investigates complaints, and disciplines those who violate the law.</p> <p>Medication abortion: Use of a synthetic steroid medication which blocks a hormone (progesterone) necessary for pregnancy to continue.</p> <p>Medical Assistants (MAs): The classification of a MA is defined under the provisions of the California Medical Practice Act (Business and Professions Code sections 2069-2071.) "Medical Assistants means a person who may be unlicensed who performs basic administrative, clerical, and technical supportive services..." who functions under the supervision of a licensed physician and physician assistant, nurse practitioner, or nurse midwife in a medical office or clinic setting. "Medical assistants are not allowed to perform such invasive procedures as: placing the needle or starting and disconnecting...an IV[intravenous line]...administering medications or injections into the IV line...inserting a urine catheter...using lasers..." (www.medbd.ca.gov)</p> <p>"Technical supportive services means simple routine medical tasks and procedures that may be safely performed by a medical assistant who has limited training..." (Business a Professions Code §2069.)</p> <p>Unlicensed Assistive Personnel: ..."Refers to those health care workers who are not licensed to</p>	D 001		

*3/8/17
efly*

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA140000241	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/08/2016
--	--	---	---

NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD - ANTIOCH	STREET ADDRESS, CITY, STATE, ZIP CODE 1104 BUCHANAN ROAD, SUITE C10 ANTIOCH, CA 94509
---	---

(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 001	Continued From page 2 perform nursing tasks; it also refers to those health care workers who may be trained and certified, but are not licensed...Tasks which require a substantial amount of scientific knowledge and technical skill may not be assigned to unlicensed assistive personnel." (The California Board of Registered Nursing's advisory statement on Unlicensed Assistive [UAPs] NPR-B-16 11/94.)	D 001		
D 046	T22 DIV5 CH7 ART4-75026(b) Basic Services--General Requirements (b) All advice, diagnosis, treatment, drugs and appliances shall be provided only by persons authorized by law to provide such services. This Statute is not met as evidenced by: Based on staff interview and record review, the facility (Clinic 1) failed to ensure that the lead clinician, nurse practitioner (NP 2), followed a standardized procedure, in accordance with California laws governing nurse practitioners, when ordering medications for Patient 1. This failure resulted in the safety elements inherent in the law not being followed and therefore had the potential to compromise the safety of Patient 1. (Standardized procedures are the legal mechanism for registered nurses and nurse practitioners to perform functions which would otherwise be considered the practice of medicine. CA Board of Registered Nursing on Nurse Practitioner Practice: NPR-B-23 04/1999 and revised 4/2011). Findings:	D 046	1. On March 3, 2017, we reviewed our standardized procedures (SPs) and determined that the following changes need to be made: a. Our standardized procedures must either include, or reference specifically, information from PPNorCal's existing protocols and procedures that address (1) how the SPs were developed and approved in collaboration by the nurse practitioners (NPs), the supervising physicians, and the administrator of the health center; (2) the extent to which physician supervision is required for specific functions; (3) the method of periodic review of the NP's competence, including peer review and review of the provisions of the SPs; (4) the entire regimen of medication the NP can administer/dispense; and (5) the supervisory relationships between the NPs and the supervising physician, provided that a physician shall not supervise more than 4 full time equivalent NPs at one time. b. As mentioned in the Statement of Deficiencies, PPNorCal's clinicians practice in accordance with written medical protocols, policies, and procedures contained in its Manual of Medical Standards and Guidelines (MS&Gs) and standard operating procedures. The MS&Gs and standing operating procedures (collectively, Protocols) are based on the evidence-based protocols issued by the Planned Parenthood national office, Planned Parenthood Federation of America. These protocols are adapted for use by each affiliate, including PPNorCal.	

