

Virginia Women's Wellness
224 Groveland Road
Virginia Beach, Va 23452
(757) 306-4706

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JUL 26 2012
VDH/OLC

June 29, 2012

Eric Bodin
Director
Office of Licensure and Certification
Virginia Department of Health
9960 Mayland Drive, Suite # 401
Henrico, Virginia 23233

Re: Plan of Correction

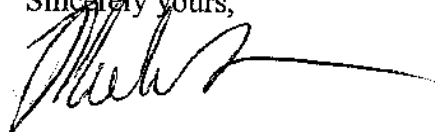
Dear Mr. Bodin:

Enclosed please find our Plan of Correction to the Statement of Deficiencies that Virginia Women's Wellness (VWW) received during our initial licensure application. This Plan of Correction contains revisions and is accompanied by 18 different attachments evidencing the corrective actions already taken. Some of these corrective actions are already fully completed, and some are in the process of being completed.

We hope that our plan of correction is acceptable to the Department.

Thank you very much for your time and attention in reviewing our Application, our Plan of Correction, and our eighteen Attachments.

Sincerely yours,



Melissa Sachnovitz
Operations Business Manager

State of Virginia

PRINTED: 05/17/2012
FORM APPROVED

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: FTAF-008	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 05/09/2012
NAME OF PROVIDER OR SUPPLIER VIRGINIA WOMEN'S WELLNESS			STREET ADDRESS, CITY, STATE, ZIP CODE 224 GROVELAND ROAD VIRGINIA BEACH, VA 23452		
(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 on May 8 & 9, 2012 by four (4) Medical Facility Inspectors from the Virginia Department of Health's, Office of Licensure and Certification. The facility had multiple complaints which were also investigated during the initial inspection. Compliant Identification numbers were: 2012-AC001 through AC005, 2012-AC007 through AC010, AC012 and AC013. Ten of the eleven complaints were UNSUBSTANTIATED. Complaint # 2012-AC010 was SUBSTANTIATED with associated deficiencies cited in this report. VA Women's Wellness Center, which is located in Virginia Beach was found out of 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			
T 015	12 VAC 5-412-140 B Organization and management B. There shall be disclosure of facility ownership. Ownership interest shall be reported to the OLC and in the case of corporations, all individuals or entities holding 5.0% or more of total ownership shall be identified by name and address. The OLC shall be notified of any changes in ownership. This RULE: is not met as evidenced by: Based on review of the policy and procedure manual and interview, it was determined that the facility failed to identify and document who the	T 015	A Separate statement of ownership will be provided to the OLC See Attachment #1	6-15-12	

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

TITLE

(X6) DATE

STATE FORM

GIFG11

If continuation sheet 1 of 22

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T 015	Continued From Page 1 owner(s) of the facility are. The findings were: On 5/9/12 during the entrance conference to the facility at approximately 9 AM, the corporate representative was asked who the owner or owners of this facility are. The representative stated, we are owned by a corporation. Again later that day the representative was asked who the owner(s) of this facility are. The representative would only say it's a corporation under another corporation. The Organizational chart in the policy and procedure manual was reviewed with the corporate representative on 5/10/12 at approximately 5:55 PM in the administrator's office. The chart did not have the name of the facility, a date, or any names in the job title/position boxes. On 5/10/12 on or about 6 PM in the administrator's office the corporation representative was asked again, who the owner of this facility is. The representative again said, "It's a corporation," when asked to be more specific the representative said, "I think it's ... (name)." When asked the percentage of interest or ownership that that person has in the corporation, the representative said, "I don't know."	T 015			
T 070	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.	T 070	Criminal background checks have been obtained on all staff/clinicians with access to controlled substances. These documents have	6-7-12	

STATE FORM

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If continuation sheet 2 of 22

