

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140009	(X2) MULTIPLE CONSTRUCTION: A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 10/03/2017
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NAME OF PROVIDER OR SUPPLIER REPRODUCTIVE SERVICES	STREET ADDRESS, CITY, STATE, ZIP CODE 1511 EAST MISSOURI EL PASO, TX 79902
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A.000 TAC 139 Initial Comments

Note: The State Form is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be referred to the Office of the Texas Attorney General (OAG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.

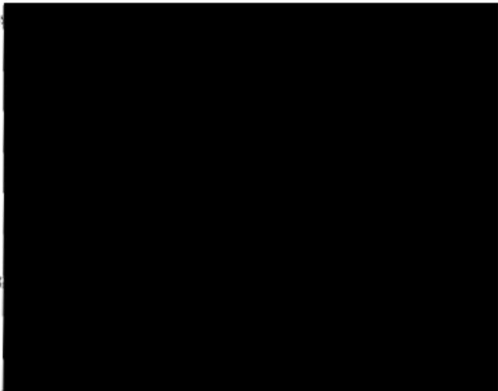
An entrance conference was held with the facility Administrator on the afternoon of 10-2-17. The purpose and process of the licensure resurvey were discussed, and an opportunity given for questions.

Continued licensure is recommended, with an approved plan of correction.

An exit conference was held with the facility Administrator the afternoon of 10-3-17.

Preliminary findings of the survey were discussed, and an opportunity given for questions.

A.037



A.000

Please see attached for all responses and plans of correction

*Reviewed 10-24-17
by: Wanda Wilson, SA*

A.037

SOD - State Form

LA [REDACTED] REPRESENTATIVE'S SIGNATURE:

