

Statement of Deficiencies

Survey Date - 7/7/2016

CAMELBACK FAMILY PLANNING

4141 NORTH 32ND STREET, SUITE 105 PHOENIX, AZ 85018 (602) 279-2337 Facility ID: MED4426

License: AC5013

Health Survey Comments

The following deficiencies were cited during the State Compliance survey conducted on 6/20/16, 6/21, & 6/23/16, with additional documentation provided on 7/2/16, 7/6, & 7/7/16 (Event #YX5P11).

ADHS Representative Date

Findings Report Summary

Findings for: Citation 1 Corrected Date: 10/03/2016 Rule/Statute: Administration Rule Text:

R9-10-1503. Administration C. A medical director shall ensure written policies and procedures are established, documented, and implemented for: 1. Personnel qualifications, duties, and responsibilities;

Survey Text: R9-10-1503.C.1~

Based on a review of facility policy and procedure, personnel files, and staff interviews, the Department determined medical director #1 failed to implement a method, for 4 of 7 registered nurses' (RNs) (#2, #3, #5, & #7) providing moderate sedation, to demonstrate specific competencies for conscious sedation as required by policy. Failure to have demonstrated competencies poses a risk to health and safety. Findings include: Review of facility policy "MODERATE SEDATION, NON-ANESTHESIA PERSONNEL" review dated: 10/22/15 by medical director #1 revealed: "...All RN's WILL EVALUATED (sic) WHEN HIRED...They must Demonstrate competency in the following: UNDERSTANDING THE DIFFERENCES IN

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SEDATION...Minimal...Moderate...Deep...De sired Patient Outcomes for...MODERATE SEDATION...Undesirable Patient Outcomes for Moderate Sedation...THE OBJECTIVES OF MODERATE SEDATION...

STAFFING...Moderate intravenous sedation requires the continuous presence of a physician who is qualified and credentialed to provide moderate sedation...qualified licensed professional (R.N.), with at least BLS (basic life support) and usually Advanced Cardiac Life Support (ACLS) certification, trained to administer moderate sedation under the supervision of the physician... PERSONNEL... LICENSED PROFESSIONALS...The following criteria must be met by all licensed professionals responsible for a patient receiving sedation

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and analgesia...Have demonstrated competency in recognizing an airway obstruction and be proficient in the skills of basic life support...Be able to rescue from deep sedation...Be familiar with the principles of oxygen delivery and respirator physiology; have demonstrated competency in assessing the patient's physiologic parameters including, but not limited to, adequacy and rate of respiration, oxygen saturation, blood pressure, heart rate, and level of consciousness...Competent to manage a compromised airway and to provide adequate oxygenation and ventilation...." Review of facility form "DOCUMENTATION (sic) OF PROFICIENCY" revealed 17 of 17 skills listed did not include moderate sedation proficiency per facility policy. RN #3 verified, during an interview conducted on 6/20/16, that the nurses only identification of training in conscious sedation is when they print out their certificate of completion from the online conscious sedation training module provided by NAF (National Abortion Federation). The facility policy failed to indicate competency was determined by competency of NAF. The surveyor requested documentation of the course description and skill assessments that are discussed and tested in the online NAF conscious sedation training module. This was to determine if program meets requirements stated in policy. None was provided. Review of the personnel files and additional documentation submitted for review on 7/7/16 revealed 4 of 7 nurses' did not have documentation of an online certificate of completion for 2015 (RN #2, #3, #5, & #7); and 3 of 7 nurses did not have documentation of an online certificate of completion for 2016 (RN #2, #5, & #7). RN #3 verified, during an interview conducted on 6/20/16, that the nurses' have to renew their conscious sedation training annually by completing the online training course provided by NAF.

Findings for: Citation 2 Corrected Date: 10/03/2016 Rule/Statute:

Personnel Qualifications and Records

Rule Text:

R9-10-1505. Personnel Qualifications and Records A licensee shall ensure that: 1. A physician who performs an abortion demonstrates to the medical director that the physician is competent to perform an abortion by: b. Observation by or interaction with the medical director;

Survey Text: R9-10-1505.1.b~

Based on a review of facility policy for contract physician job description, contract physician orientation, documentation policy for physicians, medical staff files, and staff interviews, the Department determined the licensee/medical director #1 failed to ensure medical director #2 demonstrated his competency in performing medical abortions.