3/18/17
CAY

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA140000241	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 12/08/2016
NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD - ANTIOCH		STREET ADDRESS, CITY, STATE, ZIP CODE 1104 BUCHANAN ROAD, SUITE C10 ANTIOCH, CA 94509		
(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 046	<p>Continued From page 3</p> <p>Review of Patient 1's Office Visit record, dated 10/28/14, showed NP 2 was the "provider." Under the heading of, "Meds Prescribed during this visit," for Patient 1 were:</p> <ul style="list-style-type: none"> * Micrhogam Ultra-Filtered Plus 250 unit (50 mcg), intramuscular injection given to Patient 1 in the clinic, (Micrhogam is an antibody that Patient 1 did not have in her blood. Prescribed to prevent a reaction in case the fetus was positive for the RH antibodies.) * Zithromax 500 mg, one tablet, oral medication (antibiotic) * Misoprostol 200 mcg (Quantity: 4), 4 tabs po (by mouth) for 30 minutes: swallow remainder (Used with another drug Mifeprex to end a pregnancy.) * Mifeprex 200 mg, administered to Patient 1 in the clinic (Mifeprex or Mifepristone is an abortion pill used to terminate an early pregnancy and causes cramping and bleeding from the uterus.) * Acetaminophen-Codeine 300 mg-30 mg (Quantity: 10), 1 to 2 tablets by mouth every four to six hours as needed for pain (narcotic pain medication) * Promethazine HCL 25 mg, one tablet by mouth before Misoprostol, then every six hours as needed. (Used to treat nausea and vomiting.) <p>In a phone interview on 12/30/14 at 11:25 a.m., Patient 1 said she received abortion pills from the facility on 10/28/14, and then she took another set of abortion pills on 10/29/14. She returned to Clinic 1 for a follow-up appointment on 11/4/14. Patient 1 said clinic staff informed her the vaginal ultrasound showed a "complete abortion." On 11/15/14 around 1:30 a.m., Patient 1 said she bled heavily and passed clots. On 11/16/14, Patient 1 said she went to the hospital because she "passed out." Patient 1 said, "...I could have died."</p>	D 046	<p>c. PPNorCal's Protocols are written by the Director of Quality Management and Vice President of Medical Services, who are both nurse practitioners, in collaboration with the Medical Director and the administrator before the Protocols are approved and implemented agency-wide.</p> <p>d. After the March 3, 2017 review, we determined that all of the missing components identified in the Statement of Deficiencies were actually included in the Protocols or not deficiencies at all (e.g., we adhere to the physician oversight ratio requirement of 4:1). However, because these components were not included or referenced in the Mifepristone Medication Abortion document reviewed by the inspector, they were identified as deficiencies in our SPs.</p> <p>e. The revised SPs will serve as a model for all process-specific or disease-specific SPs used by PPNorCal, which will all be revised as soon as practicable to ensure they include all of the required elements outlined in 16 CCR 1474.</p> <p>f. Our revised SPs will be distributed to all NPs providing services for PPNorCal no later than March 27, 2017. Director of Quality Management will incorporate compliance with standardized procedures into the ongoing monthly audits performed at PPNorCal to ensure that all NPs and supervising physicians are aware of and are following the current SPs.</p> <p>g. We note that the last "deficiency" cited on page 7 of the Statement of Deficiencies is not actually a deficiency. Specifically, while the inspector correctly noted that the Associate Medical Director (AMD) had oversight over 20 clinics, it should not be inferred from that statement that the AMD is the supervising physician for all NPs located at all 20 clinics at all times.</p>	

Handwritten signature and date:
3/18/17

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA140000241	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/08/2016
--	--	---	---

NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD - ANTIOCH	STREET ADDRESS, CITY, STATE, ZIP CODE 1104 BUCHANAN ROAD, SUITE C10 ANTIOCH, CA 94509
---	---