TITLE

Administrator

(X6) DATE

10-23-17

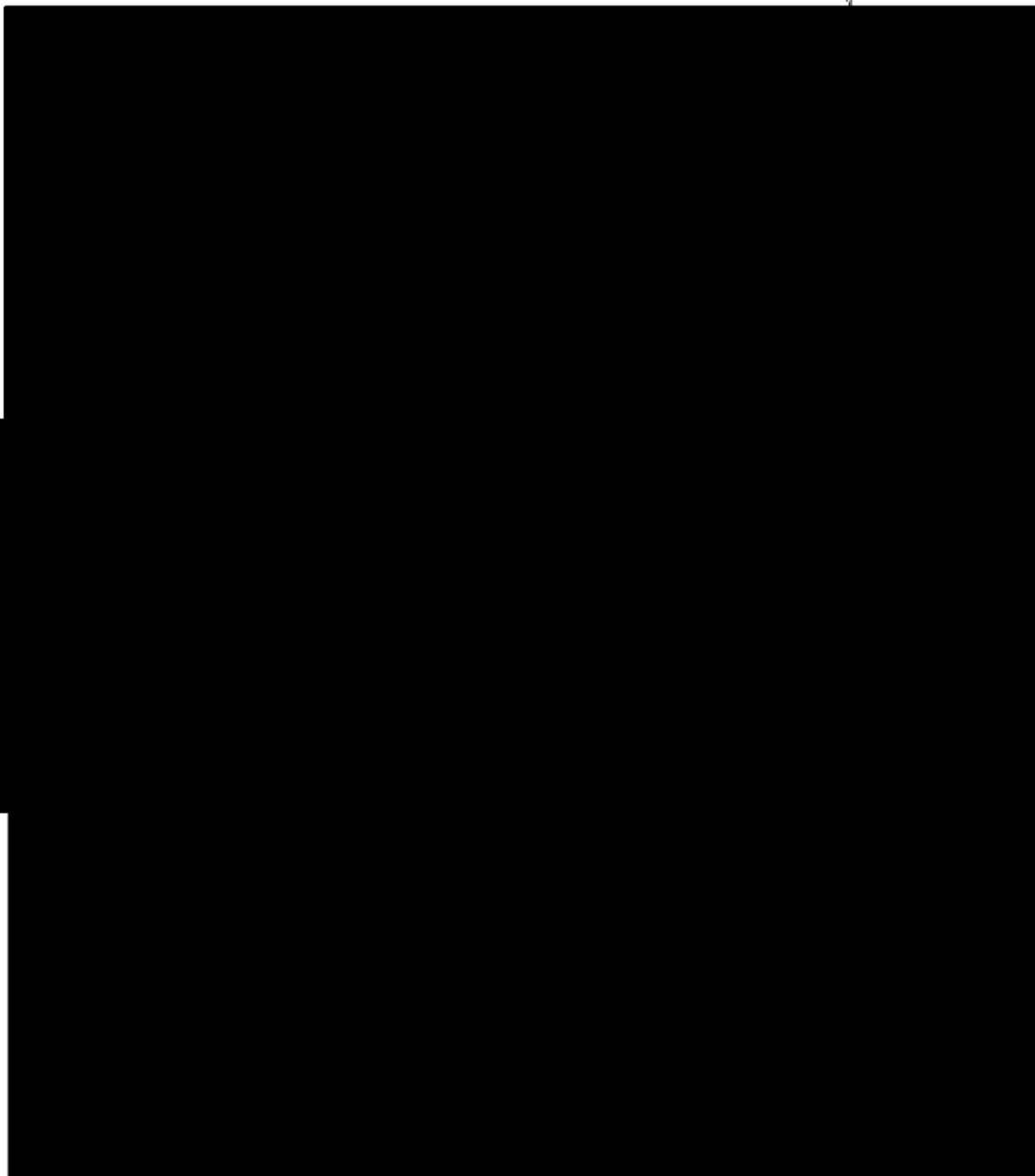
10-25-17

Attachment to Statement of Deficiencies and Plan of Correction

October 23, 2017

Tonia Thomas for Wanda Wilson, RN – Manager
Texas Health and Human Services
Health Care Quality Section

Re: Plan of Correction in Response to Summary Statement of Deficiencies, October 12, 2017



Plan of Correction for Deficiency No. 4 (A 197) – Physical and Environmental Requirements

Texas Administrative Code § 139.4(1)(A) requires that a facility “have a safe and sanitary environment . . . maintained to protect the health and safety of patients and staff at all times.”

The facility will buy a lock to secure the cabinet in which cleaning chemicals, including bleach and Envirocide, are stored. The facility has already discarded all expired solution and ordered new replacement solution. Additionally, the facility has discarded the open saline vial referenced in the Statement of Deficiencies. The nurse responsible for the open vial has been re-trained on protocols regarding open vials and dating of vials.

Complete Date: Saturday, October 28, 2017.

Plan of Correction for Deficiency No. 5 (A 260) – House Bill 15 Disclosure Requirements

Texas House Bill 15 (codified at Texas Health and Safety Code § 171.012) requires, among other things, that at least 24 hours prior to the abortion procedure, “the physician who is to perform the abortion or an agent of the physician who is a sonographer certified by a national registry of medical sonographers performs a sonogram on the pregnant woman on whom the abortion is to be performed.” The bill and statute exempt from the 24-hour requirement any patient who lives farther than 100 miles from the nearest abortion facility and instead require the sonogram be done at least 2 hours prior to the procedure.

A physician at the facility currently performs, displays, and explains all sonograms to patients, and makes heart auscultation audible and explains auscultation to the patient.

Complete Date: October 4 2017

Additionally, the facility has established a protocol for assessing the 100+ mile exception. All facility employees have been trained in the new protocol, which involves locating the patient’s home on a map and reviewing its location relative to that of all abortion facilities in Texas. This map will be available to all employees and the process will take place at the time of the patient’s first phone call to the clinic. Going forward, all patients who live over 100 miles from the nearest abortion facility will be scheduled for their procedure no less than two hours following the sonogram and informed consent process. All employees have been re-trained on the two-hour wait requirement and scheduling process.

Complete Date: October 4, 2017

Attachment to Statement of Deficiencies and Plan of Correction

Plan of Correction for Deficiency No. 6 (A 322) – Health Care Services

Texas Administrative Code § 139.54(b)(2) allows physicians to “train nonlicensed personnel, age 18 years or above, to extract blood for laboratory testing and to administer intravenous fluids.”

A physician at the facility will assess the skills of and re-train all non-licensed personnel who extract blood and will mark all personnel files to reflect this re-training. The training protocol will be addressed at the next QA meeting.

Complete Date: October 28, 2017,

Plan of Correction for Deficiency No. 7 (A 327) – House Bill 2 Medical and Clinical Services

Texas Health and Safety Code § 171.063(e) requires the physician dispensing medication abortion to “schedule a follow-up visit for the woman to occur not more than 14 days after the administration or use of the drug.”

All facility staff have been re-trained regarding this requirement to ensure that all patients receive a follow-up appointment scheduled for not more than 14 days after the administration of medication abortion. That training is reflected in the QA minutes. Furthermore, going forward, the individual responsible for conducting front desk check-out at the end of a patient's appointment will confirm that each patient receiving a medication abortion has a follow-up appointment scheduled within 14 days.