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T 070	<p>Continued From Page 2</p> <p>This RULE: is not met as evidenced by: During the survey the facility was assessed for compliance with the provisions of the Code of Virginia, 1950 as amended and (Section 32.1-162.9:1 as amended. The Code Section requires that licensed home care organizations or home care organizations exempt under 32.1-162.8:3 (a) (b) (c) of the Code of Virginia conduct criminal records check for compensated employees hired after July 1, 1992.</p> <p>These same Code sections also prohibit the employment, by abortion facility's, of persons convicted of certain crimes specified in Section 32.1-126:02. That same Section requires employees not licensed by the Board of Pharmacy, whose job duties provide access to controlled substances within the abortion facility must have a criminal record report through the Virginia State Police.</p> <p>The above Statute was not met as evidenced by:</p> <p>Based on the review of personnel files, and interview with the Administrator, it was determined that nine (#1 - #4, #9, #12 - #13, #17 and #19) of nine (#1 - #4, #9, #12 - #13, #17 and #19) personnel that had the potential to dispense narcotics failed to have criminal record checks for the Surveyor to review as required in Section 12 VAC 5-412-170.C.</p> <p>The Surveyors reviewed all personnel files at various times on 5/8/12. The staff included:</p> <ol style="list-style-type: none"> 1. Personnel #1 - #4 were Physicians. 2. Personnel #9 and #17 were Registered Nurses. 3. Personnel #13 - #14 and #19 were Licensed Practical Nurses. 	T 070	<p>been inserted in their personnel file.</p> <p>See Attachment #2</p>		

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T 070	Continued From Page 3	T 070			
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"> 1. Facility contact person; and 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. <p>This RULE: is not met as evidenced by: Based on interview and record review the facility failed to provide the patients or patient's designees with the name, address, and toll-free complaint telephone number of the state licensure agency. The findings included: An interview with Staff #13 on May 8, 2012 at approximately 9:15 a.m. revealed each patient received patient rights and complaint information as part of the admission process. Review of the admission packs for medical and surgical procedure patients did not include the name, address, and toll-free complaint telephone number of the state licensure agency (Office of Licensure and Certification). The information given to the patients or patient's designee did not include information regarding their ability to filing anonymous complaints with the state licensure</p>	T 155	<p>All patients are given 2 copy of the "Your Rights as a Patient" form which describes proper complaint procedures. This document includes the name, address and toll free phone number for the OLC.</p> <p>See Attachment #3 + 4</p>	5-9-12	

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T 155	Continued From Page 4 agency. An interview was conducted on May 8, 2012 at 3:30 p.m. with Staff #13 and Staff #21. Staff #13 and Staff #21 reviewed the admission packs. Staff #13 reported the patient or the patient's designee only received the information included in the admission packs. Staff #13 and Staff #21 verified the complaint information given did not include name, address, and toll-free complaint telephone number of the state licensure agency or related to filing an anonymous complaint with the state licensure agency.	T 155			
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); 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:	T 175	VWW maintains that our excellent track record of safe patient care proves that our infection prevention practices adequately protect our patients. In a span of more than 15 years, VWW has not had a single patient with a documented serious infection and no known cases of patient-to-patient transmission of infection. VWW vigorously disputes that any area of our office is "dirty". All aspects of the facility are cleaned daily and the DOH did not identify any portion of the facility that was soiled.		

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T 175	<p>Continued From Page 5</p> <p>(i) the level of cleaning/disinfection/sterilization to be used for each type of equipment;</p> <p>(ii) the process (e.g., cleaning, chemical disinfection, heat sterilization); and</p> <p>(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;</p> <p>8. Procedures for appropriate disposal of non-reusable equipment;</p> <p>9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations;</p> <p>10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;</p> <p>11. An effective pest control program, managed in accordance with local health and environmental regulations; and</p> <p>12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the facility as recommended or required by the department.</p> <p>This RULE: is not met as evidenced by: 12 VAC 5-412-220 (C) (4), (5), (7), (10), and (12) Based on observation, interview and record review the facility failed to have infection control procedures to prevent cross-contamination related to:</p> <ol style="list-style-type: none"> 1. Facility staff's handling of clean and dirty equipment between patients and staff's knowledge of manufacturer's recommendations for cleaning re-usable equipment between patients. 2. Transporting clean linen/blankets, for handling, temporary storage/transporting soiled linens; and 3. Cleaning environmental surfaces. <p>The findings included:</p> <ol style="list-style-type: none"> 1. Observations conducted on May 9, 2012 from 	T 175	<p>or inadequately cleaned. We believe the nomenclature used to identify "clean" and "dirty" rooms is fully inaccurate. No areas of the facility are dirty and the entire facility is clean. For each and every patient, all instruments that enter the patient's body have been sterilized prior to use and all patients are safely protected from infection by appropriate practices. In particular our scrub room is especially clean, having been scrubbed and disinfected twice daily.</p> <p>Despite the above disclaimer, VWV supports the goals of continuously improving infection prevention procedures and we will implement the changes suggested by the DOH.</p>		

