

Office of Health Care Quality

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:<br><br>SA00002 | (X2) MULTIPLE CONSTRUCTION<br>A. BUILDING: _____<br><br>B. WING _____ | (X3) DATE SURVEY COMPLETED<br><br>05/20/2015 |
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| NAME OF PROVIDER OR SUPPLIER<br><br>HILLCREST CLINIC, INC | STREET ADDRESS, CITY, STATE, ZIP CODE<br>5602 BALTIMORE NATIONAL PIKE, SUITE 600<br>BALTIMORE, MD 21228 |
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| A 000 | <p>Initial Comments</p> <p>A relicensure survey was conducted at Hillcrest Clinic in Baltimore, MD on May 19 and 20, 2015. An exit interview was conducted on May 20, 2015.</p> <p>The survey included: an on-site visit; an observational tour of the physical environment; observation of cleaning of the procedure room, patient equipment and set up; observation of the patient laboratory (blood draw) process; observation of patient ultrasound process; observation of the registered nurse pre operative assessment; observation of patient education process; observation of hand hygiene; observation of instrument cleaning/sterilization process; interview of the facility's administrator, anesthesiologist, registered nurses (RN), licensed practical nurse (LPN), laboratory technician and central supply technician; review of the policy and procedure manual; review of the personnel files; review of quality assurance and infection control program, and review of professional credentialing. No surgical procedures were observed during this survey.</p> <p>The center performs surgical abortion procedures and includes three procedure rooms. Credentialing and personnel files for physicians, certified registered nurse anesthetists (CRNA), registered nurses (RN), licensed practical nurses (LPN), laboratory technician, and central supply technician were reviewed on 05/19/15. Select clinical records were reviewed for procedures that had been performed between 12/05/14 and 05/08/15.</p> <p>Findings in this report are based on data present in the administrative records at the time of review. The agency's administrator was kept informed of</p> | A 000 | <p>JUN 25 2015</p> |  |
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OHQC  
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE: ADMINISTRATOR  
DATE: 06/19/2015

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A 000 Continued From page 1 A 000

the survey findings as the survey progressed. The agency administrator was given the opportunity to present information relative to the findings during the course of the survey.

A key code for patients, medical staff and employees contained herein was provided to the agency administrator.

A 420 .05 (A)(1)(e)(i) .05 Administration A 420

(e) Ensuring that all personnel:  
(i) Receive orientation and have experience sufficient to demonstrate competency to perform assigned patient care duties, including proper infection control practices;

This Regulation is not met as evidenced by: Based on review of policies, review of facility documentation and interview, it was determined the surgical abortion facility (SAF) staff failed to ensure training of staff.

The findings include:

1. Review of policies on 05/19/15 revealed a policy entitled 'Risk Management Program' that stated, in part, "The following are incorporated into (SAF) risk management program:

- Annual OSHA training of clinical personnel
- CPR training of nursing staff
- New employee orientation program."

A second policy, entitled 'Continuing Education for Staff' stated, in part, "(SAF) trains its staff "in-house" to the extent possible. This includes the initial training and "apprenticeship" for each position or task, and additional training as

*see next page*

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A 420 Continued From page 2

necessary to correct deficiencies. This will also include further training to foster employee growth and development. Areas for further training will be identified through observation by supervisors, feedback from patients and fellow staff members, and areas of interest identified informally or in annual employee reviews."

Another policy, entitled 'Sonography Training' stated, in part, "A yearly review is taken."

2. Review of facility documentation entitled 'Staff Training' noted the following:

- a. OSHA - last date of training 12/13;
- b. Sonogram - last date of training 12/13;
- c. Conscious sedation - last date of training 01/14;
- d. Fire drills - last date of training 06/13;
- e. Emergency transfers - last date of training 07/13.

3. Interview with Staff M on 05/20/15 at 2:45 PM revealed that the SAF has not been performing staff trainings as outlined in policy.

