



# OHIO DEPARTMENT OF HEALTH

246 North High Street  
Columbus, Ohio 43215

614/466-3543  
www.odh.ohio.gov

John R. Kasich / Governor

**JUL 30 2014**

Tara Broderick, President & CEO  
Planned Parenthood of Northeast Ohio  
444 West Exchange Street  
Akron, Ohio 44302

**Re: Proposed Civil Penalty and Plan of Correction  
Planned Parenthood, Bedford Heights  
HCF Number: 1014AS**

Dear Ms. Broderick:

You are notified that I propose to impose a civil money penalty in the amount of twenty-five thousand dollars (\$25,000) against Planned Parenthood, Bedford Heights, 25350 Rockside Road, Bedford Heights, Ohio, due to violations of Revised Code (R.C.) 3702 and Chapter 3701-83 of the Ohio Administrative Code (OAC). This action is taken pursuant to R.C. 3702.32 and OAC 3701-83-05.1(c)(2) and OAC 3701-83-05.2, and in accordance with R.C. Chapter 119.

Representatives of the Ohio Department of Health conducted a licensure inspection at Planned Parenthood Bedford Heights, on March 11, 2014. A copy of the report is enclosed and incorporated into this notice by reference.

In addition, please submit a Plan of Correction on the enclosed Statement of Deficiencies Form, within ten days of receipt of this letter and attain compliance no later than August 29, 2014. The Plan of Correction should be submitted to Drema Phelps, Chief, Bureau of Community Health Care Facilities and Services, 246 N. High St., 2<sup>nd</sup> Floor, Columbus, Ohio 43215.

You may request a hearing before me or my duly authorized representative concerning my proposal to impose a \$25,000 civil penalty against Planned Parenthood, Bedford Heights. Such request must be made in writing and received within thirty days of receipt of this letter and should be directed to Heather Coglianesse, Assistant Counsel, Ohio Department of Health, 246 N. High Street, 7<sup>th</sup> Floor, Columbus, Ohio 43215. A request is considered timely if it is received by the Department of Health via facsimile, hand delivery, or ordinary United States mail within thirty days of the date of receipt of this letter.



Planned Parenthood, Bedford Heights  
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At a hearing, you may appear in person or be represented by an attorney. You may present evidence and you may examine witnesses appearing for and against you. You also may present your position, contentions, or arguments in writing, rather than appear in person for a hearing. If you are a corporation, you must be represented at the hearing by an attorney licensed to practice in Ohio. Please be advised that if you do not request a hearing within thirty days, I will issue an order imposing the \$25,000 civil penalty.

Please contact Heather Coglianese, Assistant Counsel, at (614) 466-4882 if you have questions about this matter.

Sincerely,



Lance D. Himes  
Interim Director

Enclosure

CMRRR: 7011 2970 0001 8004 0505

cc: Sue Hirt, Administrator, Planned Parenthood Bedford Heights  
Heather Coglianese, Assistant Counsel, Office of General Counsel  
Drema Phelps, Chief, Bureau of Community Health Care Facilities and Services

Ohio Dept Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  1014AS	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____		(X3) DATE SURVEY COMPLETED  03/11/2014
NAME OF PROVIDER OR SUPPLIER  PLANNED PARENTHOOD BEDFORD HEIGHTS		STREET ADDRESS, CITY, STATE, ZIP CODE 25350 ROCKSIDE ROAD BEDFORD HEIGHTS, OH 44146		
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C 000	<p>Initial Comments</p> <p>Licensure Compliance Inspection</p> <p>Administrator: Sue Hirt</p> <p>County: Cuyahoga</p> <p>Number of ORs: 6</p> <p>The following violations are issued as a result of the licensure compliance inspection completed on 03/11/14.</p>	C 000		
C 109	<p>O.A.C. 3701-83-03 (K) Contracted Services</p> <p>An HCF may arrange for services to be provided through a contract with an outside resource. The HCF shall retain professional management responsibility for contracted services and shall ensure that those services are furnished in a safe and effective manner.</p> <p>This Rule is not met as evidenced by: Based on review of facility documentation and staff interview the facility failed to provide current contracts for services. This deficient practice had the potential to negatively effect all patients that received surgical services at the facility. The facility performed 2,987 surgical procedures in the last 12 months.</p> <p>Findings included:</p>	C 109		