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T 175	<p>Continued From Page 6</p> <p>6:26 p.m. to 8:35 p.m. revealed the facility utilized re-useable glass vacuum jars for procedures; passed by staff through an in-wall opening between the "clean" procedure room and the "dirty scrub" room. The facility staff did not set up separate clean and dirty areas for handling instruments and equipment.</p> <p>Staff #20 located within the "dirty scrub" room, placed a disposable pad on the counter top. Staff #20 retrieved a clean vacuum jar from above the designated dirty sink and placed the clean vacuum jar on the pad. From the "clean" procedure room the physician reached through the in-wall opening and placed the "dirty" instruments used during the procedure onto the pad next to the clean vacuum jar. Staff #20 retrieved the dirty instruments from the pad and placed them in the sink. Staff #20 did not change the pad on the counter top. Staff #12 located in the "clean" procedure room passed the vacuum jar utilized during the procedure with the collected conception material through the in-wall opening. Staff #12 placed the "dirty" vacuum jar on the pad. Staff #20 handed the clean vacuum jar to Staff #12. Staff #12 did not change gloves prior to receiving the clean vacuum jar.</p> <p>An interview was conducted on May 9, 2012 at 6:45 p.m. with Staff #20. Staff #20 reported the enzymatic soaking time for the dirty instruments as "a couple of minutes." The label on the enzymatic cleaner read "Recommended contact time 5 minutes." Staff #20 did not have a timer or clock available to ensure the manufacturer's recommendations were followed. Staff #20 reported the concentration of enzymatic cleanser was one (1) ounce to one (1) gallon of water. Staff #20 did not have measuring devices and could not state how much water or enzymatic cleaner had been placed in the sink.</p> <p>An observation and interview on May 9, 2012 at 8:30 p.m., by two surveyors and Staff #12 revealed the facility utilized a cloth pillow between</p>	T 175	<p>(1) All reusable equipment is cleaned as per the manufacturers recommendations. All items labeled for single use are disposed of after each patient use. Staff has been properly re-trained in the handling of equipment patients.</p> <p>(2) No reusable linens are used in this facility. See attachment #5</p> <p>(3) The Policy and Procedures Manual has been modified to include the following revisions. Staff has</p>		

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T 175	Continued From Page 7 patients. The observation revealed the disposal pillowcase did not completely cover the pillow. Staff #12 reported with the pillow became soiled it was taken home by staff and washed. An interview was conducted on May 9, 2012 at 8:35 p.m. with Staff #21. Staff #21 was informed of the findings related to the cross-contamination of clean and dirty re-useable instruments/equipment between the scrub and procedure rooms. Staff #21 acknowledged the cloth pillow was not completely covered by the disposable pillowcase and could not be wiped down between patients. 2. An observation and interview with Staff #13 on May 8, 2012 at approximately 9:59 a.m. with Staff #13 revealed the sterilized instrument pack were stored on a wire rack above the freezer used to store conception material. Staff #13 reported the freezer would be considered part of the designated dirty side of the scrub room. An observation and interview with Staff #13 on May 8, 2012 at approximately 10:15 a.m. revealed four brown blankets stored uncovered on a wire rack in the Recovery room. Staff #13 reported the blankets were used to cover patients during recovery. Staff #13 reported the blankets were not cleaned/washed between patients. Staff #13 reported when the blankets became "obviously" soiled staff took "the blankets home, washed, them and brought them back." Review of the facility's policy and procedure manual did not have procedures related to handling, temporary storage and transporting the soiled blankets. The facility did not have a procedure directing staff how to temporarily store the soiled blankets, wash the blankets at home and how to transport the clean blankets back to the facility. An interview was conducted on May 8, 2012 at 3:30 p.m. with Staff #13 and Staff #21. Staff #21 acknowledged the facility did not have a detailed	T 175	been retrained in all aspects of cleaning of environmental surfaces. See Attachment 6+4. The pass-through window located between the procedure room & scrub room is only used for passing instruments and the specimen jar through. All sterile material is returned to the procedure room via the doorway. All staff have been retained on hand hygiene and the frequency of changing gloves. The especially clean scrub room is equipped with a timer & measuring cup to assure strict adherence to manufacturer recommendations for diluting and soak time of enzymatic detergent. The cloth pillow has been replaced with a fluid resistant, antimicrobial, cleanable pillow see Attachment #8		