(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 046	<p>Continued From page 4</p> <p>Review of the hospital's Discharge Summary, dated 11/18/14 at 1:46 p.m., showed Patient 1 was admitted for treatment of "...profound vaginal bleeding due to incomplete abortion from medical abortion..."</p> <p>In a staff interview on 11/8/16 at 11:59 a.m., Associate Medical Director (AMD) said that she worked for the facility since 2011. AMD said she had oversight of twenty clinics in a network that provided similar services and had the same policies and procedures. AMD had oversight of the nurse practitioners who did the clinical work in the twenty clinics.</p> <p>On 11/8/16 at 12:25 p.m., AMD looked at the document, entitled, "Mifepristone Medication Abortion," implemented, 9/1/14, and agreed it was the standardized procedure for nurse practitioners to perform medication abortions. AMD said in the document "MD" meant physicians; "clinicians" meant nurse practitioners, midwives and physician assistants.</p> <p>On 11/10/16 at 1:20 p.m., during an interview, the Administrator, (Director) said, "We follow _____ [national organization's] protocols." Director could not say who wrote the protocols, and didn't know the process of policy development. Director said: "I only implement the protocols."</p> <p>On 11/10/16 at 2:21 p.m., during an interview, NP 2 said she didn't know what the surveyor meant by a standardized procedure. NP 2 said she followed the health organizations protocols. NP 2 said she had a furnishing number from the the Board of Registered Nursing of CA., and "That's what I need to prescribe drugs. Why would I need</p>	D 046	<p>To clarify: PPNorCal has two levels of physician supervision and oversight: agency-wide and NP-specific. The agency-wide level of supervision is performed by either the Medical Director, the AMD, or another contracted OB/GYN, at least one of whom is available (either in person, over the phone, or via electronic communication) 24 hours a day, seven days a week (any time services are being provided and after hours) for consultation and guidance. The AMD was referring to this level of oversight when she stated on 11/08/16 that she had oversight over 20 clinics.</p> <p>However, we believe the inspector was attempting to determine who the assigned supervisor for the NP in question was, which relates to the second level of review. All PPNorCal NPs are assigned an individual physician supervisor. The physician supervisor conducts chart reviews, discusses cases, and reviews the results of medical audits. Each physician supervisor is assigned no more than 4 full-time equivalent NPs. The guidelines for physician supervision are documented in PPNorCal's Protocols, and as discussed above, will be incorporated either directly into the revised SPs or referenced by name and page number.</p>	

Handwritten signature and date: 2/18/17

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA140000241	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 12/08/2016
--	--	--	---

NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD - ANTIOCH	STREET ADDRESS, CITY, STATE, ZIP CODE 1104 BUCHANAN ROAD, SUITE C10 ANTIOCH, CA 94509
---	---

(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 046	<p>Continued From page 5</p> <p>a standardized procedure if I have a furnishing number." NP 2 said that she was the lead clinician in the clinic.</p> <p>Review of one of the laws, Business and Professions Code (BPC) sections 2834 - 2837, governing the scope of practice of Nurse Practitioners in California requires that nurse practitioners who order drugs and devices must have a furnishing (to order drugs) certificate and provide drugs in accordance with approved standardized procedures.</p> <p>Also, in section 2836.1 of BPC, the nurse practitioner may order drugs when all the following apply:</p> <p>"...(a) Drugs or devices are furnished or ordered by a nurse practitioner in accordance with standardized procedures or protocols developed by the nurse practitioner and the supervising physician...when the drugs or devices furnished or ordered are consistent with the practitioner's educational preparation or for which clinical competency has been established and maintained..."</p> <p>"(b)...The standardized procedure or protocol shall be developed and approved by the supervising physician and surgeon, the nurse practitioner, and the facility administrator..."</p> <p>"...(c) (1) The standardized procedure or protocol covering the furnishing of drugs or devices shall specify which nurse practitioners may furnish or order drugs or devices, which drugs or devices may be furnished or ordered, under what circumstances, the extent of physician and surgeon supervision, the method of periodic review of the nurse practitioner's competence, including peer review, and review of the</p>	D 046		
-------	--	-------	--	--

*3/8/17
awg*

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA140000241	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 12/08/2016
--	--	--	---

NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD - ANTIOCH	STREET ADDRESS, CITY, STATE, ZIP CODE 1104 BUCHANAN ROAD, SUITE C10 ANTIOCH, CA 94509
---	---