Ohio Department of Health  
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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C 109	Continued From page 1  1) Review of the facility's contracts for the provision of hazardous biomedical waste removal revealed the facility had entered into a contract with the Stericycle-Sterisafe company on 09/26/11. The facility was unable to produce a more current contract than the 09/26/11 document.  2) Review of the facility's contract with Kleanland L.L.C. for the provision of general cleaning needs of the facility revealed the facility had entered into a contract with the cleaning company on 02/28/12. The contract verbiage documented the terms and conditions and remain the same except for the monthly charge and the duration of the contract. The contract was extended until March 1, 2013. The facility was unable to produce the contract that had been renewed after the expiration date of 03/01/13.  These findings were verified during an interview with Staff I on 03/11/14 at 5:26 PM.	C 109		
C 120	O.A.C. 3701-83-08 (B) T B Control Plan  The HCF shall develop and follow a tuberculosis control plan that is based on the provider's assessment of the facility. The control and assessment shall be consistent with the centers for disease control and prevention (CDC) "Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health Care Settings, 2005," MMWR 2005, Volume 54, No. RR-17. The HCF shall retain documentation evidencing compliance with this paragraph and shall furnish such documentation to the director upon request.	C 120		

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C 120	<p>Continued From page 2</p> <p>This Rule is not met as evidenced by: Based on review of personnel record, review of facility policies, and staff interview, the facility failed to have documented evidence a tuberculin skin test (TB) was conducted on three of three newly hired employees (Staff U, V, and W). The facility performed a total of 2987 procedures in the last 12 months.</p> <p>Findings include:</p> <p>On 03/11/14 personnel files were reviewed for Staff U, V, and W. All three employees were hired as health care assistants on the following dates:</p> <p>Staff U was hired on 02/03/14, Staff V was hired on 02/18/14, and Staff W was hired on 03/04/14.</p> <p>Review of the personnel files for these employees did not contain documentation a TB skin test had been performed. A review of the facility policy titled "Respiratory Protection Policy" stated all new hires who will work in contact with facility patients are required to provide documentation (within the past 12 months) showing their current TB status or the facility will perform a one-step TB test. The policy also stated that employment may begin after documentation has been received.</p> <p>Interview with Staff I at 5:20 PM verified the lack of documented TB skin testing for Staff U, V and W.</p>	C 120		

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C 125	Continued From page 3	C 125		
C 125	O.A.C. 3701-83-08 (G) Staff Performance Evaluation  Each HCF shall evaluate the performance of each staff member at least every twelve months.  This Rule is not met as evidenced by: Based on review of personnel files and staff interview, the facility failed to perform an evaluation on 1 of 4 staff at least every twelve months. This involved Staff L, Health Care Assistant. The facility performed a total of 2987 procedures in the last 12 months.  Findings include:  On 03/11/14, four personnel files were reviewed for staff who had been employed with the facility longer than twelve months. Staff L was hired as a Health Care Assistant on 01/11/11. There was no documented evidence an annual performance evaluation had been completed for this employee in the last twelve months.  This finding was verified with Staff A during an interview at 4:40 PM. Staff A stated the facility policy requires an annual evaluations to be conducted on each employee.	C 125		
C 139	O.A.C. 3701-83-10 (B) Safety & Sanitation  The HCF shall be maintained in a safe and sanitary manner.	C 139		