Complete Date: October 4, 2017

Plan of Correction for Deficiency No. 8 (A 362) – Discharge and Follow-up Referrals

Texas Administrative Code § 139.57(a)(2)(A)-(D) requires that facilities provide patients with discharge instructions that include “a telephone number by which the patient may reach the physician, or other health care personnel employed by the physician or by the facility at which the abortion was performed . . . 24 hours a day. . . .” The instructions must also include “assurance that the responding individual shall be a physician, advanced practice registered nurse, physician assistant, registered nurse, or licensed vocational nurse. . . .”

The facility currently gives patients instructions that include a number by which the patient may reach health care personnel employed by the facility and receive responses provided by a physician at the facility. In the case that the patient requires emergent care or otherwise requires direct communication with the physician, the patient receives that contact. Although the facility's current process meets the requirements of Tex. Admin. Code § 139.57, in response to the Department's statement of deficiencies, the facility's discharge instructions will include a phone number to a call line staffed by a licensed vocational nurse.

Complete Date: October 22, 2017

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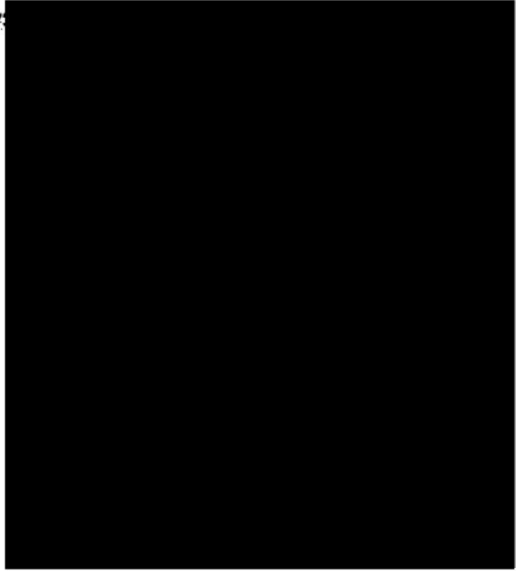
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A 037 Continued From page 1



A 037

A 07



A 073

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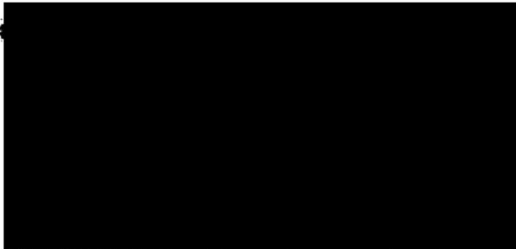
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A.073 Continued From page 2



A.073

A.14



A.143

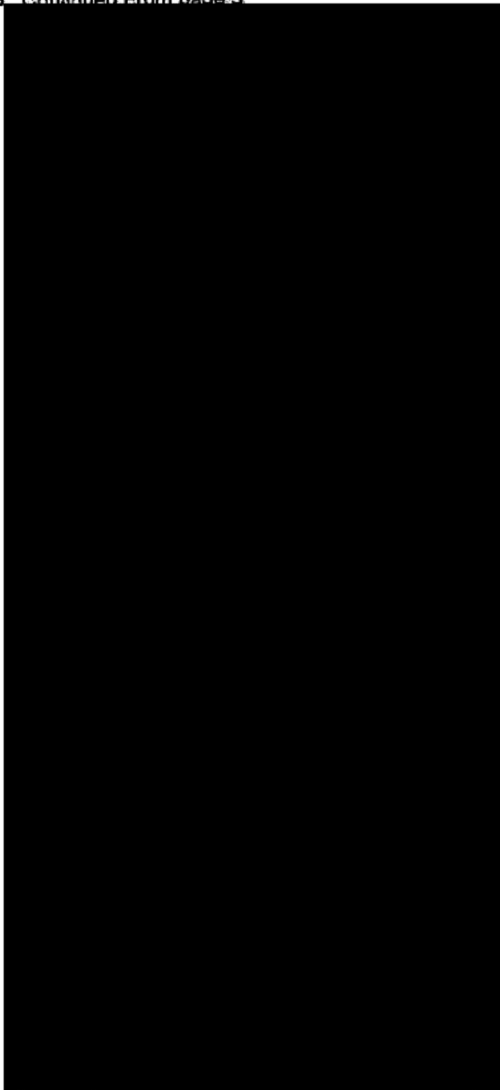
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A 143 Continued From page 3



A 143

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REPRODUCTIVE SERVICES

STREET ADDRESS, CITY, STATE, ZIP CODE
**1311 EAST MISSOURI
EL PASO, TX 79902**

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A 143 Continued From page 4



A 197 TAC 139.48(1)(A) Physical & Environmental Requirements.