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T 175	Continued From Page 8 policy or procedures related to their practice of laundering the blankets. Staff #13 verified the facility did not have procedures for handling and transporting soiled or clean linens (blankets). 3. An observation and interview related to environmental surface cleaning was conducted on May 8, 2012 at approximately 11:30 a.m. with Staff #21. Staff #21 discussed the two cleaning products used to disinfect environmental surfaces. The products in use had different surface contact times. An observation of the recovery chair recliners revealed four of the four recliners had food particles beneath the removable seat cushion. Staff #21 acknowledged the four recliners were not clean. Review of the facility's policy and procedure manual did not have procedures related to how to clean environmental surfaces. During an interview conducted on May 8, 2012 at 3:30 p.m. Staff #21 reported the facility did not have a detailed procedures related to cleaning environmental surfaces.	T 175	All sterile packs are stored in clean rooms. Although recovery room chairs were always cleaned, an additional thorough cleaning and disinfecting has been performed. The Policy + Procedures Manual has been up dated to include the proper cleaning of same. Administrator will continuously monitor Infection Prevention measures via period checks to assure compliance. If warranted retraining will be provided.	6/30	
T 285	12 VAC 5-412-260 A Administration, storage and dispensing of dru A. Controlled substances, as defined in 54.1-3401 of the Drug Control Act of the Code of Virginia, shall be stored, administered and dispensed in accordance with federal and state laws. The dispensing of drugs, excluding manufacturers' samples, shall be in accordance with Chapter 33 of Title 54.1 of the Code of Virginia, Regulations Governing the Practice of Pharmacy (18 VAC 110-30). This RULE: is not met as evidenced by: Based on observation, interview and record review the facility failed to follow manufacturer's directions for administration of controlled	T 285	All medications used for multiple patients will be drawn from multi-dose bottles. If a bottle/vial is labeled for single use, it will be used for only one patient and unused portions will be discarded Proper See Attachment #9	6/30	

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T 265	<p>Continued From Page 9</p> <p>substance single dose vials.</p> <p>The findings included:</p> <p>An observation and interview conducted on May 8, 2012 at 10:00 a.m. with Staff #13 during review of the facility's system for controlled substances. Staff #13 reported the facility's patient had a choice between local anesthesia and conscious sedation (moderate sedation). Staff #13 reported the facility used an injection of Fentanyl and Midazolam (Versed). Staff #13 opened the locked box, on inspection the box contained: an opened vial of Fentanyl 2500 mcg (micrograms)/50 ml (milliliters). The staff had not documented the opened date on the vial. Staff #13 reviewed the log sheet and reported the vial was last used on May 5, 2012 and the vial count changed on May 2, 2012. Staff #13 reported the vial "was probably opened on May 2, 2012; but there is no way to know for sure." Staff #13 reported the nurse could draw up to twenty-five (25) doses from a fifty (50) ml vial. Staff #13 reported that each dose drawn would be used for a different patient. When asked, Staff #13 read the vial label, which read: "Single dose vial." Staff #13 replaced the partially used vial of Fentanyl into the lock box. The observation revealed five vials of Midazolam 5 mg (milligrams)/5 ml. One vial was opened without a documented opened on date. The vial label read "Single use vial. Discard unused portion." Staff #13 reported that each Midazolam and Fentanyl vials were used for multiple patients. [Fentanyl is a short duration analgesic. Midazolam is a preoperative sedative.]</p> <p>Review of the controlled substance log was conducted on May 8, 2012 at 10:09 a.m. with Staff #13. Staff #13 reported the recorded amounts of medication left in the Fentanyl vial and the Midazolam vial were "guesstimates."</p>	T 265	<p>Calculation of the remaining medication left in vials will be made by subtracting the amount drawn from the starting volume of an unopened bottle/vial.</p> <p>See Attachment #9</p>		