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C 139	<p>Continued From page 4</p> <p>This Rule is not met as evidenced by: Based on observation, review of facility policies and procedures and staff interview the facility failed to adhere to facility policies and procedures for cleaning and disinfecting surgical equipment, disposal of urine samples and single use patient medical items. This deficient practice had the potential to negatively impact all patients who underwent surgical services at the facility. The facility performed 2,987 surgical procedures in the last 12 months.</p> <p>Findings included:</p> <p>An environmental tour of the facility was conducted on 03/11/14 from 1:10 PM until 3:34 PM. The environmental tour revealed the following findings:</p> <p>1) An tour of patient examination room #3 on 03/11/14 at 1:25 PM revealed a cupboard with six blood collection tubes which bore the expiration date of 02/2014. Also observed in the cupboard was Hemocu AB Hb 201 (used for the determination a patient's hemoglobin or as indicator of anemia prior to surgery). The manufacturer's label indicated the product was good for three months after opening; however, the product did not contain the date the product was opened.</p> <p>The drawer in examination room #3 contained a vaginal microbiological swab which was labeled with the expiration date of 11/30/13.</p> <p>2) A tour of examination room #2 on 03/11/14 at 1:36 PM revealed two vials of Hemocu AB Hb 201. The product did not contain the date the product was opened.</p>	C 139		



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C 139	<p>Continued From page 5</p> <p>3) A tour of examination room #1 on 03/11/14 at 1:45 PM revealed the room's cupboard contained a plastic specimen container with approximately 40 milliliters of an unidentified pale yellow liquid. Interview with Staff I at the time of discovery revealed these types of containers are used by the facility for urine and other specimen collections.</p> <p>The cupboard was observed to contain a brown glass vial with rubber dropper which was labeled as saline and a preparation date of 08/30/12. Interview with Staff I verified the saline was only good for 60 days after opening.</p> <p>The cupboard also contained a plastic basket of Band-Aids which had been removed from the manufacturer's protective packaging. Interview with Staff I stated staff pre-open the Band-Aids as a time saving effort.</p> <p>Inspection of the examination table's side drawers revealed the top side drawer was observed to contain a brown vial with rubber dropper which the label indicated was normal saline used for the preparation of wet mount slides (used to detect vaginal bacteria and fungus) with a date of 11/10/12. Staff I stated during interview the saline is good up to 60 days for use per facility policy.</p> <p>Observation of the second drawer of the examination table revealed clean rolls of paper that were used to cover the examination table for patient use and also observed was an unwrapped and extended condom. Staff I stated the facility used condoms for ultrasound probe covers used during vaginal ultrasounds.</p> <p>The drawer located at the foot end of the patient</p>	C 139		

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C 139	<p>Continued From page 6</p> <p>examination table was observed to have a 250 milliliter bottle of opened normal saline used for the preparation of wet mount microbiological slides. This end drawer was also observed to contain a plastic bottle with a dropper top and which contained a liquid solution the label identified as Potassium Hydroxide and an expiration date of 2/2014. Interview with Staff I at the time of finding revealed the facility performs approximately 10 wet mount slides per month. Additionally, the end drawer contained a plastic canister of Nitrazine Test strip paper used for gynecological examinations which bore the expiration date of 06/2013.</p> <p>4) Inspection of the patient use bathroom on 03/11/14 at 1:52 PM revealed the two-way door system used for the placement and retrieval of urine samples was found to have a plastic specimen container approximately one third full of unidentified yellow liquid. This bathroom was located adjacent to the facility's laboratory testing area. The outside label contained the first name of a female patient. Interview with Staff I at the time of discovery revealed the last day patients were seen by the facility was the previous Friday (03/07/14). Staff I stated the container was a urine specimen collected for analytical tests which failed to have analytical testing performed nor was the specimen properly disposed of.</p> <p>5) Inspection of the laboratory area of the facility on 03/11/14 at 1:54 PM revealed the presence of an opened and half-full 16 ounce bottle of 70% isopropyl alcohol which contained the manufacturer's expiration date of 09/2013. Additionally the laboratory area contained a chemical reagent vial of HCG (human chorionic gonadotrophin) control serum used to perform pregnancy tests. The manufacturer's printed</p>	C 139		

