



# COMMONWEALTH of VIRGINIA

Karen Remley, MD, MBA, FAAP  
State Health Commissioner

Department of Health  
P O BOX 2448  
RICHMOND, VA 23218

TTY 7-1-1 OR  
1-800-828-1120

July 30, 2012

**Certified Mail Delivery**

Lilly Kane, Administrator  
Women's Health Clinic  
101 South Whiting Street, Suite 215  
Alexandria, Virginia 22304

**RE: Woman's Health Clinic, Alexandria , Virginia  
Abortion Facility Initial Licensure Survey**

Dear Ms. Kane:

An announced Initial Abortion Facility Licensure survey of the above agency was completed on July 19, 2012 by a Medical Facilities Inspector team from the Virginia Department of Health's Office of Licensure and Certification (OLC).

Enclosed is the Licensure Inspection Report. This document contains a listing of deficiencies found at the time of this inspection.

You are required to file a plan for correcting these deficiencies. Your statements shall reflect the specific detailed actions you will take to correct deficiencies, prevent a recurrence of the deficiencies, and measures implemented to maintain compliance. You must also give the expected completion date of each deficiency.

***Completion of corrective actions shall not exceed 30 working days from the last day of the inspection (due August 30, 2012) except for those corrective actions for deficiencies cited under 12VAC5-412-380 of the Regulations for the Licensure of Abortion Facilities, for which corrective action must be completed within two years of the issuance of the license.***

After signing and dating your Plan of Correction, retain one copy of the report for your files and return the original to OLC within **15 working days** of receipt of this inspection report. Please provide written documentation of the corrective actions taken by your agency for each of the deficiencies cited on the enclosed Licensure Inspection Report.



A copy of the completed form "Licensure Inspection Report" will be kept on file in this office and will be available for public review. OLC is required to make copies of this report available to other Federal and State regulatory or reimbursement agencies upon request.

Should you have any questions, please feel free to call Kathaleen Creegan-Tedeschi, Supervisor, Acute Care Licensing, Office of Licensure and Certification, at (804) 367-2156.

Sincerely,



Karen Remley, M.D., M.B.A., F.A.A.P.  
State Health Commissioner

c: Erik Bodin, Director  
Office of Licensure and Certification

Enclosure



State of Virginia

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>FTAF-0016</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>07/19/2012</b>
NAME OF PROVIDER OR SUPPLIER <b>ALEXANDRIA WOMEN'S HEALTH CLINIC</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>101 S. WHITING ST. SUITE #215 ALEXANDRIA, VA 22304</b>		
(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
T 000	12 VAC 5- 412 Initial comments  An announced Initial Licensure Abortion Facility inspection was conducted at the above referenced facility July 18 and 19, 2012 by two (2) Medical Facility Inspectors from the Virginia Department of Health's, Office of Licensure and Certification.  The facility was found to not be in compliance with the State Board of Health 12 VAC 5-412, Regulations for Abortion Facility's effective December 29, 2011. Deficiencies were identified and cited, and will follow in this report.	T 000	Plan of Correction	
T 030	12 VAC 5-412-140 E Organization and management  E. The bylaws shall include at a minimum the following: 1. A statement of purpose; 2. Description of the functions and duties of the governing body, or other legal authority; 3. A statement of authority and responsibility delegated to the administrator and to the clinical staff; 4. Provision for selection and appointment of clinical staff and granting of clinical privileges; and 5. Provision of guidelines for relationships among the governing body, the administrator and the clinical staff.  This RULE: is not met as evidenced by: Based on document review and staff interview the facility failed to ensure the governing body appointed the administrator. The facility governing body also failed to ensure the clinical staff were given privileges to practice in the facility.  The findings include:	T 030	T 030  The Bylaws of the Governing Authority will be amended to specify that the governing body appoints the administrator and delegates to the administrator the authority and responsibilities as defined in the job description of the administrator.  The Governing Body minutes will be amended to appoint the (name of person) as the administrator.  The governing body minutes will be amended to contain guidelines on how clinical staff are granted privileges .	8-30-12

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

*Lilly A. Kane*

TITLE

*PRESIDENT / ADMINISTRATOR*

(X8) DATE 8-23-12

STATE FORM

021108

3BIB11

If continuation sheet 1 of 28

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# STATE WORKLOAD REPORT

Provider/Supplier Number	Provider/Supplier Name <b>ALEXANDRIA WOMEN'S HEALTH CLINIC</b>
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Type of Survey (Select all that apply)

1				
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- |                           |                         |                     |
|---------------------------|-------------------------|---------------------|
| A Complaint Investigation | E Initial Certification | I Recertification   |
| B Dumping Investigation   | F Inspection of Care    | J Sanctions/Hearing |
| C Federal Monitoring      | G Validation            | K State License     |
| D Follow-up Visit         | H Life Safety Code      | L CHOW              |
| M Other                   |                         |                     |

Extent of Survey (select all that apply)

A				
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- A Routine/Standard Survey (all providers/suppliers)  
 B Extended Survey (HHA or Long Term Care Facility)  
 C Partial Extended Survey (HHA)  
 D Other Survey

### SURVEY TEAM AND WORKLOAD DATA

Please enter the workload information for each surveyor Use the surveyor's identification number

Surveyor ID Number (A)	First Date Arrived (B)	Last Date Departed (C)	Pre-Survey Preparation Hours (D)	On-Site Hours 12am-8am (E)	On-Site Hours 8am-6pm (F)	On-Site Hours 6pm-12am (G)	Travel Hours (H)	Off-Site Report Preparation Hours (I)
1. 25746	07/18/2012	07/19/2012	1.00	0.00	10.25	0.00	6.50	8.00
2. 27661	07/18/2012	07/19/2012	0.50	0.00	10.25	0.00	3.75	2.00
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								

Total SA Supervisory Review Hours.....	1.00	Total RO Supervisory Review Hours.....	0.00
Total SA Clerical/Data Entry Hours....	1.00	Total RO Clerical/Data Entry Hours.....	0.00

Was Statement of Deficiencies given to the provider on-site at completion of the survey?.... No