A 420 →

1. We will review each staff members file and identify who is not current in a, b, c, d, e.

2 and 5. We will devise a chart and record when training for a, b, c, d, e is completed and when it is due. Staff member Q will be responsible for monitoring compliance.

3rd Sept. 1, 2015 - this will be up and running.

6 & 7 a, b, c, d, e will be on a yearly basis unless the procedure in place fails to be effective.

\*Records will be in "Training Manual"

A 450 .05 (A)(2)(a) .05 Administration

- (2) The administrator shall ensure that:
- (a) The facility's policies and procedures as described in §C of this regulation are:
    - (i) Reviewed by staff at least annually and are revised as necessary; and
    - (ii) Available at all times for staff inspection and reference; and

This Regulation is not met as evidenced by: Based on a review of policies and facility documentation, it was determined that the

A 450 →

1, 2, 5 M and Q will review the current policy binders - they will all be kept in Q's office.

3rd this will be done by Sept. 1 and then on an annual basis unless changes occur.

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A 450 Continued From page 3

Surgical Abortion Facility staff failed to ensure that the policy and procedure manual was reviewed and revised, as necessary, on an annual basis.

The findings include:

Review of the policy manual on 05/19/15 revealed an untitled policy that stated, in part, "(Name), the Clinic Administrator, will review policies, procedures and protocols annually. These will be available at all times for reference and will be placed in a named central location. They will be reviewed annually and revised as necessary."

Another policy, entitled 'Quality Assurance' stated that "Procedure manuals will be updated as changes occur. Each update or change will be dated and signed.

Procedure manual will be checked on a yearly basis beginning January 2014."

Review of facility documentation entitled 'Quality Assurance Annual Inspections' revealed that the last date of review was November, 2012.

A 530 .05(C)(1) .05 Administration

C. Policies and Procedures. The facility shall have policies and procedures concerning the following:

(1) The scope and delivery of services provided by the facility either directly or through contractual arrangements;

This Regulation is not met as evidenced by:  
Based upon review of the policy manual and

A 450

6-7. As noted in 1, 2, 3, 4 and 5.  
6. A binder for staff training in Q's office will contain evidence that this has been complied with.

A 530

see next page

We do have this policy - please see attached

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A 530 Continued From page 4

review of facility documentation, it was determined that the facility staff failed to have policies and procedures in place to provide oversight of the center.

A facility must have policies and procedures to ensure that the center is in compliance with state regulations.

The findings include:

Review of the policy manuals on 05/19/15 revealed that they were incomplete. A facility is expected to ensure that it is in regulatory compliance for all of the facility's areas of operation.

Missing policies, as outlined in regulation, include the following:

1. Accountability of personnel involved in patient care;
2. Procedures to ensure personnel are free from communicable diseases;
3. Safety practices;
4. Control of fire and mechanical hazards;
5. Preventative maintenance of equipment;
6. Credentialing and personnel policies;
7. Informed consent;
8. Protocol for transmitting patient medical records to a hospital;
9. Staff training in facility policies and procedures;
10. Laboratory turn around time;
11. Review of laboratory reports; and
12. Quality Assurance program which includes monitoring, identification, evaluation, and resolution of problems.

A 570 .05(C)(2)(c) .05 Administration

A 530

1, 2, 5 - M will obtain employee evaluation forms and evaluations will be done on an annual basis. At the same time it will be determined if 2, 3, 4, 9 are individually up to date.

M, Q, J, F, P will determine which policies are in fact missing and assign appropriate personnel to write policies as needed.

But this will be completed by Sept. 1, 2015.

6 & 7. All manuals will be up to date and evaluated on an annual basis.

A 570

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A 570 Continued From page 5

(c) Procedures to ensure personnel are free from communicable diseases;

This Regulation is not met as evidenced by: Based on review of policies, review of credentialing and personnel records and interview, the facility staff failed to comply with immunization requirements for all staff. This was evident for 15 of 15 staff members.