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C 139	<p>Continued From page 7</p> <p>material indicated once open this control reagent was only good for 90 days. The vial failed to contain the date the reagent was opened. These findings were verified at time of discovery with Staff I.</p> <p>6) Inspection of the soiled utility room and the chemical sanitation equipment on 03/11/14 at 3:34 PM revealed the presence of a chemical disinfectant used for the disinfection and reprocessing of surgical suction hoses and any medical equipment or instruments which could not tolerate exposure to high heat sterilization. Inspection of the Revital Resert XL HL gallon contained the manufacture's printed instructions which directed the product delivered a hydrogen peroxide level of 1.5% for high level medical disinfection up to 21 days after opening. The gallon jug failed to indicate the opening date or other labeling which would indicate the 21 day expiration date.</p> <p>Inspection of the test strips used to test the for the minimum recommended concentration of the Resert product for high level disinfection were observed expired as follows:</p> <p>a) one opened vial of test strip verified by Staff J as currently in use had a manufacturer's expiration date of 11/22/13. The manufacturer's label indicated the test strips were valid 90 days after opening; however, the date the vial was opened was not on the vial</p> <p>b) two full unopened boxes of vials which contained the manufacturer's expiration date of 3/9/14</p> <p>c) one full unopened box of two vials with an expiration date of 11/22/13, and</p> <p>d) one full unopened box of two vials with an expiration date of 02/02/14.</p> <p>These findings were verified at the time of</p>	C 139		

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C 139	<p>Continued From page 8 discovery with Staff I.</p> <p>Interview with Staff P on 03/11/14 at 4:05 PM revealed he/she and another staff member were trained internally by the facility staff to reprocess reusable surgical equipment using the product Revital Resert XL HL (a hydrogen peroxide based disinfectant for high level disinfection). Staff P verbalized the process he/she followed to perform this task which included physically washing equipment, rinsing and placing reusable equipment to soak in a solution of Resert. Staff P verbalized he/she always used the test strip from the company to test the effectiveness of the Resert solution. Staff P stated after the instruments or equipment had been immersed in the solution for the directed minimum time of eight minutes the equipment was removed, dried as best as possible and the surgical suction hoses were hung in the clean utility to drip and air dry. Staff P stated surgical procedures are usually performed two days per week. Staff P was unaware of the specified expiration date of the Resert and test strips.</p> <p>Review of the Resert XL HL manufacturer's instructions directed the product must be verified by use of the Verify Chemical Monitoring Strips for Resert Solutions prior to each use. The printed instructions further directed the Resert XL HL solution was suitable for the high level disinfectant when used for a maximum of 21 days. These instructions directed the product must be discarded after 21 days even if the Verify test strip indicated a concentration above the minimum recommended concentration.</p> <p>7) Inspection of the dirty utility room on 03/11/14 at 3:34 PM revealed the presence of a refrigerator marked with a biohazard label. Staff I</p>	C 139		

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C 139	Continued From page 9  stated the freezer portion of the refrigerator was used for storage of human tissue removed during surgical procedures. The freezer compartment was observed to contain eight plastic specimen containers which contained frozen tissue. Neither the refrigerator or freezer was equipped with a thermometer. Additionally, the facility was unable to provide any documentation this unit was monitored by the facility for approved temperature ranges, malfunction or was tested as part of the biomedical preventative maintenance checks. Interview with Staff I verified this finding at the time of discovery.	C 139		
C 158	O.A.C. 3701-83-13 (B) Complaints Hot Line  The HCF shall post the toll free complaint hotline of the department's complaint unit in a conspicuous place in the HCF.  This Rule is not met as evidenced by: Based on observations and staff interview the facility failed to post the State of Ohio's toll free complaint hotline telephone number. This deficient practice had the potential to negatively effect all patients who received services at the facility and wanted to report to a complaint via the confidential hotline number. The facility performed 2,987 surgical procedures in the last 12 months.  Findings included:  The environmental tour was conducted on 03/11/14 from 1:10 PM until 3:34 PM with Staff I.	C 158		