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T 285	Continued From Page 10 The estimation of the medication left in the single use vials for later use ranged from 4/5 to 19/20. Staff #13 reported the staff had not calculated the amount left but had "eyeballed" the amount. Staff #13 agreed that 4/5 for one person could be different for another person estimating the same amount. Review of the package insert for Fentanyl indicated the medication "Contained no preservatives" and listed the 50 ml vial as a single dose vial. The package insert for Midazolam indicated the vial was for single use and unused portions of the vial were to be discarded.	T 285			
T 280	12 VAC 5-412-260 D Administration, storage and dispensing of dru D. The mixing, diluting or reconstituting of drugs for administration shall be in accordance with regulations of the Board of Medicine (18 VAC 85-20-400 et seq). This RULE: is not met as evidenced by: Based on observations made during the initial tour of the facility and interviews, it was determined that the facility's staff failed to ensure that injectable medications for local anesthesia were mixed and labeled in accordance with the regulations for the Board of Medicine, 18 VAC 85-20-400. More specifically, 23 multi-dose 50 cc vials of 1% Lidocaine each had a label attached to them that stated two additional drugs had been added to each the vials. The attached label did not contain the amount or strength of the medications added or the date the additional medications were added. The findings were:	T 280	All medications will be mixed by an RN or MD, or by a trained staff member with a second check performed by a registered nurse or physician. These mixed medications will be properly labeled with the amounts of medications mixed, date and time of mixing, and the initials of the person mixing the medications. If a second check is performed then		

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NAME OF PROVIDER OR SUPPLIER VIRGINIA WOMEN'S WELLNESS			STREET ADDRESS, CITY, STATE, ZIP CODE 224 GROVELAND ROAD VIRGINIA BEACH, VA 23452		
(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 280	<p>Continued From Page 11</p> <p>An initial tour of the facility was conducted on May 8, 2012 beginning at 9:55 AM. The Recovery room, a room used for patients to recover from their procedure in, contained a large locked metal cabinet. The Administrator was asked if she could open the cabinet for this inspector to view its content. The Administrator opened the cabinet, the cabinet contained various types of injectable and oral medications. On the second shelf were multiple boxes of medications that are used during procedures. In the back on the right hand side of the shelf was an open box containing 23 vials; each had a manufacturer's label on it that read, "1% Lidocaine, 50 ml (amount)." Each vial also had an additional label attached to it that read: "Lidocaine 1%, Pitocin, Vassopressin Date mixed: ____."</p> <p>All 23 vials with the attached labels failed to have the amount or strength of the Pitocin or Vassopressin written on the labels and also failed to have the "Date mixed," filled in. On the side of each vial was a date, 5/2/12, and a set of initials written with black magic marker. The administrator was shown one of the vials and asked who mixed these vials; the administrator stated it was employee #25, an LPN (Licensed Practical nurse). The administrator was also asked where was it written on the vials the amount of Pitocin (a hormone) and Vassopressin (constricts blood vessels) that was added and when; she replied, "It's not," and then pointed to the handwritten date with initials on the side of the vial and said, "here's when she mixed them." When asked who was the person who mixed the vials the administrator said (name) an LPN. The administrator was asked what the vials were used for and she replied, every patient gets this, it's their local anesthetic that the doctor injects.</p>	T 280	<p>Registered Nurse or Physician providing the second check will also initial.</p> <p>Mixed medications will be disposed of if not used within 10hrs of mixing.</p> <p>All medications will be mixed, diluted or drawn in a designated sanitary area.</p> <p>Administrator to continually monitor compliance via periodic checks.</p> <p>See Attachment #9</p>		