(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 046	<p>Continued From page 5</p> <p>a standardized procedure if I have a furnishing number." NP 2 said that she was the lead clinician in the clinic.</p> <p>Review of one of the laws, Business and Professions Code sections 2834 - 2837, governing the scope of practice of Nurse Practitioners in California requires that nurse practitioners who order drugs and devices must have a furnishing (to order drugs) certificate and provide drugs in accordance with approved standardized procedures.</p> <p>Also, in section 1236.1 of BPC, the nurse practitioner may order drugs when all the following apply:</p> <p>"...(a) Drugs or devices are furnished or ordered by a nurse practitioner in accordance with standardized procedures or protocols developed by the nurse practitioner and the supervising physician...when the drugs or devices furnished or ordered are consistent with the practitioner's educational preparation or for which clinical competency has been established and maintained..."</p> <p>"(b)...The standardized procedure or protocol shall be developed and approved by the supervising physician and surgeon, the nurse practitioner, and the facility administrator..."</p> <p>"...(c) (1) The standardized procedure or protocol covering the furnishing of drugs or devices shall specify which nurse practitioners may furnish or order drugs or devices, which drugs or devices may be furnished or ordered, under what circumstances, the extent of physician and surgeon supervision, the method of periodic review of the nurse practitioner's competence, including peer review, and review of the</p>	D 046		
-------	--	-------	--	--

*3/18/17
galy*

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA140000241	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 12/08/2016
--	--	--	---

NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD - ANTIOCH	STREET ADDRESS, CITY, STATE, ZIP CODE 1104 BUCHANAN ROAD, SUITE C10 ANTIOCH, CA 94509
---	---

(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 046	<p>Continued From page 6</p> <p>provisions of the standardized procedure..."</p> <p>"...(d) The furnishing or ordering of drugs or devices by a nurse practitioner occurs under physician and surgeon supervision. Physician and surgeon supervision shall not be construed to require the physical presence of the physician, but does include (1) collaboration on the development of the standardized procedure, (2) approval of the standardized procedure, and (3) availability by telephonic contact at the time of patient examination by the nurse practitioner."</p> <p>"(e) For purposes of this section, no physician and surgeon shall supervise more than four nurse practitioners at one time..."</p> <p>Review of the document, "Mifepristone Medication Abortion," showed it did not comply with standardized procedure elements described in the above law in that:</p> <ul style="list-style-type: none"> *There was no evidence of collaboration on the development and approval of the standardized procedure by the nurse practitioner, the supervising physician, and administrator. *The extent of physician and surgeon supervision was not included. *The method of periodic review of the nurse practitioner's competence, including peer review, and review of the provisions of the standardized procedure were not specified in the document. *The document had a "IX. Medication Regimens" section which included Mifepristone and Misoprostol (medication abortion pills) and antibiotics (Azithromycin.) The regimen did not include the other medications prescribed: Micrhogam, acetaminophen-codeine, and Promethazine. *The physician had oversight of nurse practitioners in twenty clinics as stated in an 	D 046		

3/8/17
GAY

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA140000241	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 12/08/2016
--	--	--	---

NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD - ANTIOCH	STREET ADDRESS, CITY, STATE, ZIP CODE 1104 BUCHANAN ROAD, SUITE C-10 ANTIOCH, CA 94509
---	--

(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 046	Continued From page 7 interview on 11/8/16 at 11:59 a.m. as reported above.	D 046		
D 068	<p>T22 DIV5 CH7 ART4-75029(b) Basic Services--Other Health Personnel</p> <p>(b) The professional director shall ensure that, in addition to meeting the licensing, certification or other legal requirements, all health personnel are qualified by training and experience to perform those services they are assigned to provide.</p> <p>This Statute is not met as evidenced by: Based on staff interview and record review, the professional directors: Associate Medical Director, Vice President of Medical Services, and the Regional Director of Clinic 1:</p> <p>1. Failed to provide qualified staff to perform transvaginal ultrasounds for Patient 1, who had a medication abortion. A "Reproductive Health Specialist" (RHS 1), with a high school diploma and a medical assistant class, was trained by the clinic's staff to perform transvaginal ultrasounds. The performance of a transvaginal ultrasound is an invasive procedure and outside the scope of service of a medical assistant. (See Business and Profession Code §2069 - §2070.) This failure resulted in staff, without the required educational background and certification performing an invasive procedure which could potentially result in patient injury and poor quality, ultrasound images.</p> <p>2. Failed to ensure the RHS' job description complied with the laws of California when the job description included giving advice, and providing comprehensive education and options counseling. The listed clinic responsibilities</p>	D 068	<p>On March 3, 2017, PPNorCal reviewed its entire clinical operations system and policies and made the following changes:</p> <p>1. Transvaginal ultrasounds.</p> <p>a. As of Friday March 3, 2017, unlicensed Reproductive Health Specialists (RHS) no longer perform transvaginal ultrasounds (TVUs). All PPNorCal policies and procedures, training materials, and forms related to TVUs have been updated to reflect this change.</p> <p>b. On Thursday March 2, 2017, this change was communicated via teleconference to all health center managers and Senior Regional Directors. On Thursday March 2, 2017, PPNorCal also distributed a memorandum about this change to all health center staff, including all RHS staff.</p> <p>c. No later than Friday, March 17, 2017, a chart audit of all TVUs performed after March 3, 2017, will be completed by Director of Quality Management to ensure that all health personnel are performing only those services they are authorized and assigned to provide. If any TVU is found to be not in compliance with PPNorCal's revised policies and procedures, the Director of Quality Management will inform the health center manager who oversees the staff member who performed the procedure, and specific corrective action will be taken as needed, under the direction of the health center manager, the Director of Quality Management and the Senior Regional Director.</p>	