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C 158	Continued From page 10  All of the patient care areas of the building were toured and observed for the required postings. At no time during the environmental tour was the State of Ohio's complaint hot line telephone number observed posted.  Interview with Staff 1 on 03/11/14 at 4:55 PM stated he/she was unaware of this requirement and further queried the surveyors as to where this poster and or number could be obtained from.	C 158		
C 201	O.A.C. 3701-83-16 (B) Governing Body Duties  The governing body shall:  (1) At least every twenty-four months review, update, and approve the surgical procedures that may be performed at the facility and maintain an up-to-date listing of these procedures;  (2) Grant or deny clinical (medical-surgical and anesthesia) privileges, in writing and reviewed or re-approved at least every twenty-four months, to physicians and other appropriately licensed or certified health care professionals based on documented professional peer advice and on recommendations from appropriate professional staff. These actions shall be consistent with applicable law and based on documented evidence of the following: (a) Current licensure and certification, if applicable; (b) Relevant education, training, and experience; and (c) Competence in performance of the procedures for which privileges are requested, as indicated in part by relevant findings of quality assessment and improvement activities and other	C 201		

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C 201	<p>Continued From page 11</p> <p>reasonable indicators of current competency.</p> <p>(3) In the case of an ASF owned and operated by a single individual, provide for an external peer review by an unrelated person not otherwise affiliated or associated with the individual. The external peer review shall consist of a quarterly audit of a random sample of surgical cases.</p> <p>This Rule is not met as evidenced by: Based on review of governing body minutes, personnel files, credentialing documentation, and staff interview, the governing body failed to grant privileges in writing to one of one staff who serves as a Physician and Medical Director (Staff Q), two physicians currently working an as needed basis in the facility (Staff R and S), and for a physician (Staff T) who performed abortions in the facility in 2013 but was no longer working at this facility. This could affect all patients receiving surgical services in the facility. The facility performed a total of 2987 procedures in the last 12 months.</p> <p>Findings include:</p> <p>During this visit on 03/11/14, a review was conducted of the personnel files of physicians. Also reviewed was documentation for credentialing of professional medical staff, and governing body minutes. An interview with Staff I at 5:30 PM revealed that Staff Q was hired as the physician for performing surgical abortions on 10/07/13. According to Staff I, this employee</p>	C 201		

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NAME OF PROVIDER OR SUPPLIER  PLANNED PARENTHOOD BEDFORD HEIGHTS		STREET ADDRESS, CITY, STATE, ZIP CODE 25360 ROCKSIDE ROAD BEDFORD HEIGHTS, OH 44146		
(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
C 201	Continued From page 12  (Staff Q) became the Medical Director of the facility.  A review of the credentialing records for Staff Q, and for 2 of 3 other physicians (Staff R and S) who performed abortions in the facility during 2013, revealed no documentation related to competence in the performance of the procedures for which the physicians provided (surgical abortions).  A review of the governing body meeting minutes dated 02/17/14 revealed a discussion was held for the review of providers and of provider privileges: a) Surgical privileging every 24 months. Most MDs due 2015. b) Plan to renew privileges for current physicians c) Plan for privileging new physicians.  At 5:30 PM on 03/11/14, Staff I verified the facility did not use peer review of medical records, references, or data base query to determine physician competency prior to granting privileges to Staff R and S who performed abortions in the facility in 2013, or for Staff Q who was currently performing the surgical abortions on patients. Staff A stated an additional physician (Staff T) performed abortions in 2013 but was no longer an employee of this facility. Staff I verified the governing body minutes for February 2014 lacked the names of physicians who were granted privileges to perform abortion procedures in the facility.	C 201		
C 211	O.A.C. 3701-83-17 (F) MR With Patient Transport  Patients transported to a hospital shall be accompanied by their medical records that are of	C 211		