State of Virginia

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T 030	Continued From Page 1  On 7/18/12 the facility policy and procedure manuals were reviewed. The administrator was asked to provide the governing body minutes on 7/18/12, they were not available until 7/19/12. The governing body minutes did not have evidence of appointing (name of person) as the administrator. The governing body minutes also did not contain guidelines on how clinical staff were granted privileges.	T 030		
T 035	12 VAC 5-412-150 Policy and procedure manual.  Each abortion facility shall develop, implement and maintain an appropriate policy and procedures manual. The manual shall be reviewed annually and updated as necessary by the licensee. The manual shall include provisions covering at a minimum, the following topics: 1. Personnel; 2. Types of elective and emergency procedures that may be performed in the facility; 3. Types of anesthesia that may be used; 4. Admissions and discharges, including criteria for evaluating the patient before admission and before discharge; 5. Obtaining written informed consent of the patient prior to the initiation of any procedures; 6. When to use ultrasound to determine gestational age and when indicated to assess patient risk; 7. Infection prevention; 8. Risk and quality management; 9. Management and effective response to medical and/or surgical emergency; 10. Management and effective response to fire; 11. Ensuring compliance with all applicable federal, state and local laws; 12. Facility security; 13. Disaster preparedness;	T 035	T 035  There will be a reorganization of the existing policies and procedures in individual binders to make a policy and procedures manual readily available for review by the Office of Licensure and Certification inspectors.  The policy and procedure manual shall include:  1. type of elective procedures 2. types of anesthesia 3. admission and discharge criteria 4. obtaining the patient's written consent prior to the procedure 5. management and effective response to fire, 6. disaster preparedness 7. patient rights	8-30-12

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T 035	Continued From Page 3  to fire, disaster preparedness and patient rights.  The findings include:  On 7/18/12 a review of the facility policies and procedures was performed with the facility administrator present. There were no policies related to types of elective procedures and whether or not emergency procedures were performed, types of anesthesia used, admission and discharge criteria, obtaining the patients' written consent prior to the procedures, management and effective response to fire, disaster preparedness and patient rights.  The administrator stated, "No we don't have policies specific to those things (topics listed above)."	T 035	T 045  A written statement will be adopted by the governing body that the governing body will appoint the administrator and define the administrator's authority, qualifications and duties.	8-30-12
T 045	12 VAC 5-412-160 A Administrator  A. The governing body shall select an administrator whose qualifications, authority and duties shall be defined in a written statement adopted by the governing body.  This RULE: is not met as evidenced by: Based on document review and staff interview the facility failed to ensure the governing body appointed the administrator.  The findings include:  On 7/1/19 the facility administrator was interviewed regarding her appointment and approval by the governing body as the administrator. She stated, "My husband and I are the governing body. I did not know I needed to appointment myself as the administrator."	T 045		

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T 055	<p>12 VAC 5-412-160 C Administrator</p> <p>C. A qualified individual shall be appointed in writing to act in the absence of the administrator.</p> <p>This RULE: is not met as evidenced by: Based on document review and staff interview the facility failed to ensure the governing body appointed, in writing, a person to act in the absence of the administrator.</p> <p>The findings include:</p> <p>On 7/1/19 the facility administrator was interviewed regarding who would be responsible for the day to day management of the facility should she be absent. She stated, "Oh that would be (name of person). I don't have that in writing anywhere."</p>	T 055	<p>T 055</p> <p>The governing body will appoint in writing, an assistant administrator, an individual to act in the absence of the administrator.</p>	8-30-12
T 065	<p>12 VAC 5-412-170 B Personnel</p> <p>B. The licensee shall obtain written applications for employment from all staff. The licensee shall obtain and verify information on the application as to education, training, experience, appropriate professional licensure, if applicable, and the health and personal background of each staff member.</p> <p>This RULE: is not met as evidenced by: Based on document review and staff interview the facility failed to ensure they verified the licenses of the nursing and medical staff who perform duties in the facility.</p> <p>The findings include:</p> <p>A review of the administrators' (who is a registered nurse), the CRNA (Certified Registered Nurse Anesthetist) and the physicians' credentials</p>	T 065	<p>T 065</p> <p>The facility will verify the licenses of the nursing and medical staff through the respective Va. Board of Medicine and Va. Board of Nursing (license look-up)</p>	8-30-12

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T 065	Continued From Page 5	T 065		
T 070	revealed no verification of their respective licenses. The administrator stated, "I have a copy of their licenses but I guess I need more."  12 VAC 5-412-170 C Personnel  C. Each abortion facility shall obtain a criminal history record check pursuant to 32.1-126.02 of the Code of Virginia on any compensated employee not licensed by the Board of Pharmacy, whose job duties provide access to controlled substances within the abortion facility.  This RULE: is not met as evidenced by: Based on document review and staff interview the facility failed to ensure the criminal records checks pursuant to § 32.1 - 126.02 of the Code of Virginia were performed on employees not licensed by the Board of Pharmacy, whose's job duties proved access to controlled substances within the facility. The findings include: On 7/18/12 the facility administrator provided the personnel files of all employees, CRNA's (Certified Registered Nurse Anesthetist) and physicians who have access to controlled substances. Only the administrators personnel file had a criminal record check performed. The administrator stated, "I will get those done."	T 070	T 070  All CRNA's (Certified Registered Nurse Anesthetist) and physicians were given criminal history check forms (between July 28 and Aug. 1, 2012) to be completed and mailed to the Va. State Police.	8-30-12
T 080	12 VAC 5-412-170 E Personnel  E. The facility shall develop, implement and maintain policies and procedures to document that its staff participates in initial and ongoing training and education that is directly related to staff duties, and appropriate to the level, intensity and scope of services provided. This shall include documentation of annual participation in fire safety and infection prevention in-service training.	T 080		