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Failure to verify a physician is qualified to perform a medical abortion may result in an unexpected outcome for the patient and fetus. Findings include: Review of facility policy "CONTRACT PHYSICIAN JOB DESCRIPTION" revealed: "...Physician is responsible for performing abortion services at...according to policies and procedures of this office...I agree to adhere to the Medical protocols set forth by the Medical Director...I will provide a copy of my current Curriculum Vitae (CV) and Medical License...." Review of facility policy "CONTRACT PHYSICIAN ORIENTATION" revealed: First column "...Review patient forms...Date completed ... Review clinic policies & procedures...Date completed_____... Review lab manual...Date completed Review Department of Protective Services, reporting child abuse & sign form once completed ... Medical Director has verified medical skills...Date completed_____... MFX (Mifeprex) Abortion/24 hour info session/Mod. Sedation... Orientation is based on the individual's prior knowledge and experience as well as the requirements of the specific job...." The facility document did not contain a date to demonstrate when the orientation was completed. Medical Director #2 verified, during an interview conducted on 6/23/16, that he had no prior experience performing abortion procedures before coming to this facility. The following tasks have been handwritten in as part of the "CONTRACT PHYSICIAN ORIENTATION" tasks: "...MFX abortion/24 hour info session/mod. Sedation...." There is no date or signature next to the aforementioned task to indicate completion of orientation for these tasks. Medical Director #2 has signed and dated the orientation form on 10/22/15. Medical Director #1 has signed this form as the "Administrator" but failed to document a completion date. Review of facility policy "DOCUMENTATION POLICY FOR PHYSICIANS" revealed: "...A physician who performs an abortion demonstrates to the medical director that the physician is competent to perform an abortion, prescribe and administer medication and lawfully practice medicine by: a...Submission of documentation of education and experience (CV), and b...Observation by or interaction with the medical director... c...Verification of

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qualifications, training, or licensure... e...Documentation of verification of competency that is signed and dated by the medical director; and f...Documentation of completion of a course as required for a physician performing ultrasounds... Responses to requirements identified above: b. Medical Director #2 verified, during an interview conducted on 6/23/16, that he does not have documentation reflecting the observation and interaction process with medical director #1 demonstrating he is competent to perform a medical abortion. c. Review of Medical Director #2's CV revealed" Anesthesiology...Work Experience... anesthesiologist for pediatric and adult special needs dental procedure...anesthesiologist for outpatient and occasional hospital surgeries...." There is no prior history of performing medical or surgical abortion procedures documented. Medical Director #1 verified, during an interview conducted on 6/21/16, that he did not perform abortions prior to working at this facility. e. 1) The surveyor requested documentation on 6/21/16 and 7/7/16 verifying medical director #2 is competent to perform medical abortions that is signed and dated by the medical director #1. None was provided. 2) The surveyor requested documentation on 6/23/16 verifying medical director #2 is competent to perform a bimanual examination and palpation of the adnexa signed and dated by medical director #1. None was provided. f. The facility ultrasound computer disk training is through "...a r m s (sic) (Affiliates Risk Management Services, Inc)...Ultrasound in Abortion Care...CME (Continuing Medical Education) Education and Ultrasound Training Program...." The surveyor requested documentation demonstrating medical director #2 has completed the ultrasound training course per facility policy. None was provided. Employee #1 and medical director #2 verified, during an interview on 7/7/16, that there is no documentation demonstrating medical director #2 is competent to perform medical abortions per facility policy identified above. Medical Director #2 verified, during an interview on 6/23/16, that he has performed over 150 medical abortions since mid-July, 2015.

Findings for: Citation 3 Rule/Statute: Abortion Procedures Survey Text: R9-10-1508.A.2~

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Rule Text:

R9-10-1508. Abortion Procedures A. A medical director shall ensure that a medical evaluation of a patient is conducted before the patient 's abortion is performed that includes: 2. A physical examination performed by a physician that includes a bimanual examination to estimate uterine size and palpation of adnexa; and