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C 211	Continued From page 13  sufficient content to ensure continuity of care.  This Rule is not met as evidenced by: Based on review of the medical records, review of facility policy, and staff interview, the facility did not have documentation one patient's medical record accompanied the patient to the hospital at the time of transfer by ambulance. This affected 1 of 2 patients (Patient #2) who were transferred to the hospital since August 2013. The facility performed a total of 2987 procedures in the last 12 months.  Findings include:  During this visit, medical record of Patient #2 was reviewed. According to this record, the patient received a surgical abortion conducted by Staff T on 10/03/13 for uterine size fetal age of 13 weeks. According to the medical record, the patient began bleeding during the abortion and was taken to the hospital per squad on that same date at 2:55 PM. The medical record did not have documentation the medical record accompanied the patient to the hospital nor documentation the facility notified the hospital's emergency department of Patient #2's transfer.  This finding was verified with Staff I at 5:30 PM. A review of the facility's policy with Staff I revealed the policy was not followed.	C 211		
C 222	O.A.C. 3701-83-18 (C) Director of Nursing  Each ASF shall have a director of nursing who is an RN with experience in surgical and recovery room nursing care. The director of nursing shall	C 222		

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C 222	<p>Continued From page 14</p> <p>be responsible for the management of nursing services.</p> <p>This Rule is not met as evidenced by: Based on facility documentation and staff interview the facility failed to employ an experienced director of nursing (DON) with operating room experience. This deficient practice had the potential to negatively effect all patients who received surgical services at the facility from September 2013 until the current date (03/11/14). The facility performed 2,987 surgical procedures in the last 12 months.</p> <p>Findings included:</p> <p>Review of the facility's nursing staff roster revealed the facility currently employed nine nurses. Interview with Staff I on 03/11/14 at 4:55 PM revealed the facility did not have a director of nursing (DON). Two of the nine nurses (Staff E and I) were advanced practice nurses and were hired as administrative nurses. Staff E was employed as Regional Director of Clinical Services and Staff I was employed as Regional Director of Quality Assurance.</p> <p>Staff E's administrative employment date was documented as November, 2012 and Staff I's administrative employment date was documented as April 2012. Staff I further verbalized that as advanced practice nurses and administrative staff neither Staff E nor I worked in the operating rooms (OR). Staff E further offered that Staff E's job duties included the reading of inconclusive and difficult ultrasounds. Staff I stated that his/her job duties encompassed quality assurance duties. Staff I verbalized that neither</p>	C 222			

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C 222	Continued From page 15  he/she nor Staff E were designated as DONs, and that neither Staff E or I possessed any prior surgical operating room experience. Staff I verbalized that the previous nurse who over saw the operating room had left the facility's employment in September of 2013 and that the facility had recently hired an experienced operating room nurse whose employment had not yet started as of the date of survey (03/11/14).	C 222		
C 255	O.A.C. 3701-83-21 (A) - (E) Medical Records  Each ASF medical record shall contain at least the following information as applicable for the surgery to be performed:  (A) Admission data: (1) Name, address, date of birth, gender, and race or ethnicity; (2) Date and time of admission; and (3) Pre-operative diagnosis, which shall be recorded prior to or at the time of admission.  (B) History and physical examination data: (1) Personal medical history, including but not limited to allergies, current medications and past adverse drug reactions; (2) Family medical history; and (3) Physical examination.  (C) Treatment data: (1) Physician's, podiatrist's or dentist's orders; (2) Physician's, podiatrist's or entist's notes; (3) Physician assistant's notes, if applicable; (4) Nurse's notes; (5) Medications; (6) temperature, pulse, and respiration; (7) Any special examination or report, including but not limited to, x-ray, laboratory, or pathology reports; (8) Signed informed consent form; (9) Evidence of advanced directives, if applicable; (10) Operative record; (11) Anesthesia record, if applicable; and (12) Consultation record, if	C 255		