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T 080	Continued From Page 6  This RULE: is not met as evidenced by: Based on document review and staff interviews the facility staff failed to ensure policies and procedures were implemented and maintained regarding initial and ongoing training and education related to their duties.  The findings include:  The policy and procedure manuals were reviewed on 7/18/12 with the administrator present. There were no policies related to staff training and education at hire or on an ongoing basis.  The administrator stated, "I guess I have to have policies about their training even though they are trained."	T 080	T 080  The policy regarding staff training at hire and the policy regarding on-going training and education related to their duties will be included in the policy and procedure manual.  On-going in-service training will be documented to include the following:	8-30-12  8-30-12
T 095	12 VAC 5-412-170 H Personnel  H. Personnel policies and procedures shall include, but not be limited to: 1. Written job descriptions that specify authority, responsibility, and qualifications for each job classification; 2. Process for verifying current professional licensing or certification and training of employees or independent contractors; 3. Process for annually evaluating employee performance and competency; 4. Process for verifying that contractors and their employees meet the personnel qualifications of the facility; and 5. Process for reporting licensed and certified health care practitioners for violations of their licensing or certification standards to the appropriate board within the Department of Health Professions.	T 095	1. date of in-service 2. names of attendees 3. topic of in-service 4. name of trainer 5. signed approval of Administrator/Assist. Administrator	

PRINTED: 07/25/2012  
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T 095	Continued From Page 7  This RULE: is not met as evidenced by: Based on document review and staff interview the facility failed to ensure they verified the licenses of the nursing and medical staff who perform duties in the facility. The facility also failed to have a policy in place that addressed how they would report a licensed and or certified health care provider to the appropriate board within the Department of Health Professions.  The findings include:  On 7/18/12 a review of the administrator's, who is a registered nurse, the CRNA (Certified Registered Nurse Anesthetist) and the physicians' credentials revealed no verification of their respective licenses. The administrator stated, "I have a copy of their licenses but I guess I need more."  Also on 7/18/12 a review of the facility policies and procedures with the administrator present was performed. A policy on how they would report a licensed and or certified health care provider to the appropriate board within the Department of Health Professions could not be located. The administrator stated, "No, I don't have one (a policy)."	T 095	3. The process for evaluating employees' performance and competency shall include: a) an annual self evaluation and review of the evaluation utilizing a checklist and verified by the immediate supervisor/surgical coordinator and the Administrator. b) an evaluation of performance and competency after assignment/training of any new job duties.  4. There will be a process for verifying that contractors and their employees meet the personnel qualifications .  5. A policy and procedure will be formulated to include the process for reporting licensed and certified health care practitioners for any violations of their licensing or certification standards to the appropriate board within the Dept. of Health Professions. (Ref: Commonwealth of Virginia enforcement division.)	8.30-12
T 110	12 VAC 5-412-180 B Clinical staff  B. Abortions shall be performed by physicians who are licensed to practice medicine in Virginia and who are qualified by training and experience to perform abortions. The facility shall develop, implement and maintain policies and procedures to ensure and document that abortions that occur in the facility are only performed by physicians who are qualified by training and experience.	T 110		

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If continuation sheet 6 of 29

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T 110	Continued From Page 8  This RULE: is not met as evidenced by: Based on a review of facility personnel files and an interview it was determined the facility failed to ensure physicians were licensed to practice medicine in Virginia and had the necessary training and experience to perform abortions.  The findings were:  A review of the personnel files for the physicians and certified registered nurse anesthetist (CRNA) revealed the facility staff failed to run a NPDR (National Data Bank Request) on practitioners as required by the regulations. The facility failed to verify through the NPDR the practitioners met the training and experience required to perform the job requirements.  An interview was conducted with the administrator on 7/18/2012 at approximately 3pm and the he/she stated the facility does not require the physicians to be board certified in Obstetrics and Gynecology.	T 110	T 110  The administrator will run a NPDR (National Data Bank Request) on all physicians to verify through the NPDR that the physicians meet the training and experience required to perform first trimester abortions and fulfill their job requirements.	8-30-12
T 135	12 VAC 5-412-210 A Patients' rights  A. Each abortion facility shall establish a protocol relating to the rights and responsibilities of patients consistent with the current edition of the Joint Commission Standards of Ambulatory Care. The protocol shall include a process reasonably designed to inform patients of their rights and responsibilities, in a language or manner they understand. Patients shall be given a copy of their rights and responsibilities upon admission.  This RULE: is not met as evidenced by: Based on interviews and document review the	T 135		

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T 095	Continued From Page 7  This RULE: is not met as evidenced by: Based on document review and staff interview the facility failed to ensure they verified the licenses of the nursing and medical staff who perform duties in the facility. The facility also failed to have a policy in place that addressed how they would report a licensed and or certified health care provider to the appropriate board within the Department of Health Professions.  The findings include:  On 7/18/12 a review of the administrator's, who is a registered nurse, the CRNA (Certified Registered Nurse Anesthetist) and the physicians' credentials revealed no verification of their respective licenses. The administrator stated, "I have a copy of their licenses but I guess I need more."  Also on 7/18/12 a review of the facility policies and procedures with the administrator present was performed. A policy on how they would report a licensed and or certified health care provider to the appropriate board within the Department of Health Professions could not be located. The administrator stated, "No, I don't have one (a policy)."	T 095	T 095  The licenses of all nurses and physicians have been verified through license lookup.  A policy and procedure will be formulated to include the process for reporting licensed and certified health care practitioners for any violations of their licensing or certification standards to the appropriate board within the Dept. of Health Professions. (Ref: Commonwealth of Virginia Enforcement Division)	8-30-12
T 110	12 VAC 5-412-180 B Clinical staff  B. Abortions shall be performed by physicians who are licensed to practice medicine in Virginia and who are qualified by training and experience to perform abortions. The facility shall develop, implement and maintain policies and procedures to ensure and document that abortions that occur in the facility are only performed by physicians who are qualified by training and experience.	T 110		