Staff A, B, C, D, E, F, G, H, I, J, K, L, M, N, O

The findings include:

1. A Surgical Abortion Facility should have policies that reflect facility procedures for ensuring infection control practices. Review of the policy manual on 05/19/15 failed to reveal a policy to require staff to get a tuberculosis (TB) screening.

A manual entitled 'Occupational Exposure to Blood-borne Pathogens, Airborne & Droplet Transmitted Diseases' was reviewed on 05/20/15. A policy entitled 'Vaccine/Immunization Program' stated "(Facility) will adopt the CDC guidelines for vaccination/immunization of health-care personnel that were published in November, 2011.

- HICPAC and CDC have recommended that secure, preferably computerized, systems should be used to manage vaccination records for HCP so records can be retrieved easily as needed.

- Each record should reflect immunity status for indicated vaccine-preventable diseases, as well as vaccinations administered during employment." HCP is an abbreviation for Healthcare professional. CDC stands for the Centers for Disease Control and HICPAC stands

A570

1. Management - M. has already assigned G to oversee employee health (immunizations, TB testing)

2, 6, 7. M will write a policy for employee health.

3 & 4. Will be implemented by Sept. 1, 2015.

5. M & G will be responsible for this.

6 & 7 All employees will be TB tested by 9/1/2015 and on an annual basis. Documentation will be provided in each employee file.

Employee files will be reviewed by G annually.

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| A 570 | <p>Continued From page 6</p> <p>for Healthcare Infection Control Practices Advisory Committee.</p> <p>Another policy, entitled 'Employees Deemed at Risk for Tuberculosis' stated "At Risk Personnel: Nursing staff, Reception staff, EMT/CMAs, Doctors."</p> <p>Employees listed in the at risk group for possible exposure to tuberculosis will be offered baseline PPD/TST skin testing and annual skin testing. PPD/TST administration for baseline and annual testing will be administered on site by a registered nurse.</p> <p>Note **** "(facility) offers testing to all staff."</p> <p>EMT is an abbreviation for Emergency Medical Technicians, CMAs is for Certified Medical Assistant and PPD/TST is a skin test for TB exposure.</p> <p>Review of the policy manual also revealed a facility form entitled 'Tuberculosis (Mantoux) Screening Test Informed Denial'. Employees cannot refuse tuberculin testing or screening.</p> <p>2. Review of credentialing and personnel files on 05/19/15 revealed that current (2014-2015) documentation of compliance with immunization requirements were incomplete. 15 of 15 credentialing and personnel files did not have documentation of tuberculosis immunization or tuberculosis signs/symptom screening for Staff A, B, C, D, E, F, G, H, I, J, K, L, M, N, O.</p> <p>3. Interview with Staff M on 05/20/15 at 2:55 PM revealed that she was unaware that the facility needed to maintain documentation regarding immunization against TB.</p> | A 570 |  |  |
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| A 650 .06(B)(1) .06 Personnel | <p>B. Credentialing of Physicians. The facility shall collect, review, and document the following information concerning a physician licensed under Health Occupations Article, Title 14, Annotated Code of Maryland:</p> <p>(1) The physician 's education;</p> <p>This Regulation is not met as evidenced by:<br/>Based on a review of the policy manual and review of physician files, the facility staff failed to credential the medical staff.</p> <p>Staff #A, B, C, D, N, O</p> <p>The findings include:</p> <p>1. Review of the policy manual on 05/19/15 failed to reveal a policy relevant to the process of accreditation of the medical staff.</p> <p>2. Physician and allied health professional files were reviewed on 05/19/15. The files did not contain documentation regarding the granting of initial or temporary privileges. Credentialing information, as outlined in regulation, was missing from the files as follows:</p> <ul style="list-style-type: none"> <li>a. Current license - Staff D</li> <li>b. Current hospital affiliation - Staff A, B, C, D</li> <li>c. Annual review of policies - Staff A, B, C, D</li> <li>d. Current curriculum vitae - Staff B</li> <li>e. Board certification - Staff A, B, D</li> <li>f. Current Drug Enforcement Administration (DEA) license - Staff D.</li> <li>g. Documentation of any disciplinary action - Staff B</li> <li>h. Current liability insurance - Staff A</li> <li>i. Liability insurance carrier last five years - Staff A</li> </ul> | A650 | <p>1. M will designate an employee to write a policy.</p> <p>2 and 5. M will review and see that all physician files are current. This includes CRNA files.</p> <p>3 and 4. This will be implemented by Sept. 1, 2015. Reviewed on an annual basis.</p> |  |
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A 650 Continued From page 8 A 650