Handwritten signature and date: 2/8/17

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA140000241	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B WING _____	(X3) DATE SURVEY COMPLETED 12/08/2016
NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD - ANTIOCH		STREET ADDRESS, CITY, STATE, ZIP CODE 1104 BUCHANAN ROAD, SUITE C10 ANTIOCH, CA 94509		
(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 068	<p>Continued From page 8</p> <p>exceeded the scope of service of the RHS. This failure had the potential RHS' and other staff would rely on the job description and be unaware of the limitations of an RHS.</p> <p>Findings:</p> <p>1. Review of Patient 1's clinic Office Visit, dated 11/4/14, showed that Patient 1 received medication abortion pills; Mifepristone on 10/28/14 and Misoprostol on 10/29/14. Review with the Vice President of Medical Services (VP and also a nurse practitioner,) showed NP 2 interpreted the ultrasound and documented Patient 1 had an empty uterus and a complete abortion.</p> <p>In a phone interviews, on 12/30/14 at 11:25 a.m., Patient 1 said she returned to Clinic 1 for a follow-up appointment on 11/4/14. Patient 1 said clinic staff informed her the vaginal ultrasound showed a complete abortion, and she was released. Patient 1 said, on 11/15/14 around 1:30 a.m., she bled heavily, and passed clots. On 11/16/14, she went to an emergency room because she passed out at home. Patient 1 said she was hospitalized and had surgery to remove the contents from inside her uterus, and had a blood transfusion. Patient 1 said hospital staff told her the uterus' opening was not closed yet, and she still had blood and pregnancy tissue in her uterus.</p> <p>On 12/9/16 at 1:05 p.m., during a phone interview, Patient 1 said NP 2 did not check whether her cervix (opening of the uterus) in the follow-up appointment on 11/4/14. Patient 1 said she did a manual check herself later at home, and felt a huge blood clot, the size of a baseball.</p> <p>Review of the hospital's Emergency Department Physician Notes, dated 11/16/14 at 2:09 p.m.,</p>	D 068	<p>d. The PPNorCal Medical Quality Assurance Committee reviews all medical incidents on a quarterly basis. At Monday, March 6, 2017 meeting, a retrospective review of all abortion-related incidents was performed to determine whether any incidents from 2014 to date may have been related to an RHS' performance of a TVU. No incidents were determined to have been the result of RHS performance of a TVU. The Medical Quality Assurance Committee will continue to monitor and discuss all incidents on a quarterly basis.</p> <p>2. RHS job descriptions.</p> <p>a. The current job description for RHS position will be reviewed no later than Thursday, March 9, 2017 by legal counsel and the VP of Medical Services to ascertain compliance with all relevant rules and regulations, including but not limited to California Business and Professions Code §§ 2069-2070. Any needed revisions to the job description will be completed no later than Monday, March 13, 2017. Health center managers will review with all RHS staff the scope of their work and limitations of their scope, using the revised job description as a guide.</p> <p>b. The revised job description will reflect existing PPNorCal policy with respect to RHS staff, which includes the direction that unlicensed staff may not give advice or provide recommendations to patients. Rather, RHS staff provide patient information and instruction, as authorized under 16 CCR 1366. This includes reviewing written information sheets with patients and directing any patient questions to a licensed clinician or physician. To ensure compliance, staff observations will be conducted on an ongoing basis by both health center managers and lead clinicians to ensure that all health personnel are performing only those services they are authorized and assigned to provide.</p>	