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T 135	Continued From Page 9  facility staff failed to ensure each patient was given a copy of their rights and responsibilities upon admission.  The findings include:  On 7/18/12 the administrator was interviewed regarding what information is given to the patient on admission. When asked if the patients are given a copy of their rights she stated, "No, we show it to them and if they want a copy we give them one."	T 135	T 135  All patients will be given a copy of their rights and responsibilities upon admission.	8-30-12
T 145	12 VAC 5-412-210 C Patients' rights  C. The facility shall designate staff responsible for complaint resolution, including: 1. Complaint intake, including acknowledgement of complaints; 2. Investigation of the complaint; 3. Review of the investigation findings and resolution for the complaint; and 4. Notification to the complainant of the proposed resolution within 30 days from the date of receipt of the complaint.  This RULE: is not met as evidenced by: Based on interviews and document review the facility staff failed to ensure a person was designated as the person responsible for handling complaints which includes intake, investigation, review of findings and notification to the complainant of the resolution with 30 days.  The findings include:  The administrator was interviewed on 7/18/12 regarding how the facility handles complaints. She stated, "I handle complaints but we have not had any in all the years I have been here'.	T 145	T 145  The patient rights and responsibilities protocol will show that the administrator or her designee is responsible for complaint resolution which will include: complaint intake, acknowledgment of complaint, review of findings, resolution, and notifying the complainant of the proposed resolution within 30 days from the date of receipt of the complaint.	8-30-12

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NAME OF PROVIDER OR SUPPLIER <b>ALEXANDRIA WOMEN'S HEALTH CLINIC</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>101 S. WHITING ST, SUITE #215 ALEXANDRIA, VA 22304</b>		
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T 155	<p>12 VAC 5-412-210 E Patients' rights</p> <p>E. The facility shall provide each patient or her designee with the name, mailing address, and telephone number of the:</p> <ol style="list-style-type: none"> <li>1. Facility contact person; and</li> <li>2. The OLC Complaint Unit, including the toll-free complaint hotline number. Patients may submit complaints anonymously to the OLC. The facility shall display a copy of this information in a conspicuous place.</li> </ol> <p>This RULE: is not met as evidenced by: Based on interviews and document review the facility staff failed to ensure each patient was given a copy of their rights and responsibilities upon admission.</p> <p>The findings include:</p> <p>On 7/18/12 the administrator was interviewed regarding what information is given to the patient on admission. When asked if the patients are given a copy of their rights she stated, "No, we show it to them and if they want a copy we give them one." The information shown to the patients failed to include the complaint information for the Office of Licensure and Certification.</p> <p>During the tour of the facility on 7/18/12 with the administrator the rights and responsibilities of patients was not posted anywhere in the facility.</p>	T 155	<p>T 155</p> <p>The facility shall provide each patient or her designee with the name, mailing address and telephone number of the facility contact person.</p> <p>In addition, the rights and responsibilities form shall include the OLC Complaint Unit's address and toll-free complaint hotline number.</p> <p>The facility shall display a copy of the rights and responsibilities of patients to include the above contact information in the main reception room.</p>	8-30-12
T 170	<p>12 VAC 5-412-220 B Infection prevention</p> <p>B. Written infection prevention policies and procedures shall include, but not be limited to:</p> <ol style="list-style-type: none"> <li>1. Procedures for screening incoming patients and visitors for acute infectious illnesses and</li> </ol>	T 170		

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T 170	<p>Continued From Page 11</p> <p>applying appropriate measures to prevent transmission of community acquired infection within the facility;</p> <p>2. Training of all personnel in proper infection prevention techniques;</p> <p>3. Correct hand-washing technique, including indications for use of soap and water and use of alcohol-based hand rubs;</p> <p>4. Use of standard precautions;</p> <p>5. Compliance with blood-bourne pathogen requirements of the U.S. Occupational Safety &amp; Health Administration.</p> <p>6. Use of personal protective equipment;</p> <p>7. Use of safe injection practices;</p> <p>8. Plans for annual retraining of all personnel in infection prevention methods;</p> <p>9. Procedures for monitoring staff adherence to recommended infection prevention practices; and</p> <p>10. Procedures for documenting annual retraining of all staff in recommended infection prevention practices.</p> <p>This RULE: is not met as evidenced by: Based on observations, document review and staff interviews the facility failed to ensure all staff followed an infection prevention program.</p> <p>The findings include:</p> <p>On 7/19/12 the following observations were made: the attending physician was sitting at a desk reading the newspaper. He put the paper away when the patient arrived. The physician interviewed the patient. The staff escorted the patient to the exam room. The physician went into the room (followed immediately by the surveyor who stood by the sink and continued the observation). The physician put on gloves and preceded to perform a vaginal ultrasound of the patient.</p>	T 170	<p>T 170</p> <p>All staff will be reminded verbally and through posted hand-hygiene posters that hand washing/hand rub hygiene is mandatory before and after any contact with any patient, including hand washing/hand rub hygiene before and after donning gloves, for any type of procedure including but not limited to: handling any specimens (blood, urine, tissue), performing sonograms, performing surgical procedures, handling of surgical trays, initiating any blood-drawing procedures, and starting and removing any intravenous fluids.</p>	8-30-12

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T 170	Continued From Page 12  Once the procedure had been completed the physician told the patient to get dressed and he would see her outside the exam room. The surveyor followed the physician out of the exam room. The physician picked up the patients medical record and began to make notations. He removed a prescription pad from a drawer. At no time was the physician observed washing his hands or performing hand hygiene.  The observations were pointed out to the physician who stated, "I was not doing a procedure only an ultra sound. If I had been doing a procedure I certainly would have washed my hands."  The above information was discussed with the administrator who stated, "He never washes his hands, he always uses gloves." When it was pointed out that sometimes the gloves may have holes in them the administrator stated, "Oh! That is gross!"	T 170		
T 175	12 VAC 5-412-220 C Infection prevention  C. Written policies and procedures for the management of the facility, equipment and supplies shall address the following: 1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air dryers); 2. Availability of utility sinks, cleaning supplies and other materials for cleaning, disposal, storage and transport of equipment and supplies; 3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals used for cleaning) and product-specific instructions for use of cleaning agents (e.g., dilution, contact time, management of accidental exposures);	T 175		