- j. Documentation of physical or mental disability - Staff A, B, C, D
  - k. Data from National Practitioner Data Bank (NPDB) - Staff B
  - l. Letter with initial and/or biennial reappointment to center - Staff A, B, C, D
  - m. documentation of peer review - Staff A, B, C, D
  - n. Utilization, quality and risk data - Staff A, B, C, D
  - o. Adherence to policies, bylaws and procedures - Staff A, B, C, D
  - p. MD practice patterns via QA program - Staff A, B, C, D
  - q. Documentation of current certification in Basic Life Support (BLS)/Advanced Cardiac Life Support (ACLS) - Staff B, D
- In addition, the type of information typically seen in a Certified Registered Nurse Anesthetists (CRNA) file was missing, as follows:
- Proof of current liability insurance coverage - Staff N
  - Evidence of CRNA certification - Staff N, O
  - Current copy of the signed agreement between the nurse anesthetist and collaborating anesthesiologist(s) pursuant to the Code of Maryland Regulations - Staff N, O
  - Evidence that the nurse anesthetist has reported the name of the collaborating anesthesiologist(s) to the State - Staff N, O.

A 810 .06(D)(1) .06 Personnel A 810

- D. The administrator shall establish a procedure for the biennial reappointment of a physician which includes:
  - (1) An update of the information required in §B of this regulation; and

→ *It will include this in policy, procedure and implementation*

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A 810 Continued From page 9

A 810

This Regulation is not met as evidenced by:  
Based on review of the physician credentialing files and interview of the registered nurse administrator, it was determined that there was no evidence that the scope of procedures performed and medical staff privileges were reappraised by the administrator for four of four files reviewed.

Staff: A, B, C, D

The findings include.

Review of medical staff credentialing files for medical staff A, B, C and D revealed none of the medical staff privileges and scope of procedures were reappraised.

Interview of the administrator on May 19, 2015 at 3:00 PM revealed the privileges have not been reappraised.

A 870 .06(E)(1)(a) .06 Personnel

E. Credentialing of Health Professionals.

(1) Direct Hires.

(a) The facility shall collect, review, and verify evidence of the following information for all licensed or certified health professionals that are employed by the facility:

This Regulation is not met as evidenced by:  
Based on review of the policy manual, review of personnel files and interview, the Surgical Abortion Facility staff failed to implement personnel policies for facility staff. This was

with A 650. All the same files.

A 870

→ 1, 5, 6 M & G will review each employee chart to determine if a. through j. are up to date and collect info and update files as needed. (2)  
But will be completed by Sept. 1, 2015