The physical and environmental requirements for a licensed abortion facility are as follows.
(1) A facility shall:
(A) have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients and staff at all times;

This Requirement is not met as evidenced by:
Based on a tour of the facility, the facility failed to be maintained in a safe and sanitary manner to protect the health and safety of patients and staff at all times.

Findings were:

During a tour of the lab area on 10-3-17, a container of bleach and a container of Envirocide were stored underneath the sink and accessible to patients.

During an inspection of the emergency cart on 10-3-17, 2 of 2 ampules of epinephrine 1:1000 solution had expired 4-1-17 but were available for patient use.

During a tour of the medication room on 10-3-17, a 30 milliliter, multi-dose vial of 0.9% normal saline had been accessed but was not dated to

A 143

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A 197	Continued From page 5 indicate when it had been accessed. According to www.cdc.gov, "Medication vials should always be discarded whenever sterility is compromised or questionable. In addition, the United States Pharmacopeia (USP) General Chapter 797 [16] recommends the following for multi-dose vials of sterile pharmaceuticals: If a multi-dose has been opened or accessed (e.g., needle-punctured) the vial should be dated and discarded within 28 days, unless the manufacturer specifies a different (shorter or longer) date for that opened vial." The above was confirmed in an interview with staff #2 on the afternoon of 10-3-17.	A 197	
A 260	House Bill 15 Disclosure Requirements: A physician must perform a sonogram on a woman seeking an abortion at least 24 hours prior to performing the abortion, unless the woman lives 100 miles from the closest abortion provider in which case the sonogram must be performed at least 2 hours prior to the abortion. A physician must provide a list of agencies offering sonograms at no cost to the pregnant woman. The physician who will be performing the abortion must: a. Display the sonogram images to the pregnant woman; b. Provide a verbal explanation of the sonogram images, including descriptions of the fetus, its heart activity, and its internal organs; and c. Provide the heart auscultation of the fetus for the pregnant woman to hear, as well as a verbal explanation of it. Abortion procedures are exempt from the sonogram provisions in the case of a medical emergency; and requires a physician, not later	A 260	

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A 260 Continued From page 6

than the 30th day after the date the abortion is performed, to certify to DSHS the specific medical condition that constituted the emergency. The physician must provide the pregnant woman with information about paternity establishment and child support if she chooses not to have the abortion after having the sonogram.

This Requirement is not met as evidenced by: Based on a review of clinical records and an interview with staff, the facility physician failed to perform the sonogram on a woman seeking an abortion at least 24 hours prior to performing the abortion, unless the woman lives 100 miles from the closest abortion provider in which case the sonogram must be performed at least 2 hours prior to the abortion.

Findings were:

A total of 18 clinical records were reviewed and findings were as follows:

-None of the 18 clinical records reviewed contained documentation that the physician performed the sonogram on the patients prior to the procedure. 18 of 18 records contained documentation that the sonogram was performed by unlicensed staff members. Of the 18 sonograms, 15 had been performed by staff #6, 2 by staff #2 and 1 by staff #8. In an interview with staff #6 on the afternoon of 10-3-17, staff #6 confirmed that the (unlicensed) office staff perform the ultrasounds prior to the abortion procedure and that the facility physician reviews the sonogram images with the patient at a later time during the appointment.

-Eight patients (100 mile patients #1 through #8)

A 260

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A 260 Continued From page 7

had stated that they lived 100 miles or more from the nearest abortion provider and had been provided an abortion without the 24 hour wait. Of these 8 patients, 2 patients (100 mile patients #1 & #5) had their procedure done less than 2 hours after their sonogram was performed. Patient #1 had a sonogram performed on 8-11-17 at 10:51 am; her abortion procedure was begun on 8-11-17 at 12:25 pm. Patient #5 had a sonogram performed on 5-27-17 at 10:23 am; her abortion procedure was begun on 5-27-17 at 12:00 pm.

-Eight patients (100-mile patients #1 through #8) had stated that they lived 100 miles or more from the nearest abortion provider and had been provided an abortion without the 24 hour wait. Patient #2 stated her city of residence as [redacted] Tx. With the use of online resources including www.google.com and www.bing.com, an abortion provider was found within 100 miles of the patient's home address, disqualifying her from receiving abortion services without the 24 hour wait.

The above was confirmed in an interview with staff #2 on the afternoon of 10-3-17.

A 260

A 322 TAG 139.54(b)(2) Health Care Services

(b) Licensed health care professionals.
(2) A licensed abortion facility may allow physicians to train nonlicensed personnel, age 18 years or above, to extract blood for laboratory testing and to administer intravenous fluids.