3/8/17
GPH

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA140000241	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/08/2016
NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD - ANTIOCH		STREET ADDRESS, CITY, STATE, ZIP CODE 1104 BUCHANAN ROAD, SUITE C10 ANTIOCH, CA 94509	
(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)
D 068	<p>Continued From page 9</p> <p>showed Patient 1: "Presents with vaginal bleeding--patient had a tab [therapeutic abortion] about 2 weeks ago, had large amount of spotting and clots. Saturday [11/15/14] started heavy vaginal bleeding...had a syncopal [fainting] episode..."</p> <p>Review of the hospital's Discharge Summary, dated 11/18/14 at 1:46 p.m., showed that Patient 1: "Was admitted to the hospital for treatment of profound vaginal bleeding due to incomplete abortion from medical abortion 10/29/14. She had acute blood, symptomatic blood loss that required 2 units of PRBC [packed red blood cells] to be transfused and D and C by a gynecology [women health] physician." Patient 1's post-operative diagnosis indicated incomplete abortion.</p> <p>In staff interviews on 10/25/16 at 2:58 p.m. - 4 p.m., the Vice President of Medical Services (VP) said the staff person who performed the transvaginal ultrasound was a Reproductive Health Specialist (RHS 1.) VP said RHS 1 performed the ultrasound scans of Patient 1, before and after the medication abortion, on 10/28/14 and 11/4/14. RHS 1 loaded the images into the computer and NP 2 interpreted the images at a computer outside the exam room. VP said RHS' were unlicensed staff, trained by clinic staff to perform ultrasounds.</p> <p>On 10/25/16 at 2:59 p.m., during an interview, Director said she "pretty much runs the clinic." Director said that some RHS' had medical assistant certificates, and some had college degrees and all had extensive in-house training. Director said a physician initially signed off on the RHS' skill and annually audited their skills to perform transvaginal ultrasounds. Director also said she did not know Title 22 (California</p>	D 068	<p>3. Informed consent.</p> <p>a. RHS staff will no longer witness informed consent documents. As of Monday, March 27, 2017, PPNorCal's policy with respect to obtaining informed consent from a patient in advance of a complex procedure will include asking a licensed clinician to obtain a patient's signature on a written informed consent form and to have that licensed clinician witness the signature. This practice will better document PPNorCal's existing policy of ensuring that a patient has the ability to ask questions about obtain information from a licensed clinician before consenting to a complex procedure.</p> <p>b. All PPNorCal policies and procedures, training materials, and forms will be updated no later than Monday, March 27, 2017 to reflect this change.</p> <p>c. To ensure compliance, staff observations will be conducted on an ongoing basis by both health center managers and lead clinicians to ensure that all health personnel are performing only those services they are authorized and assigned to provide.</p>

3/8/17
[Signature]

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA140000241	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 12/08/2016
NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD - ANTIOCH		STREET ADDRESS, CITY, STATE, ZIP CODE 1104 BUCHANAN ROAD, SUITE C10 ANTIOCH, CA 94509		
(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 068	Continued From page 10 regulations which pertain to legal operations of health care facilities including primary care clinics): "I can't say I heard of it." Director said she followed OSHA guidelines (Occupational Safety and Health Administration: federal and state organizations which protects and improves the health and safety of working men and women), the policies and procedures of Clinic 1, and HIPAA (Health Insurance Portability and Accountability Act of 1996, federal legislation that provides privacy and security provisions for safeguarding medical information) to guide her in running the clinic. On 11/8/16 at 11:59 a.m., during an interview, the Associate Medical Director (AMD) said she had oversight of Clinic 1 and 19 other clinics in a network of clinics providing similar services. AMD said the network of 20 clinics were run the same and had the same policies and procedures. AMD said she had clinical oversight of the nurse practitioners but did not supervise RHS'. AMD said to ask the Director about policies related to the RHS'. On 11/8/16 at 12:35 p.m., AMD said the head of ultrasound trainers was also trained in-house and was not a certified ultrasound technician. AMD said performing a transvaginal ultrasound was not outside the scope of a medical assistant/RHS. AMD said many other health care settings had medical assistants performing ultrasounds. AMD was unable to name another health care setting, outside the clinic network for whom she worked, which allowed medical assistants to perform ultrasounds. AMD then said it was her medical opinion that performing ultrasounds was within the scope of service of a medical assistant and RHS.	D 068		