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| A 870 | <p>Continued From page 10</p> <p>evident for nine of nine facility staff reviewed during the survey.</p> <p>Staff E, F, G, H, I, J, K, L, M</p> <p>The findings include:</p> <p>1. Review of the policy manual on 05/19/15 failed to reveal detailed personnel policies.</p> <p>A policy entitled 'Emergency Services' stated, in part, "Basic Life Support: Licensed medical staff will have CPR training every two (2) years. This person will be on duty whenever there is a patient in the facility."</p> <p>2. Credentialing files for two Certified Registered Nurse Anesthetists (CRNAs) and personnel files for five registered nurses (RN), two licensed practical nurses (LPN), one laboratory technician, and one central supply technician were reviewed on 05/19/15. The reviews revealed that required items of documentation were missing from the files as follows:</p> <ul style="list-style-type: none"> <li>a. documentation of date of hire - Staff E, F, H, N, O</li> <li>b. current license - Staff G, H, L, M,</li> <li>c. documentation of training in facility policies and procedures - Staff E, F, G, H, I, J, K, L, M, N, O</li> <li>d. documentation of orientation - Staff E, F, G, H, I, J, K, L, M, N, O</li> <li>e. documentation of competency/skills assessment - Staff E, F, G, H, I, J, K, L, M, N, O</li> <li>f. documentation of annual infection control training - Staff E, F, G, H, I, J, K, M, N, O</li> <li>g. copy of a signed job description - Staff E, H, I, L, N, O</li> <li>h. documentation of immunization - Staff E, F, G, H, I, J, K, L, M, N, O</li> <li>i. documentation of current Basic Life Support -</li> </ul> | A 870 | <p><i>7. Will be reviewed on an annual basis or within a week of hiring.</i></p> |  |
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A 870 Continued From page 11  
Staff E, G, H, J, L, M  
j. documentation of training in emergency transfer of patient - Staff I, L, M, N, O.  
  
3. Interview with Staff M on 05/20/15 at 2:40 PM revealed that the information in the credentialing and personnel files was all the information available at the time of survey.

A 870

A1280 .11 (B)(1) .11 Pharmaceutical Services  
  
B. Administration of Drugs.  
(1) Staff shall prepare and administer drugs according to established policies and acceptable standards of practice.

A1280

→ 1, 2, 3, 4 M will schedule an inservice to address A1280. Nurses and CRNAs will be required to attend as well as B. This will be scheduled no later than 9/1/2015.  
5, 6, 7. E, G, H, J, I, will be responsible for monitoring meds in all procedure rooms and recovery room and discarding outdated vials. Every morning.

This Regulation is not met as evidenced by: Based on interview of the registered nurse administrator, review of the policies and procedures and observation during a tour of the facility, it was determined that the registered nurse (RN) failed to implement procedures for the use of single dose medications, to discard expired medication, and failed to label and discard opened medication vials.

Medication vials must be labeled with the date that they are opened and the initials of the person who opened the vial. Once opened, medication vials may only be used for twenty eight days after the date they were opened or follow manufactures instructions.

The findings included:

Review of the policies and procedures for use and storage of medications, multi-dose vials, outdated medications, procedure for drawing up