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C 255	<p>Continued From page 16 applicable.</p> <p>(D) Discharge data: (1) Final diagnosis; (2) Procedures and surgeries performed; (3) Condition upon discharge; (4) Post-treatment care and instructions; and (5) Attending physician's, podiatrist's or dentist's signature.</p> <p>(E) Other information required by law.</p> <p>This Rule is not met as evidenced by: Based on medical record review, review of facility policies, and staff interview, the facility did not have legible and complete documentation in the medical records of 2 of 2 patients who were transferred to the hospital by ambulance since August 2013 to current date. This affected 2 of 2 patients (Patients #2 and #1). The facility performed a total of 2987 procedures in the last 12 months.</p> <p>Findings include:</p> <p>During this visit, a medical record review was conducted of Patient #2. According to this record, the patient received a surgical abortion conducted by Staff T on 10/03/14 for uterine size fetal age of 13 weeks. According to the medical record, the patient began bleeding during the abortion and was taken to the hospital per squad on that same date at 2:55 PM.</p> <p>The medical record was illegible and could not be deciphered by Staff I. The medical record was incomplete as follows: a) The medical record did not have documentation of which squad took the patient to the hospital</p>	C 255		

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C 255	<p>Continued From page 17</p> <p>b) The moderate sedation record did not have a complete date as the year was missing. A write-over was noted on the time the sedation medication was given between 1:52 PM and 2:00 PM.</p> <p>c) A progress note by a health care assistant was dated 10/24/13 for a 10/03/13 entry regarding the patient's bleeding post surgical abortion. The documentation revealed a "cath" was inserted; however, did not specify what type of catheter or where the catheter was inserted. This progress note was authored 21 days after the patient was transferred to the hospital.</p> <p>d) The medical record did not have documentation of the patient's post transfer status, in accordance with facility policy titled "First Response and Hospital Transfer". The policy stated call the client within 72 hours and obtain information about the hospitalization and its outcome. Document information on the client's medical record. This lack of documentation and failure to follow the First Response and Hospital Transfer policy was verified with Staff I at 5:30 PM.</p> <p>A review of Patient #1's medical record revealed the patient received a surgical abortion on 08/28/14 by Staff T for gestational age fetus of 14 weeks according to uterus size at 2:25 PM.</p> <p>The medical record was illegible as follows: a) The physician's note on the in-clinic abortion report regarding the patient's transfer to the hospital could not be interpreted by Staff I. b) The medical record lacked a legible name of the physician performing the abortion.</p> <p>The facility policy for transfers to the hospital stated call the patient within 72 hours and obtain information about the hospitalization and its</p>	C 255		

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C 255	Continued From page 18  outcome. The patient's medical record lacked this documentation within 72 hours. A progress note dated 12/03/13 (over 3 months later) stated the patient underwent laparoscopic surgical repair of confirmed uterine perforation and surgery and recovery at hospital was uncomplicated.  This finding was verified with Staff I at 3:50 PM.	C 255		
C 266	O.R.C. 3702.30(B) Infection Control Program  An ambulatory surgical facility shall maintain an infection control program by creating and administering a plan designed to prevent, identify, and manage infections and communicable diseases; ensure that the program is directed by a qualified professional trained in infection control; ensure the program is an integral part of the ambulatory surgical facility's quality assessment and performance improvement program; and implement in an expeditious manner corrective and preventive measure that result in improvement.  This Rule is not met as evidenced by: Based on observation, review of facility policies and procedures and staff interview the facility failed to adhere to infection control policies and procedures for cleaning and disinfecting surgical equipment, the disposal of urine samples and single use patient medical items. This deficient practice had the potential to negatively affect all patients who underwent surgical services at the facility. The facility performed 2,987 surgical procedures in the last 12 months.  Findings included:  Environmental tour of the facility on 03/11/14 from	C 266		