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T 175	Continued From Page 13  4. Procedures for handling, storing and transporting clean linens, clean/sterile supplies and equipment; 5. Procedures for handling/temporary storage/transport of soiled linens; 6. Procedures for handling, storing, processing and transporting regulated medical waste in accordance with applicable regulations; 7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address: (i) the level of cleaning/disinfection/sterilization to be used for each type of equipment, (ii) the process (e.g., cleaning, chemical disinfection, heat sterilization); and (iii) the method for verifying that the recommended level of disinfection/sterilization has been achieved. The procedure shall reference the manufacturer's recommendations and any applicable state or national infection control guidelines; 8. Procedures for appropriate disposal of non-reusable equipment; 9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations; 10. Procedures for cleaning of environmental surfaces with appropriate cleaning products; 11. An effective pest control program, managed in accordance with local health and environmental regulations; and 12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the facility as recommended or required by the department.  This RULE: Is not met as evidenced by: Based on observations and staff interviews the facility staff failed to ensure a policy and procedure was in place to address how scrub attire and blankets for patient use were to be	T 175	T 175  The facility will implement a policy and procedure for the use of blankets for patient use. The facility will employ a hospital linen service to provide blankets for patient use.  All staff will wear impermeable, disposable surgical scrub gowns, disposable head covers and disposable foot covers with each surgical procedure and with any procedure involving contact with and/or exposure to blood and blood products.  Patients will be given disposable patient gowns.  Individual surgical attire will be laundered at home if the staff member will not be in contact with contamination. Staff may opt to wear hospital linen service scrubs.	8-30-12

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T 175	<p>Continued From Page 14</p> <p>laundered in a manner to prevent the spread of infections.</p> <p>The findings include:</p> <p>During the tour of the facility on 7/18/12 with the administrator scrub attire was observed hanging in an office area and blankets used by patients were in and on cabinets in the recovery area. The administrator stated, "The scrubs and blankets were laundered in the building laundromat." The administrator explained the first 3 floors of the building are zoned for commercial use and the remaining 12 or 13 floors are private apartments. She stated, "The laundromat is in the basement."</p> <p>The 2010 Perioperative Standards and Recommended Practices: Aseptic Practice of AORN (Association of Perioperative Registered Nurses) recommended the following. Home laundering of surgical attire is not recommended. Without clear evidence about the safety for patients, health care workers, and their family members, AORN does not support the practice of home laundering of surgical attire. Reusable surgical attire, including cover jackets and cloth hats, should be laundered by a designated facility-approved and monitored commercial laundry after daily use. Commercial laundries are required to follow strict guidelines that incorporate:</p> <ul style="list-style-type: none"> <li>- proper and controlled water temperatures;</li> <li>- use of detergents;</li> <li>- use of oxidizing agents (e.g., chlorine bleach) in specified and monitored concentrations;</li> <li>- repeated changes of water; and</li> <li>- dryer or iron and press drying temperatures that typically are not found in home laundry equipment.</li> </ul> <p>Home laundering of surgical attire that is not visibly soiled is controversial, and there is no concrete evidence to either support or refute the</p>	T 175		

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T 175	Continued From Page 15  practice. Surgical attire becomes soiled or contaminated with microorganisms during wear. Taking worn, soiled, or contaminated surgical attire into the home can result in the spread of contamination to the home environment. AORN is aware that some provider facilities require personnel to launder scrub attire at home. Although AORN does not support this practice, steps should be taken to minimize contaminants to the home environment.	T 175		
T 230	12 VAC 5-412-250 C Anesthesia service  C. The facility shall develop, implement and maintain policies and procedures outlining criteria for discharge from anesthesia care. Such criteria shall include stable vital signs, responsiveness and orientation, ability to move voluntarily, controlled pain and minimal nausea and vomiting.  This RULE: is not met as evidenced by: Based on interviews and document review the facility failed to have in place policies and procedures related to the criteria for discharge from anesthesia care.  The findings include:  On 7/18/12 the administrator was asked to provide a copy of the policies outlining their criteria for discharge. The administrator provided a copy of a blank medical record indicating where vital sign were to be entered. The administrator stated, "I don't have a policy related to discharge."	T 230	T 230  The facility will implement a policy and procedure providing the necessary criteria for the discharge from anesthesia care. Such criteria shall include documentation of : stable vital signs, responsiveness and orientation ,, ability to move voluntarily, controlled pain and minimal nausea and vomiting.	8-30-12
T 285	12 VAC 5-412-260 E Administration, storage and dispensing of dru  E. Records of all drugs in Schedules I-V	T 285		

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T 285	<p>Continued From Page 16</p> <p>received, sold, administered, dispensed or otherwise disposed of shall be maintained in accordance with federal and state laws, to include the inventory and reporting requirements of a theft or loss of drugs found in 54.1-3404 of the Drug Control Act of the Code of Virginia.</p> <p>This RULE: is not met as evidenced by: Based on observations, interviews and document review the facility failed to maintain records regarding Scheduled I-V drugs in such a manner as to be able to regularly perform a narcotic count to ensure accuracy.</p> <p>The finding include:</p> <p>On 7/18/12 and 7/19/12 during the tour of the facility with the administrator the procedure room was inspected. The inspection revealed a locked metal box to which no one had a key to open. The administrator stated, "That box is (name of CRNA (Certified Registered Nurse Anesthetist)) and only he has a key to the box. He keeps his drugs, needles and syringes in there and I don't know what else." The administrator stated, "I will try to contact him and ask him to come and open the box." The administrator located the CRNA who told her where a hidden key was kept.</p> <p>The box was opened on 7/19/12 and needles, syringes, propofol, tourniquets and a sign out sheet for medications were in the box. The medication sign out sheet was for versed and fentanyl. On a shelf was a notebook with a medication sign out sheet for versed and fentanyl. The administrator was asked why there are 2 separate sign out sheets and she stated, "One is for (name of CRNA) and the other is for (name of another CRNA). When asked how she as the registered nurse on duty does a count of the narcotics she stated, "I don't, the CRNAs do the</p>	T 285	<p>T 285</p> <p>There will be implementation of specific forms to be filled out:</p> <ol style="list-style-type: none"> <li>Daily narcotic sign out and sign in sheets, with the amounts of medication given, and co-signatures of the CRNA and clinical staff.</li> </ol> <p>No CRNA will have any locked box containing any forms, or drug sign-out sheets.</p> <p>There will only be one (not individual) medication sign out sheet for versed and fentanyl.</p> <p>The medication sign-out sheet will be kept in a locked cabinet.</p>	8-30-12