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T 280	<p>Continued From Page 12</p> <p>On 5/9/12 at approximately 6 PM, again in the Recovery room the administrator was asked where does the nurse mix the Lidocaine, Pitocin and Vassopressin vials? The administrator pointed to the desk where nurses sit and observe patients and write their progress notes and said, "Here." The desk sits in front of the recliners where patients recover after their procedures.</p> <p>Part IX. of the Virginia Board of Medicine, reads in part: "Mixing, Diluting or Reconstituting of Drugs for Administration. 18VAC85-20-400. Requirements for immediate-use sterile mixing, diluting or reconstituting.</p> <p>A. For the purposes of this chapter, the mixing, diluting or reconstituting of sterile manufactured drug products when there is no direct contact contamination and administration begins within 10 hours of the completion time of preparation shall be considered immediate-use. If manufacturers' instructions or any other accepted standard specifies or indicates an appropriate time between preparation and administration of less than 10 hours, the mixing, diluting or reconstituting shall be in accordance with the lesser time. No direct contact contamination means that there is no contamination from touch, gloves, bare skin or secretions from mouth or nose. Emergency drugs used in the practice of anesthesiology and administration of allergens may exceed 10 hours after the completion of the preparation, provided administration does not exceed the specified expiration date of a multiple use vial and there is compliance with all other requirements of this section.</p> <p>B. Doctors of medicine or osteopathic medicine who engage in immediate-use mixing, diluting or</p>	T 280			

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T 280	Continued From Page 13 reconstituting shall... 3. Establish and implement procedures for verification of the accuracy of the product that has been mixed, diluted, or reconstituted to include a second check preformed by a doctor of medicine or osteopathic medicine or a pharmacist, or by a physician assistant or a registered nurse who has been specifically trained pursuant to subdivision 2 of this subsection in immediate-use mixing, diluting or reconstituting... 4. Provide a designated, sanitary work space and equipment appropriate for aseptic manipulations; The administrator acknowledged on 5/8/12 at 10:15 AM that the vials did not have the amount or strength of Pitocin and Vassopressin documented in the label.	T 280			
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 policies and practices, as necessary. This RULE: is not met as evidenced by: Based on interview and record review the facility failed to develop a quality assurance program with processes for data collection, analysis, assessment based on data, improvement and evaluation of the facility. The findings included:	T 315	We believe that we are in full compliance with 12VAC5-412-300 as written. We dispute this deficiency. VWW does have and has had an ongoing, comprehensive, integrated self-assessment program. Furthermore, staff #21 claims she was misquoted in the statements which form part of the evidence for this deficiency.	5/8/12	

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T 315	Continued From Page 14 Review of the facility's policy and procedure manual included the wording from the State of Virginia, 12VAC5-412-300 (A). The facility did not provide evidence of a quality assurance plan or documented processes for data collection, analysis, or assessment based on the data collected. The facility did not have a written process for improvement and evaluation of their overall program. An interview was conducted on May 8, 2012 at 3:40 p.m. with Staff #13 and Staff #21. Staff #21 verbally confirmed the facility did not have quality assurance processes. Staff #21 reported data had not been collected for the outcomes discussed during the May 2012 Quality Assurance Committee meeting.		T 315	The data was collected for the May 2012 QI meeting. This includes complication logs, chart reviews, random samples of phone interviews with patients feedback for follow-up examinations. Patient complaint reviews, emails, staff attendance & performance & competency evaluations. All of this formed the basis of the QI Committee's analysis, assessment & evaluation. The May 2012 QI committee documented their meeting & its findings. All parties signed the minutes.	5-9-12
T 340	12 VAC 5-412-310 Medical records An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, but not limited to the following: 1. Patient identification; 2. Admitting information, including a patient history and physical examination; 3. Signed consent; 4. Confirmation of pregnancy; and 5. Procedure report to include: a. Physician orders; b. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays; c. Anesthesia record; d. Operative record; e. Surgical medication and medical treatments; f. Recovery room notes; g. Physician and nurses' progress notes, h. Condition at time of discharge,		T 340	See Attachment #10 From hence forward The operative report was updated to include the documentation of the dosing of Pitocin & Vassopressin continued on bottom See Attachment #11 The examination tables will be repaired or replaced to eliminate the tiny, minute tears at the bend points and at the feet.	5-9-12

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If continuation sheet 15 of 22

The staff and physicians have been trained in the use of the operative updated report. The administrative will continuously monitor use of same.