This Requirement is not met as evidenced by:
Based on a review of personnel files and

A 322

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A 322 Continued From page 8
interview, the facility failed to ensure that a physician trained nonticensed personnel, age 18 years or above, to extract blood for laboratory testing.

Findings included:

In an interview on 10/03/17, staff member #2 verified all employees were trained to draw blood at the facility. Review of the personnel files revealed that 3 of 3 personnel (#3, 4, and 6) had lab competencies that were completed, however the trainer indicated on the competencies were listed as staff members #2 and 4, who are not the physician. According to regulations the training to extract blood should be completed by the physician.

A 322

A 327 House Bill 2 Medical and Clinical Services

Physicians must ensure that abortion-inducing drugs are used according to FDA regulations that require the women to visit the physician in person for each of the two doses of the abortion pill, as well as for a follow-up appointment within 14 days. The physician must provide the woman with a copy of the final printed label of the abortion-inducing drug.

A 327

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A 327	<p>Continued From page 9</p> <p>This Requirement is not met as evidenced by: Based on a review of documentation, the physician failed to ensure that patients given abortion-inducing drugs were scheduled a follow-up appointment within 14 days.</p> <p>Findings were:</p> <ul style="list-style-type: none"> - Clinical records for 11 patients (medication patients #1 through #11) that had received abortion-inducing drugs were reviewed. 5 of the 11 patients had not been scheduled a follow-up appointment within 14 days. - Patient #5 was seen in the office for the 1st dose of her abortion-inducing drug on 8-29-17. Her follow-up appointment was scheduled for 9-15-17, 17 days later. - Patient #6 was seen in the office for the 1st dose of her abortion-inducing drug on 5-20-17. Her follow-up appointment was scheduled for 6-5-17, 16 days later. - Patient #8 was seen in the office for the 1st dose of her abortion-inducing drug on 9-29-17. Her follow-up appointment was scheduled for 10-17-17, 18 days later. - Patient #9 was seen in the office for the 1st dose of her abortion-inducing drug on 9-29-17. Her follow-up appointment was scheduled for "17 or 18/17", an unknown amount of time later. - Patient #10 was seen in the office for the 1st dose of her abortion-inducing drug on 9-30-17. Her follow-up appointment was scheduled for "10-14 - 10/17/17", 14-17 days later. 	A 327		
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A 327 Continued From page 10
 The above was confirmed in an interview with staff #2 on the afternoon of 10-3-17.

A 327

A 362 TAC 139.57(a)(2)(A)(B)(C)(D)(3) Discharge and Follow-up Referrals

A 362

(a) A licensed abortion facility shall develop and implement written discharge instructions which shall include:
 (2) a statement of the facility's plan to respond to the patient in the event the patient experiences any of the complications listed in the discharge instructions to include:
 (A) a telephone number by which the patient may reach the physician, or other health care personnel employed by the physician or by the facility at which the abortion was performed or induced with access to the woman's relevant medical records; 24 hours a day to request assistance for any complications that arise from the performance or induction of the abortion or ask health-related questions regarding the abortion;
 (B) the name and telephone number of the nearest hospital to the home of the patient at which an emergency arising from the abortion would be treated;
 (C) assurance that the responding individual shall be a physician, advanced practice registered nurse, physician assistant, registered nurse, or licensed vocational nurse; and
 (D) information that the patient may also contact the emergency medical service or present for care at the emergency room of a hospital in addition to contacting the facility; and
 (3) information concerning the need for a post-abortion examination.

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A 362 Continued From page 11

This Requirement is not met as evidenced by:
Based on a review of facility documentation and an interview with staff, the facility failed to discharge patients with assurance that the responding individual would be a physician, advanced practice registered nurse, physician assistant, registered nurse, or licensed vocational nurse.

Findings were:

Facility discharge instructions contained the following statement:
"Twenty-four (24) hour medical coverage is provided by calling [facility phone number #1] or [facility phone #2]. A nurse will make every reasonable effort to return your call within thirty (30) minutes."

In a review of documentation of 4 post-procedure calls received between 2-14-17 and 5-17-17, the documentation indicated that all calls with questions, concerns or complications had been received and answered by staff #2, who was not a physician, advanced practice registered nurse, physician assistant, registered nurse, or licensed vocational nurse.

In an interview with staff #2 on 10-3-17, staff #2 confirmed that [staff #2] took the patient's calls, advised the patient and contacted the physician if [staff #2] felt it was necessary.

The above was confirmed in an interview with staff #2 on the afternoon of 10-3-17.

A 362