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T 285	Continued From Page 17 count."	T 285		
T 290	12 VAC 5-412-270 Equipment and supplies  An abortion facility shall maintain medical equipment and supplies appropriate and adequate to care for patients based on the level, scope and intensity of services provided, to include: 1. A bed or recliner suitable for recovery; 2. Oxygen with flow meters and masks or equivalent; 3. Mechanical suction; 4. Resuscitation equipment to include; as a minimum, resuscitation bags and oral airways; 5. Emergency medications, intravenous fluids, and related supplies and equipment; 6. Sterile suturing equipment and supplies; 7. Adjustable examination light; 8. Containers for soiled linen and waste materials with covers; and 9. Refrigerator.  This RULE: is not met as evidenced by: Based on observations and interviews the facility staff failed to ensure equipment was maintained to ensure proper infection control and failed to ensure expired supplies were not available for use.  The findings include:  On 7/18/12 during the tour of the facility with the administrator and assistant administrator, the following items were noted to have tears which would prevent the items from being cleaned properly after each patient use: The table in the ultrasound room had large tears in the vinyl covering and paper towels were found under the sink in the ultrasound room.	T 290	T 290  The exam table in the ultrasound room has been replaced with another table without any tears in the vinyl covering.  All items under the sink have been removed.  The wait area for medical abortions will be replaced with chairs free of any tears.  The pre-procedure room wait area will have viny-covered chairs  The gurneys used for recovery from IV sedation will be re-upholstered with vinyl covering..  There will be no supplies stored under the gurney.  There will be a monthly check for expiration date of all curettes . All curettes will be placed in individual plastic bags indicating: size and type of curette and expiration date.	8-3-12

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T 290	Continued From Page 18  The areas described as the wait area for medication abortions and ultrasounds had 4 chairs with tears in the vinyl. The area described as the pre-procedure room had 4 cloth chairs that could not be wiped clean after use by patients. The recovery area had 3 of 4 chairs with tears in them. The stretcher used for recovery from IV sedation was torn and items for multi patient use was stored under the stretcher.  The administrator stated, "We will get the chairs and tables replaced and will move the supplies."  On 7/18/12 during a tour of the procedure room with the administrator and assistant administrator the following expired items were observed: 19 - 12 mm (milliliter) disposable rigid curettes 7 - 12 mm flexible curettes 14 - 10 mm flexible curettes 2 - 9 mm flexible curettes 4 - 11 mm flexible curettes 23 - 5 mm flexible curettes 2 - 7 mm flexible curettes 6 - 4 mm flexible curettes The facility administrator stated, "We will get rid of those right now."	T 290			
T 315	12 VAC 5-412-300 A Quality assurance  A. The abortion facility shall implement an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care or services provided, including services provided under contract or agreement. The program shall include process, design, data collection/analysis, assessment and improvement, and evaluation. The findings shall be used to correct identified problems and revise	T 315			



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T 315	Continued From Page 19  policies and practices, as necessary.  This RULE: is not met as evidenced by: Based on interviews and document reviews the facility staff failed to implement an ongoing comprehensive integrated, self assessment program of the quality and appropriateness of care or service provided.  The finding include:  On 7/18/12 the administrator was asked to provide documentation related to the services that provide related to quality improvement. She stated, "I don't collect data." When asked if the facility collects data on patient satisfaction she stated, "We used to but we stopped because we were not getting anything back from the patient after they left." The administrator was asked how she and the staff knew what areas to improve or where improvement was needed she stated, "We just know when we do something that needs to be fixed."	T 315	T 315 T320  The facility will implement a quality assurance program to include: staffing patterns and performance; supervision appropriate to the level of service; patient records; patient satisfaction; complaint resolution; recording and reporting of infections, complications and other adverse events; staff concerns regarding patient care.  The program shall provide an ongoing, comprehensive assessment of the quality and appropriateness of services, and evaluations to correct any identified problems and revise any policy to better serve the needs of our patients.  There will also be a survey given to each patient to address any concerns in the provision of her care, including positive and negative feedback. All surveys	8-30-12
T 320	12 VAC 5-412-300 B Quality assurance  B. The following shall be evaluated to assure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences: 1. Staffing patterns and performance; 2. Supervision appropriate to the level of service; 3. Patient records; 4. Patient satisfaction; 5. Complaint resolution; 6. Infections, complications and other adverse events; and 7. Staff concerns regarding patient care.	T 320		8-30-12

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T 320	Continued From Page 20  This RULE: is not met as evidenced by: Based on interviews and document reviews the facility staff failed to implement an ongoing comprehensive integrated, self assessment program of the quality and appropriateness of care or service provided.  The finding include:  On 7/18/12 the administrator was asked to provide documentation related to the services that provide related to quality improvement. She stated, "I don't collect data." When asked if the facility collects data on patient satisfaction she stated, "We used to but we stopped because we were not getting anything back from the patient after they left." The administrator was asked how she and the staff knew what areas to improve or where improvement was needed she stated, "We just know when we do something that needs to be fixed."	T 320	will not be signed or dated, unless the patient would like a response. All surveys will be placed in a suggestion box which will be reviewed and any actions will be made to improve our services.  T 325  The quality improvement committee responsible for the oversight and supervision of the program shall be established and shall consist of a physician, a non-physician health care practitioner; a member of the administrative staff and a staff member/patient representative	
T 325	12 VAC 5-412-300 C Quality assurance  C. A quality improvement committee responsible for the oversight and supervision of the program shall be established and at a minimum shall consist of: 1. A physician 2. A non-physician health care practitioner; 3. A member of the administrative staff; and 4. An individual with demonstrated ability to represent the rights and concerns of patients. The individual may be a member of the facility's staff. In selecting members of this committee, consideration shall be given to the candidate's abilities and sensitivity to issues relating to quality of care and services provided to patients.  This RULE: Is not met as evidenced by:	T 325		8-30-12