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T 340	<p>Continued From Page 15</p> <p>i. Patient instructions, preoperative and postoperative; and j. Names of referral physicians or agencies.</p> <p>This RULE: is not met as evidenced by: Based on observations made during the initial tour of the facility and clinical record review, it was determined that facility staff failed to ensure all medications given to each patient were documented in their clinical record. Specifically, thirteen (13) of thirteen (13) patients who had a surgical abortion performed at the facility failed to have listed in their record that received Lidocaine, Pitocin and Vassopressin medications in the local anesthetic that the doctor gave to each patient, (patient records #1, 3 - 8, 10, 11, 13 - 15 & 17).</p> <p>The findings were:</p> <p>Clinical records were reviewed in the Counseling office on 5/8/12 beginning at 12 noon. Records #1, 3 - 8, 10, 11, 13 - 15 & 17, all had documented evidence that the patients had surgical abortions performed at the facility. All of the above referenced records had documented evidence that the patient(s) received 20 cc of 1% Lidocaine. There was no mention of Pitocin or Vassopressin in the records reviewed.</p> <p>The administrator who is also a nurse stated in an interview on 5/8/12 that all patients who have a surgical abortion receive Lidocaine, Pitocin and Vassopressin as a local. Staff member #21 stated, "We have a policy about this."</p> <p>On 5/8/12 at 2:45 PM the facility's policy regarding Local Anesthesia was reviewed and read in part, "Local anesthesia consists of a series of injections into the cervix, typically with medications.</p>	T 340			

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T 340	Continued From Page 16 Lidocaine, Oxytocin and Vassopressin. Every patient will receive local anesthesia unless allergies prohibit its administration." Cross reference to 12VAC5-412-260 D. Tag T 280.	T 340			
T 375	12 VAC 5-412-360 A Maintenance A. The facility's structure, its component parts, and all equipment such as elevators, heating, cooling, ventilation and emergency lighting, shall be all be kept in good repair and operating condition. Areas used by patients shall be maintained in good repair and kept free of hazards. All wooden surfaces shall be sealed with non-lead-based paint, lacquer, varnish, or shellac that will allow sanitization. This RULE is not met as evidenced by: Based on observations, and interview with Staff #21, it was determined that four of four (#1 - #4) of (#1 - #4) reclining chairs for the Patients in the Recovery Room, and three (#1 - #3) of three (#1 - #3) examination tables were not in good repair as required in Section 12 VAC 5-412.360. A. The findings included: Observations doing a tour of the Abortion Facility by the Surveyors and Staff #21 revealed that four (#1 - #4) of four (#1 - #4) patients' reclining chairs in the Recovery Area revealed that the reclining chairs were not cleaned and four (#1 - #4) of four (#1 - #4) reclining chairs had broken areas along the bilateral lacquered arms. Three (#1 - #3) of three (#1 - #3) patients' examination tables had tears at the bend points and at the feet, in the Exam, Ultrasound and Procedure Rooms.	T 375	Our recovery room chairs have always been and will continue to be cleaned after every patient and kept in sanitary condition. Staff #21 denies ever stating the chairs were "unclean". They have always been cleaned (w/4) regularly. Furthermore, the arms of our chairs were not broken. However, the small line scratches in the Lacquer on the surface of the arms of our intact, structurally sound chairs will be sanded & resealed to eliminate all scratches in the lacquer. See Attachment #1a		

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T 375	Continued From Page 17 Staff #21 verified that the recovery room reclining chairs were unclear and had breaks in the wooded surfaces and tears were present in all Examination Tables. This interview occurred during the tour of the facility, on 5/8/12, between 10:10 a.m.-10:28 a.m.	T 375	The examination tables will be repaired or replaced to eliminate the tiny, minute tears at the bend points and at the feet.	5/31/12	
T 380	12 VAC 5-412-360 B Maintenance B. When patient monitoring equipment is utilized, a written preventative maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with manufacturer's specifications at periodic intervals, no less than annually, to ensure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper operation before it is returned to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance. This RULE: is not met as evidenced by: Based on interview and tour of the facility, it was determined that the facility failed to show that there was preventative maintenance service on one (1) EKG machine, one (1) lamp and two (2) microscopes. The findings include: 1. On May 8, 2012 a facility tour was conducted with the Administrator (LPN, employee #13) and Operations Business Manager (interviewee #21) between 9:00 am and 11:30 am. In the Recovery Room there was an EKG machine with no evidence of its preventative maintenance service. In the supply closet was a lamp with no evidence of its preventative maintenance service. There	T 380	See Attachment # 13 (1) EKG machine (1) lamp & (2) microscopes have all had preventative maintenance performed by a licensed biomed technician and have been properly labeled. See Attachment # 14	5/31/12	