Handwritten signature and date:
3/8/17

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA140000241	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 12/08/2016
--	--	--	---

NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD - ANTIOCH	STREET ADDRESS, CITY, STATE, ZIP CODE 1104 BUCHANAN ROAD, SUITE C10 ANTIOCH, CA 94509
---	---

(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 068	<p>Continued From page 11</p> <p>On 11/10/16 at 1:20 p.m., during an interview, Director said she did not contact the Medical Board of California to determine what MAs/RHS' can do: "We follow _____ [national organization's] protocols." Director could not say who wrote the protocols, and didn't know the process of policy development. Director said: "I only implement the protocols." Director said that she was the RHS' supervisor. Director said that RHS' had to submit a certain number of ultrasound views to the clinic's medical services, and they were evaluated and signed off by one of the physicians. Clinic 1 had three to four RHS' who performed the transvaginal ultrasounds. Director said that a high school diploma was the minimum qualification to become an RHS.</p> <p>In a staff interview, on 11/10/16 at 2:45 p.m., NP 2 said she was the lead clinician and clinical supervisor of RHS 1, who performed the transvaginal ultrasound on Patient 1 by inserting a probe into the vagina. NP 2 was not in the room during the procedure. NP 2 said she relied on Clinic 1's policies and procedures about what medical assistants could do and not do.</p> <p>In a staff interview on 11/10/16 at 3:32 p.m. - 4:10 p.m., RHS 1 said she inserted the vaginal probe into Patient 1's vagina to take pictures of the uterus in different planes, and at least two different views. RHS 1 said that she did a final swipe, but the swipe was not a video for different views. RHS 1 said that no staff observed how she did the swipe. RHS 1 said she attended a school for medical assistants. RHS 1 said she performed vaginal ultrasounds since 2004, and the former medical director signed her off to do ultrasounds. RHS 1 also said she submitted various ultrasound images to a physician for annual ultrasound competency renewal. The physician</p>	D 068		

*3/8/17
afly*

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA140000241	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/08/2016
--	--	---	---

NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD - ANTIOCH	STREET ADDRESS, CITY, STATE, ZIP CODE 1104 BUCHANAN ROAD, SUITE C10 ANTIOCH, CA 94509
---	---

(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 068	<p>Continued From page 12</p> <p>viewed the images, off site, through a shared computer drive and did not observe the performance of the ultrasound. RHS 1 did not remember if the clinic had any policy regarding the limitations of her job classification.</p> <p>2. Review of the "Reproductive Health Specialist" job description, undated, included a list of clinic responsibilities including: "...Answer questions about birth control, health, and pregnancy. Screen calls, give advice...Abortion services: Provide comprehensive education and options counseling to client, allowing client to make informed decision...answer questions regarding the abortion procedure, possible complications, and birth control options...Primary Care/Well Child Services: Provide health education about prevention..."</p> <p>On 11/8/16 at 9:32 a.m., after an inquiry regarding the above job description, an e-mail from the MBC had the following: "This position would require, at the minimum the training required by law for a medical assistant; however, many of the duties listed in the job description do not fall within the scope of practice for a medical assistant, and may only be performed by a licensed RN or above...A medical assistant is not permitted to counsel patients or give medical advice, which is mentioned several times in the job description. A medical assistant is not permitted to examine the patient or to obtain informed consent from a patient...A medical assistant may provide only technical supportive services that are simple, routine medical tasks and services."</p> <p>On 11/10/16 at 1:20 p.m., Director said the RHS' "...Don't give advice--they relay advice." Director said RHS' follow information sheets and explain</p>	D 068		