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T 325	Continued From Page 21  Based on interviews and document reviews the facility staff failed to have a quality improvement committee and to identify who should be on the committee.  The finding include:  On 7/18/12 the administrator was asked to provide documentation related to the services/program provided related to quality improvement. She stated, "We don't have a program."	T 325		
T 335	2 VAC 5-412-300 E Quality assurance  E. Results of the quality improvement program shall be reported to the licensee at least annually and shall include the deficiencies identified and recommendations for corrections and improvements. The report shall be acted upon by the governing body and the facility. All corrective actions shall be documented. Identified deficiencies that jeopardize patient safety shall be reported immediately in writing to the licensee by the quality improvement committee.  This RULE: is not met as evidenced by: Based on interviews and document reviews the facility staff failed to have a quality improvement committee and to identify who should be on the committee.  The finding include:  On 7/18/12 the administrator was asked to provide documentation related to the services that provide related to quality improvement. She stated, "I don't collect data." When asked if the facility collects data on patient satisfaction she stated,	T 335	T 335  Results of the quality improvement program shall be reported to the licensee at least annually and shall include the problems identified and recommendations for corrections and improvement. All corrective actions shall be documented. Any deficiencies that jeopardize patient safety shall be reported immediately in writing to the licensee by the quality improvement committee.	8-30-12

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T 335	Continued From Page 22  "We used to but we stopped because we were not getting anything back from the patient after they left." The administrator was asked how she and the staff knew what areas to improve or where improvement was needed she stated, "We just know when we do something that needs to be fixed."	T 335		
T 365	12 VAC 5-412-350 A Disaster preparedness  A. Each abortion facility shall develop, implement and maintain policies and procedures to ensure reasonable precautions are taken to protect all occupants from hazards of fire and other disasters. The polices and procedures shall include provisions for evacuation of all occupants in the event of a fire or other disaster.  This RULE: is not met as evidenced by: Based on document review and staff interviews the facility failed to implement and maintain policies and procedures to ensure reasonable precautions were taken to protect staff and patients in the event of a fire or disaster.  The findings include:  On 7/18/12 the administrator was asked to provide the policies and procedures related to fire drills and disaster drills. She stated, "We don't have policies about fire and disaster drills. We just move all patients and staff to the hall way."	T 365	T 365  The facility shall maintain a policy and procedure with specific steps to be taken to ensure all staff and patients are protected from the hazards of fire and other disasters.  The fire and disaster preparedness plans shall be implemented and fire drills shall be documented . There shall be mock fire drills and documentation of same.	8-30-12
T 370	12 VAC 5-412-350 B Disaster preparedness  B. A facility that participates in a community disaster plan shall establish plans, based on its capabilities, to meet its responsibilities for providing emergency care.	T 370		



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T 370	Continued From Page 23  This RULE: is not met as evidenced by: Based on document review and staff interviews the facility failed to implement and maintain policies and procedures to ensure reasonable precautions were taken to protect staff and patients in the event of a fire or disaster and their community disaster plan.  The findings include:  On 7/18/12 the administrator was asked to provide the policies and procedures related to fire drills and disaster drills. She stated, "We don't have policies about fire and disaster drills. We just move all patients and staff to the hall way. We have never had a community disaster plan."	T 370	T 370-B  The facility does not participate in a community disaster plan as the facility does not have the capability to provide emergency care.	N/A 8-30-12
T 385	12 VAC 5-412-370 A Fire-fighting equipment and systems  A. Each abortion facility shall establish a monitoring program for the internal enforcement of all applicable fire and safety laws and regulations and shall designate a responsible employee for the monitoring program.  This RULE: Is not met as evidenced by: Based on document review and staff interviews the facility failed to implement and maintain policies and procedures to ensure reasonable precautions were taken to protect staff and patients in the event of a fire or disaster and to designate who would be in charge of ensure the program was maintained.  The findings include:  On 7/18/12 the administrator was asked to provide the policies and procedures related to fire drills and disaster drills. She stated, "We don't have	T 385	T 385  Fire-fighting equipment and systems  There shall be a monitoring program and implementation of fire and disaster drills.  The administrator and assistant administrator shall be responsible for the enforcement of the monitoring program.  The Fire Marshall's office from the City of Alexandria shall be called upon to conduct an annual fire safety plan and in-service training for the staff.	8-30-12

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T 385	Continued From Page 24  policies about fire and disaster drills. I guess I would be the person in charge of making sure we did fire and disaster drills. I don't think that is in my job description though."	T 385			
T 390	12 VAC 5-412-370 B Fire-fighting equipment and systems  B. All fire protection and alarm systems and other fire fighting equipment shall be inspected and tested in accordance with current edition of the Virginia Statewide Fire Prevention Code (27-94 et seq. of the Code of Virginia) to maintain them in serviceable condition.  This RULE: is not met as evidenced by: Based on observations, document review and staff interviews the facility failed to ensure firefighting equipment (fire extinguishers) were inspected and safely secured.  The findings include:  On 7/18/12 during a tour of the facility with the administrator fire extinguishers without inspection stickers or tags were observed sitting on the floor on both the exam side of the suite and the procedure side of the suite. The administrator stated, "I guess we need to get those mounted to the wall or something."	T 390	T 390  The facility shall ensure the fire extinguishers are safely secured and the fire extinguishers will be inspected annually maintained in serviceable condition, and appropriate labels of said inspection are in place.	8-30-12	
T 400	12 VAC 5-412-380 Local and state codes and standards  Abortion facilities shall comply with state and local codes, zoning and building ordinances, and the Uniform Statewide Building Code. In addition, abortion facilities shall comply with Part 1 and sections 3.1-1 through 3.1-8 and section	T 400			