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C 266	<p>Continued From page 19</p> <p>1:10 PM until 3:34 PM revealed the following findings:</p> <p>1) A tour of examination room #1 on 03/11/14 at 1:45 PM revealed the room's cupboard contained a plastic specimen container with approximately 40 milliliters of an unidentified pale yellow liquid. Interview with Staff I at the time of discovery revealed these types of containers are used by the facility for urine and other specimen collections.</p> <p>The cupboard also contained a plastic basket of Band-Aids which had been removed from the manufacturer's protective packaging. Interview with Staff I stated staff pre-open the Band-Aids as a time saving effort.</p> <p>Observation of the second drawer of the examination table where clean rolls of paper used to cover the examination table for patients was observed to contain an unwrapped and extended condom. Staff I stated the facility used condoms for ultrasound probe covers used during vaginal ultrasounds.</p> <p>2) Inspection of the patient use bathroom on 03/11/14 at 1:52 PM revealed the two-way door system used for the placement and retrieval of urine samples was found to have a plastic specimen container approximately one third full of unidentified yellow liquid. This bathroom was located adjacent to the facility's laboratory testing area. The outside label contained the first name of a female patient. Interview with Staff I at the time of discovery revealed the last day patients were seen by the facility was the previous Friday (03/07/14). Staff I stated the container was a urine specimen collected for analytical tests which failed to have analytical testing performed</p>	C 266		

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C 268	<p>Continued From page 20</p> <p>nor was the specimen properly disposed of.</p> <p>3) Inspection of the soiled utility room and the chemical sanitation equipment on 03/11/14 at 3:34 PM revealed the presence of a chemical disinfectant used for the disinfection and reprocessing of surgical suction hoses and any medical equipment or instruments which could not tolerate exposure to high heat trivialization. Inspection of the Revital Resert XL HL gallon contained the manufacture's printed instructions which directed the product delivered a hydrogen peroxide level of 1.5% for high level medical disinfection up to 21 days after opening. The gallon jug failed to indicate the opening date or other labeling which would indicate the 21 day expiration date.</p> <p>Inspection of the test strips used to test the for the minimum recommended concentration of the Resert product for high level disinfection were observed expired as follows:</p> <ul style="list-style-type: none"> <li>a) one opened vial of test strip verified by Staff J as currently in use had a manufacturer's expiration date of 11/22/13. The manufacturer's label indicated the test strips were valid 90 days after opening; however, the date the vial was opened was not on the vial</li> <li>b) two full unopened boxes of vials which contained the manufacturer's expiration date of 3/9/14</li> <li>c) one full unopened box of two vials with an expiration date of 11/22/13, and</li> <li>d) one full unopened box of two vials with an expiration date of 02/02/14.</li> </ul> <p>These findings were verified at the time of discovery with Staff I.</p> <p>Interview with Staff P on 03/11/14 at 4:05 PM revealed he/she and another staff member were</p>	C 268		



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C 266	Continued From page 21  trained internally by the facility staff to reprocess reusable surgical equipment using the product Revital Resert XL HL (a hydrogen peroxide based disinfectant for high level disinfection. Staff P verbalized the process he/she followed to perform this task which included physically washing equipment, rinsing and placing reusable equipment to soak in a solution of Resert. Staff P verbalized he/she always used the test strip from the company to test the effectiveness of the Resert solution. Staff P stated after the instruments or equipment had been immersed in the solution for the directed minimum time of eight minutes the equipment was removed, dried as best as possible and the surgical suction hoses were hung in the clean utility to drip and air dry. Staff P stated surgical procedures are usually performed two days per week. Staff P was unaware of the specified expiration date of the Resert and test strips.  Review of the Resert XL HL manufacturer's instructions directed the product must be verified by use of the Verify Chemical Monitoring Strips for Resert Solutions prior to each use. The printed instructions further directed the Resert XL HL solution was suitable for the high level disinfectant when used for a maximum of 21 days. These instructions directed the product must be discarded after 21 days even if the Verify test strip indicated a concentration above the minimum recommended concentration.	C 266		