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| A1280 | <p>Continued From page 12</p> <p>any medications and safe injection practices revealed, "The director of the clinical department is responsible for ensuring support and assistance in the expectation of the policies in this document and in its application to the performance of employees under her/his direction. Medications bearing an expiration date will not be dispensed or distributed beyond the expiration date. Expiration dates on all medications will be checked on a monthly basis. Expired, discolored, damaged or inappropriately labeled medications shall be discarded. All clinic personnel must observe proper storage and labeling requirements for all medications during the performance of their daily tasks and shall demonstrate safety in regard to the potency of medications administered. Removal of outdated medications from active stock. Labeling of all medications prepared with the date, time of preparation, employees initials, name and dose of medication. Multiple dose vials must be discarded 28 days after it is opened. Vials marked for single dose must be discarded after each patient use. Intravenous solutions: Single use IV solutions should be administered to one patient only, during one treatment. Never use intravenous solutions containers (i.e. bags or bottles) to flush solutions for more than one patient. Single use medications expires within 24 hours of being opened or punctured. Any medication that is drawn up into a syringe is considered single use. All predrawn drugs will be discarded after 24 hours. "</p> <p>During a tour of procedure room #2 on May 19, 2015 at 8:55 AM revealed the following expired medications:</p> <ol style="list-style-type: none"> <li>1. One ten milliliter multiple dose vial of Naloxone HCL (reverses the effects of narcotic medication) expired on October 1, 2014.</li> <li>2. Dextrose 50% (replacement fluid) for</li> </ol> | A1280 |  |  |
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| A1280 | <p>Continued From page 13</p> <p>injection one bottle expired on May 1, 2015 and one bottle expired on April 1, 2015.</p> <p>3. One five hundred milliliter intravenous solution bag of lactated ringers solution (replacement fluid) expired on May 1, 2015.</p> <p>4. One single dose vial of hydrozone HCL (steroid) that expired on July 2014.</p> <p>5. One 2% vial of Lidocaine HCL (local anesthetic) expired on March 1, 2014.</p> <p>During a tour of procedure room #4 on May 19, 2015 at 9 AM revealed the following expired medications:</p> <p>6. One fifty milliliter vial of 1% Lidocaine was opened and some of the medication had been used. The bottle was not labeled with the date opened and the initials of the person who opened it.</p> <p>7. One fifty milliliter vial of 1% Lidocaine was opened and some of the medication had been used. The bottle was not labeled with the initials of the person who opened it.</p> <p>8. One ten milliliter syringe labeled Lidocaine 1% was dated May 16, 2015 10:45 am. The syringe of medication was not discarded within 24 hours of drawing the medication into the syringe. Once medication is drawn into a syringe the medication is considered single use and must be discarded after 24 hours.</p> <p>During a tour of procedure room #1 on May 19, 2015 at 11:30 AM revealed the following expired medications:</p> <p>9. One 500 milliliter bag of 0.9% IV (intravenous, fluid replacement) solutions was hanging on an IV pole above the surgical bed. Two hundred milliliters of the solution had been used.</p> <p>Interview of the registered nurse (H) at 11:30 AM</p> | A1280 |  |  |
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| A1280   | <p>Continued From page 14</p> <p>revealed that the anesthesia provider uses the single dose solution as a multidose solution to withdraw three milliliters of the solution to flush the patients intravenous line. The intravenous solution is for single patient use and must be discarded after each patient.</p> <p>10. Interview of physician (B) on May 19, 2015 at 11:40 AM revealed that the fifty milliliter vials of Propofol (anesthetic/sedation) are used for more than one patient.</p> <p>Review of the label located on the Propofol (anesthetic/sedation) medication vial revealed, "single patient infusion vial" and "single patient use." Review of the package instructions revealed, "Propofol Injectable Emulsion should be prepared for single patient use only. Strict aseptic technique must always be maintained during handling. Propofol Injectable Emulsion is a single-use parenteral product which contains benzyl alcohol and sodium benzoate to retard the rate of microorganisms in the event of accidental extrinsic contamination. However, Propofol Injectable Emulsion can still support the growth of microorganisms as it is not an antimicrobially preserved product under USP (United States Pharmacopoeia) standards.</p> <p>Interview of the registered nurse administrator (M) on May 19, 2:45 PM revealed the administrator was not aware that the medications and solutions were expired, that the single use medications were being used for more than one patient and that the policies were not being followed.</p> | A1280   |   |
| A1380   | .13 (A) .13 Medical Records   | A1380   |   |