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T 400	<p>Continued From Page 25</p> <p>3.7 of Part 3 of the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute, which shall take precedence over Uniform Statewide Building Code pursuant to Virginia Code 32.1-127.001. Entities operating as of the effective date of these regulations as identified by the department through submission of Reports of Induced Termination of Pregnancy pursuant to 12 VAC 5-550-120 or other means and that are now subject to licensure may be licensed in their current buildings if such entities submit a plan with the application for licensure that will bring them into full compliance with this provision within two years from the date of licensure. Refer to Abortion Regulation Facility Requirements Survey workbook for detailed facility requirements.</p> <p>This RULE: is not met as evidenced by: Based on observations, interviews and a facility tour it was determined that the facility failed to ensure full compliance with state/local codes, building ordinances as well as the Uniform Statewide Building Code. Additionally, the facility failed to comply with having the following: an architect attestation that the facility meets all FGI standards, proper ventilation, humidity, temperature controls, waste management program/services, HVAC duct system and inspection reports, proper ventilation of the treatment rooms, proper air exchange for all treatment rooms, the heating/cooling and plumbing system to meet all codes, electrical system meets the National Electrical Code ordinance and all hand washing stations meet the necessary width, length, depth &amp; splash prevention.</p> <p>The findings include:</p>	T 400	<p>T 400</p> <p>The following findings of the OLC inspectors and the responses are:</p> <ol style="list-style-type: none"> <li>1. The ultrasound room shall maintain full privacy by ensuring the sliding plastic window remains closed.</li> <li>2. A waiver is needed for the laboratory cannot accommodate a reclining chair nor a ventilation hood.</li> <li>3. The patient bathroom door is deliberately left unlocked and patients are informed that staff personnel will be standing outside the door should the patient require any help or assistance.</li> <li>4. The staff bathroom shall be kept locked at all times and a key will</li> </ol>	<p>8-30-12</p> <p>#2 WAIVER NEEDED</p> <p>8-30-12</p> <p>8-30-12</p>

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T 400	<p>Continued From Page 26</p> <p>On July 18, 2012 a facility tour was conducted with the Administrator and Assistant Administrator. During the facility tour the following findings were noted to include but not limited to:</p> <ol style="list-style-type: none"> <li>1. The ultrasound room had a sliding plastic window that was partially open to the room on the other side preventing full privacy for the patient receiving an ultrasound.</li> <li>2. The laboratory failed to have a hood for ventilation and a reclining chair for patients who become unsteady.</li> <li>3. The administrator stated the door did not lock on the patient bathroom. The door was found to have a functioning lock however, no key was available for the lock and no emergency alarm is available in the bathroom.</li> <li>4. The staff bathroom is kept locked at all times and the staff have no key to open the door. Staff use their fingernail to open the door.</li> <li>5. The procedure and recovery area of the facility has no toilet facilities available to patient's.</li> <li>6. The soiled utility room has no floor drain.</li> <li>7. None of the sinks in the facility meet regulation codes.</li> <li>8. The procedure room failed to have a sink readily available for use and the staff use the sink located in the soiled utility room.</li> <li>9. The facility failed the have a janitor closet.</li> <li>10. The facility failed to have laundry services for uniforms and blankets used for recovery patients that meet the regulations. Laundry is being done in the building laundry room used by residential tenants.</li> <li>11. The facility failed to have any indication of an air ventilation system within the facility. All air vents were blowing air out with the exception of one vent that was located in the hall way separate from the actual facility and it was found to be dirty, also unclear if it was functional.</li> </ol> <p>On day two of the survey, the administrator</p>	T 400	<p>be used and kept in the staff lounge.</p> <ol style="list-style-type: none"> <li>5. The procedure and recovery area will be moved to Suite 215, expanding the workroom to be the procedure and recovery area. A waiver will be needed to allow time and resources with the property management's input and approval to complete the renovations.</li> <li>6. A waiver will be needed. It is impossible to place a floor drain in the utility room as the flooring is made of concrete, and we are on the second floor</li> <li>7. All the faucets in sinks in the facility will be</li> </ol>	<p>#5 WAIVER NEEDED</p> <p>#6 WAIVER NEEDED</p> <p>8-30-12</p>	

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T 400	Continued From Page 27  presented a report from an Architect that surveyed the facility. The report is a summary and there is no indication of when the survey was done. In addition the report failed to contain the name of the architect completing the report. The report list the necessary items needed to get the facility in compliance with the regulations and contained the following to include but not limited to: 1. Signage required to identify restricted, semi-restricted an unrestricted areas of the center and proper attire for each area. 2. Ultrasound room does not meet requirements for acoustical and visual privacy and a hand washing sink. 3. 6' wide corridor required from surgery to public corridor for emergency ambulance transfer. Hand washing sinks brought into compliance. 4. no janitor closet or eyewash station. 5. no air exchange. 6. no 100 square ft. clean storage room 7. building elevators do not comply with required regulations or ADA requirements 8. wall surfaces not washable 9. pre and post op don't meet square footage requirements per ARC report 10. no emergency communication system 11. pass through between soiled and clean workroom must have self closing door 12. Overall building does not meet ADA standards as to exterior access, elevators and toilet facilities. 13. HVAC system likely will not meet current standards. 14. Fire and smoke alarm and control systems will not meet current standard. 15. Mechanical equipment rooms and exit corridors do not meet fire code requirements. 16. The 2 pipe perimeter HVAC system will likely not meet current standards but should be evaluated by and engineer or contractor.	T 400	replaced to meet regulation codes.  8. A waiver is needed to allow time to move the procedure room to Suite 215 (see #5) Use of current Procedure room could be moved to the Ultrasound Room where there is a sink available for staff use.  9. A janitor's closet can be maintained in the current storage area in Suite 217  10. See T 175 regarding use of Hospital Linen service. Use of the building laundry room will cease immediately.  11. Air ventilation system is controlled by the Building management.  <i>all above are continued from pg 27</i>	<i>#8 WAIVER NEEDED  #9 WAIVER error OK  8-30-12</i>	

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	<i>Survey report was done on May 12, '12 by George Johannes AIA</i>		T 400 re: Architect survey/report Our facility will not be able to comply with the 2010 Guidelines because our facility occupies office space designated as a doctor's office. The first 3 floors are coded for commercial use. Our facility is located on the 2 <sup>nd</sup> floor, with doctors and dentists occupying other floors. If the current amendments to the emergency regulations are subsequently approved by the Governor, our facility will be able to continue to provide abortion services. Our facility has been in this location for the past 25+ years, and patient safety, patient care and	

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			<p>abortion services have not been adversely affected. We request a waiver for the 2010 Guidelines for design and construction to make changes to our facility that are allowable by the building management and if necessary to review the possibility of moving to another location.</p>	

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