*3/8/17
afg*

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA140000241	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 12/08/2016
--	--	--	---

NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD - ANTIOCH	STREET ADDRESS, CITY, STATE, ZIP CODE 1104 BUCHANAN ROAD, SUITE C10 ANTIOCH, CA 94509
---	---

(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 068	<p>Continued From page 13</p> <p>choices/options counseling depending on the situation. "The RHS' may ask a few clarifying questions to get them [patients] close to making a decision." Director said she did not question what was in the job description. Regarding whether there was a written guidance for RHS' limitations, Director said there was nothing specifically written: "They follow the protocols."</p> <p>In a staff interview, on 11/10/16, beginning at 2:45 p.m., NP 2 said she was the lead clinician in Clinic 1 and the clinical supervisor of RHS'. NP 2 said she relied on the clinic's policies and procedures about what medical assistants could do and could not do. NP 2 said she did not get involved in policy-making and she did not contact the California Medical Board to inquire about the medical assistants' scope of service.</p> <p>On 11/10/16 at 3:54 p.m., RHS 1 said she didn't give advice. She reviewed educational forms, mainly about birth control, with patients. RHS 1 said she discussed side effects of birth control. RHS 1 did not recommend one type of birth control or another. Regarding consent forms, RHS 1 described her process. RHS 1 obtained the patient's signature on a service consent form and on the medication abortion consent out of the presence of the NP or physician. RHS 1 read off what the consent was and gave a copy to the patient. RHS 1 said after the patients received the information they decided to sign or not and then she witnessed the signature. Mutual review of Patient 1's Client Information For Informed Consent Using The Abortion Pill, dated 10/30/14, showed that RHS 2 witnessed Patient 1's signature. Typed in above RHS 2's signature was: "The patient got this information. She said she read and understood it. She [Patient 1] was able to ask any questions she had."</p>	D 068		

*3/8/17
amy*

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA140000241	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/08/2016
--	--	---	---

NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD - ANTIOCH	STREET ADDRESS, CITY, STATE, ZIP CODE 1104 BUCHANAN ROAD, SUITE C10 ANTIOCH, CA 94509
---	---

(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 068	<p>Continued From page 14</p> <p>In a phone interview on 12/9/16 at 12:58 p.m., Patient 1 said the staff who reviewed the medication abortion informed consent and witnessed her signature, was a different person from the NP who provided the medication for the abortion.</p> <p>Review of the AMD's job description, last revised 8/3/16, had the following: "...The Associate Medical Director is responsible with the Medical Director for providing medical leadership and direction...for implementing medical protocols that are consistent with clinical standards set by _____ [national organization] and all federal and state regulations and for assuring on-going compliance by all licensed staff in the provision of medical care..."</p> <p>Review of the job description of the Director, undated, showed: "The Regional Director is responsible for the internal systems and personnel management of the health centers, assuring compliance with regional and state regulations and standards.</p> <p>Review of the clinic network's organizational chart, updated 11/4/16, showed the VP of Medical Services had oversight of the medical services of all 20 clinics as well as Quality Management.</p> <p>Review of the clinic's Ultrasound Services document, implemented 6/1/14, showed that "Both licensed and non-licensed personnel may be trained in the provision of ultrasound where allowed by state and local law. Non-licensed personnel may perform ultrasound for abortion, early pregnancy evaluation."</p> <p>On 11/8/16 at 8:55 a.m., after an inquiry, the</p>	D 068		

*3/8/17
atxy*

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA140000241	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 12/08/2016
--	--	--	---

NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD - ANTIOCH	STREET ADDRESS, CITY, STATE, ZIP CODE 1104 BUCHANAN ROAD, SUITE C10 ANTIOCH, CA 94509
---	---

(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 068	Continued From page 15 Medical Board of California's Analyst sent an email with the following statements: "According to the Medical Board of California's legal counsel, conducting a vaginal ultrasound is outside of the scope of a medical assistant. This is an invasive procedure, and is not authorized under the statutes and regulations applicable to medical assistants."	D 068		

*3/8/17
amy*