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| A1380 | <p>Continued From page 15</p> <p>A. The facility shall maintain a complete, comprehensive, and accurate medical record for a patient.</p> <p>This Regulation is not met as evidenced by: Based on review of the policy and procedure manual, medical records, and interview of the administrator, it was determined that the Certified Registered Nurse Anesthetists (CRNA) failed to maintain an individualized medical record for all patients. This was evident for three of three records reviewed for sleep anesthesia.</p> <p>Patients #1, 7, 8</p> <p>The findings include:</p> <p>(1.) Review of the policy and procedure for medical records revealed, "Each patient will have a complete comprehensive and accurate medical record. The patient's medical record will include a patient identifier, medical history, documentation of care and services provided, evidence of consent and a discharge note."</p> <p>(2.) The CRNA uses a combined preanesthesia evaluation/anesthesia record form. Review of patient clinical records on May 19 and 20, 2015 revealed the same information was on three clinical records.</p> <p>The preanesthesia evaluation/anesthesia record form used by the CRNA contained documented or checked off information that was preprinted on the form that includes: preanesthesia evaluation that includes respirations (10), problem list/diagnostics (IUD), planned anesthesia/special monitors (MAC), pre-anesthesia medications ordered (0), evaluator signature, anesthesia</p> | A1380 | <p>(1) I thought 7. Our patient charts already contain this info. Charts will be reviewed by the procedure nurse prior to procedure. The recovery room nurse prior to discharge. Delegated nurses at the end of the day. This will go into effect immediately. M will make sure this is done.</p> <p>(2) This issue has (I thought 7) already been resolved. M had a meeting with the doc -</p> |  |
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| A1380   | <p>Continued From page 16</p> <p>record that includes EKG (electrocardiogram, SR sinus rhythm), % (percent) of O2 (oxygen) inspired (32), O2 saturation (99), equipment checklist that includes machine, equipment, suction and ambu bag are all checked off, position (lithotomy), monitors for blood pressure, EKG, SaO2, airway natural are checked off, recovery that includes stable, airway are checked off, spontaneous ventilation, vital signs stable are pre-documented, O2 saturation (99), and respirations (10).</p> <p>This form was noted in the records of patients #1, 7, and 8 and contained the same information for each of the three sleep records reviewed.</p> <p>3. Interview of the administrator (M) on May 19, 2015 at 2:45 PM revealed the administrator was not aware that the CRNA was using a pre-printed anesthesia form.</p> | A1380   | <p>compliant staff member and he is now in compliance. The counsellors are responsible for seeing CRNAs are in compliance.</p>            |
| A1510   | <p>.15 (A) .15 Physical Environment</p> <p>A. The administrator shall ensure that the facility has a safe, functional, and sanitary environment for the provision of surgical services.</p> <p>This Regulation is not met as evidenced by: Based on review of policies and procedures, review of spore testing documentation, observations and interview of the administrator/registered nurse, it was determined that the administrator failed to implement infection control policies and failed to ensure that measures to prevent infection were practiced at the facility.</p> <p>These measures include failure to follow policy on</p>   | A1510   |   |

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| A1510 | <p>Continued From page 17</p> <p>the cleaning of surgical equipment and failure to perform weekly spore testing for the Surgical Abortion Facility's two autoclaves.</p> <p>The findings include:</p> <p>1. Review of policies on 05/19/15 revealed a policy entitled 'Infection Prevention-Autoclave Sterilization' that stated, in part, "1. Surgical instruments: Steps for cleaning include:</p> <ul style="list-style-type: none"> <li>- Rinsing and washing away gross contamination with hot water and scrubber.</li> <li>- Once gross contamination is removed, all instruments will be washed with soap and water.</li> <li>- Endozime AW Triple Plus solution will be diluted 1/2 ounce per one gallon of warm water. After instruments have soaked in Endozime solution for 2 minutes they will be rinsed thoroughly in warm tap water."</li> </ul> <p>Observations of the process of pre-cleaning surgical instruments on 05/19/15 revealed that equipment was being cleaned in a mixture of 1 ounce of Endozime solution per 1 gallon of water. Practice should match policy.</p> <p>2. A tour of the physical environment revealed that the facility had two autoclave (machine used for the reprocessing/sterilization of surgical instrument) machines.</p> <p>The Centers for Disease Control and Prevention (CDC) recommends weekly use of biological indicators (spore testing) to ensure the efficacy of an autoclave machine in the sterilization process.</p> <p>Review of the policy and procedure for spore testing revealed, "Hillcrest Clinic conducts weekly spore testing on its two autoclaves. In the event</p> | A1510 | <p>1-7<br/>         (1) Policy will be re-written to match actual practice. P will write the new procedure on 6/18/2015.</p> <p>(2) 1-7<br/>         This issue has already been resolved. K is responsible for weekly spore testing - is documenting when it is done and G is overseeing this and keeping a record of all results.</p> |  |
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A1510 Continued From page 18 A1510

of a positive spore test, Hillcrest Clinic will have the autoclave evaluated."