Based on a review of facility policy and procedure, redacted medical records, and staff interviews the Department determined 2 of 2 medical directors (#1 and #2) failed to perform a bimanual exam to estimate uterus size and palpate the adnexa on 6 of 6 medical abortion patients (#1, #2, #3, #4, #5, & #6). Findings include: Medical abortion: Review of facility policies "MIFEPREX PROTOCOL" revealed: "...Patient will be less than or equal to 10 weeks...She will have 24 hour informational session with the doctor and the ultrasound 24 hours before starting the Mifeprex abortion...If nothing is seen on the ultrasound, see flow sheet to manage different scenarios for nothing seen vs. (verses) gestational sac without yolk sac...Hb (hemoglobin) and RH (Rhogam) testing will be done...The chart and medical history will be reviewed for contraindications for Mifeprex per FDA (Food and Drug Administration) recommendations...." Surgical abortion: Review of facility policy "AB ORDERS" revealed: "...Pre-op...Confirm gestational age on ultrasound, review of systems, vital signs, and history of allergies to medications...Complete Pre-Op check list...Review 24 hour information session documentation/Minor consent if applicable...Review lab work: Rh factor, Hgb (hemoglobin)...." Review of facility policy "PRE-OP DAY 1: LAMINARIA INSERTION " revealed: "...Confirm gestation from ultrasound...Perform review of systems...Obtain vital signs and history of allergies to medications .. Complete Pre-Op check list...Review documentation of 24 hour information session (and minor consent if applicable)...Review lab work: Rh factor, Hgb...." Review of facility policy "18 WEEKS **GESTATION-MEDICAL INDUCTION"** revealed: " .. Pre-Op Day 1: Mifeprex/Digoxin...Confirm dates from ultrasound, review of systems, vital signs, and history of allergies to medications...Complete Pre-Op check list...Review 24 hour information session documentation/Minor consent if applicable...Review lab work: Rh factor, Hgb...." The facility policy failed to require a bimanual exam and palpation of the adnexa as part of the evaluation of a patient presenting for an abortion procedure. Review of 6 of 10 redacted medical records identified 6 of 10 patients (#1, #2, #3, #4, #5, & #6) presented for a medical abortion. Review of 6

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of 10 redacted medical records revealed no documentation a bimanual exam and palpation of the adnexa was performed by medical director #1 or medical director #2. Medical Director #2 and employee #1, verified during an interview on 6/23/16, that he has not performed a bimanual exam and palpation of the adnexa on any of the medical abortion procedures he has performed since mid-July, 2015. Medical Director #2 reports he has performed over 150 medical abortion procedures at this facility. Medical Director #2 verified, during an interview conducted on 7/7/16, that documentation of competency, signed off by medical director #1 or designee. attesting to his competency in performing this procedure was not provided. RN # 4 verified, in an interview conducted on 6/23/16, that a bimanual exam and palpation of the adnexa are not performed on patients presenting for a medical abortion at this facility.

Findings for: Citation 4 Corrected Date: 10/03/2016 Rule/Statute:

Equipment Standards

Rule Text:

R9-10-1513. Equipment Standards A licensee shall ensure that: 6. Equipment and supplies are clean and, if applicable, sterile before each use;

Survey Text: R9-10-1513.6~

Based on review of facility policies/procedures, professional standards, manufacturer guidelines, and interview with staff, the Department determined that the licensee failed to ensure providers and staff adhere to professionally acceptable standards of practice for sterilization/highlevel disinfection of equipment, to decrease the potential risk of transmission of infections to patients, as evidenced by: 1. Staff not routinely placing chemical indicators within all individual peel packs and wrapped trays prior to steam sterilization and; 2. Staff not performing high-level disinfection for reusable intracavity transvaginal probes between each patient use; Findings include: Camelback Family Planning "Standard Precautions Policy," contains: "...Standard Precautions are to be followed by all employees for all patients ... Standard Precautions include...exercising General infection control practices...Patient-Care Equipment and Articles...Reusable patient care equipment...should be covered, handled, and decontaminated or sterilized...." 1. Camelback Family Planning document, "Policy and Procedure...Nursing/Back Office Duties...Autoclave daily/weekly logs/cleaning," contains: "...Chemical Indicator (CI) log will record each load done and results for each machine...." RN # 3 stated during an interview conducted



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06/20/2016 at 0910 hours, that chemical indicators for each sterilization batch are currently placed within the autoclave chamber prior to each sterilization cycle, but no indicator is placed within individual packages. RN #4 confirmed at interview on 06/21/2016 at 1315 hours, that staff do not currently place chemical indicator strips inside individual peel packs or within blue clothwrapped trays prior to steam sterilization to ensure sufficient penetration of steam and heat. 2. Camelback Family Planning document, "Policy and Procedure: Nursing/Back Office duties ...5. Ultrasound cleaning," contains: "...To clean the transducer...Remove any transducer sheath...Use a germicidal disposal cloth to remove any particulate matter or body fluids...Use a clean germicidal disposable wipe to clean the surface of the transducer...." RN#4 confirmed during an interview conducted at 1015 hours on 06/21/2016, that the current ultrasound transducer cleaning policy and clinical procedure do not address high level disinfection, and additionally confirmed that staff do not currently perform high-level disinfection on vaginal ultrasound transducers

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