Review of the spore testing documentation revealed that spore testing was not performed on the autoclave machine labeled "O" three times in January, August and December of 2014, twice in February and March 2014 and none in April, May, June, July, September, October and November of 2014. In 2015 the documentation revealed that spore testing was not performed twice in March and May of 2015, three times in April of 2015 and none in February of 2015.

Review of the spore testing documentation revealed that spore testing was not performed on the autoclave machine labeled "M" three times in December, August and February of 2014 and twice on January and February of 2014 and none in April, May, June, July, September, October and November of 2014. In 2015 the documentation revealed that spore testing was not performed twice in March of 2015, three times in April and May of 2015 and none in February of 2015.

Interview of the registered nurse administrator (M) on May 19, 2:45 PM revealed that she was unaware that spore testing was not performed weekly.

A1520 .15 (B) .15 Physical Environment A1520

B. A procedure room shall be designed and equipped to ensure that surgical abortion procedures conducted can be performed in a manner that ensures the safety of all individuals in the area.

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A1520 Continued From page 19

This Regulation is not met as evidenced by:  
Based on the observational tour of the facility and interview of the registered nurse administrator, it was determined that the nurses failed to identify and discard the expired surgical supplies.

The findings include.

During a tour of the procedure room #4 on May 19, 2015 at 9:00 AM revealed the following surgical supplies were expired:

1. One LMA (laryngeal mask airway), expired on May 2007.

A tour of the storage room on May 19, 2015 at 9:30 AM revealed the following surgical supplies were expired:

2. One Synevac vacuum curette medical devise (used to remove tissue from the uterus) expiration date was no longer visible.

3. Two Synevac vacuum curette's expired on February 2012.

4. Two disposable rigid curette's expired on May 2011.

Interview of the registered nurse administrator (M) on May 19, 2:45 PM revealed the administrator was not aware the supplies had expired.

A1570 .16 (B) .16 Quality Assurance Program

B. The facility shall conduct ongoing quality assurance activities and document the activities on a continuous basis, but not less than quarterly.

This Regulation is not met as evidenced by:  
Based on review of the policy manual and

A1520

→ LMA will designate staff members to be responsible for assuring there is no expired equipment.

3. This will go into effect immediately.

5, 6, 7. All procedure nurses are responsible for checking rooms for expired equipment each morning. Recovery nurse is responsible for

disposing of recovery room expired equipment.

E is responsible for storage room equipment.

A1570.

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| A1570   | Continued From page 20<br><br>interview of the registered nurse administrator, it was determined that the administrator has not implemented an ongoing quality assurance program.<br><br>The findings include:<br><br>1. Review of policies on 05/19/15 failed to reveal policies pertinent to Quality Assurance (QA).<br><br>2. Interview of the administrator (M) on May 20, 2015 at 9:50 AM revealed that the Surgical Abortion Facility failed to have a quality assurance program.                           | A1570<br>→  | The clinic does have QA policies. There is a separate QA binder. 1-7 policies were reviewed by J and P and updated on 01/8/2015. Binder is stored in O's office. M will be made aware of QA policies and review them annually. |                    |
| A9999   | Final Comments<br><br>An exit conference was conducted with the administrator on May 20, 2015 and the survey findings were reviewed.<br><br>The administrator was directed to submit a written plan of correction in response to the State of Maryland 2567 form, following the attached guidelines, within ten calendar days. Failure to submit an acceptable plan of correction may result in revocation of your license from the Department of Health and Mental Hygiene Surgical Abortion Facilities program. | A9999   |  |                    |