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T 380	Continued From Page 18 were two (2) microscopes, one (1) in the Procedure Room and one (1) in the Treatment Room with no evidence of preventative maintenance service 2. On May 8, 2012 an interview was conducted with the Operations Business Manager (interviewee #21) in the facility between 9:00 am and 11:30 am. The Operations Business Manager acknowledged that the one (1) EKG machine, one (1) lamp and two (2) microscopes failed to have the preventative maintenance service.	T 380		
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 facility tour and interview, it was determined that the facility failed to have a monitoring program for fire and safety nor a responsible employee for the monitoring program. The findings include: 1. On May 8, 2012 a facility tour was conducted with the Administrator (LPN, employee #13) and the Operations Business Manager (interviewee #21) between 9:00 am and 11:30 am. Present were fire extinguishers and fire exit plans located throughout the facility. 2. On May 8, 2012 an interview was conducted with the Administrator (LPN, employee #13) in the facility between 1:00pm and 3:00pm. The	T 385	We dispute this deficiency. Employee #13 claims she was misquoted and that we are in full compliance with this deficiency. The designated individual to monitor the fire safety program is the JSM Administrator. Fire safety training & the proper use of a fire extinguisher was performed on May 04, 2012. This is documented both in the employee files & in the Emergency Disaster Plan. See Attachment #15	

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T 385	Continued From Page 19 Administrator acknowledged that the facility did not have an individual responsible to monitor a fire and safety program. The Administrator acknowledged that there had been no training on the use of the fire extinguishers and/or other fire and safety activities. The Administrator acknowledged that there was no evidence to show for a monitoring program for fire/safety activities.	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 facility tour and interview it was determined that the facility failed to have evidence that the fire alarm was inspected and tested in accordance with the current edition of the Virginia Statewide Fire Prevention Code (27-94 et seq. of the Code of Virginia) to maintain them in serviceable condition. The findings include: 1. On May 8, 2012 a facility tour was conducted with the Administrator (LPN, employee #13) and the Operations Business Manager (interviewee #21) between 9:00 am and 11:30 am. During the tour the Administrator identified that the fire alarm system was integrated within the safety alarm system under contract with ADT Company. 2. On May 8, 2012 an interview was conducted	T 390	All fire protection and alarm systems and other fire fighting equipment shall be inspected and tested as required. See Attachment #'s 16, 17, 18	6/25/12

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T 390	Continued From Page 20 with the Administrator (LPN, employee #13) in the facility between 1:00 pm and 3:30 PM. The Administrator acknowledged that ADT alarm company was responsible for the inspection and testing of the facility fire alarm system. The Administrator was unable to provide evidence that the fire alarm system had been 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.	T 390			
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 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. This RULE is not met as evidenced by:	T 400	As per the Virginia Department of Health letter dated May 23, 2012, all deficiencies cited under 12 VAC 5-412-380 will be completed within two years of issuance of license.	5/30/12	

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T 400	<p>Continued From Page 21</p> <p>Based on interview and facility tour it was determined the facility failed to have an architect attestation, HVAC duct inspection reports, documentation of test for fire alarm system, ventilation of treatment room (MERV 7), air exchange information for treatment rooms and rating of insulation.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. On May 8, 2012 a facility tour was conducted with the Administrator (LPN, employee #13) and Operations Business Manager (interviewee #21) between 9:00am and 11:30am. During the facility tour there was no evidence that the facility met the state and local codes and building ordinances. 2. On May 8, 2012 an interview was conducted with the Operations Business Manager (interviewee #21) in the facility between 2:00pm and 3:00pm. The Operations Business Manager acknowledged that the facility was unable to provide evidence that the facility met the state and local codes and building ordinances. <p>The Operations Business Manager (interviewee #21) provided a written acknowledgment that contained the following content: "At this time we do not have the following requested documents available: architect attestation, HVAC duct inspection reports, documentation of test for alarm system, ventilation of treatment room (MERV 7), air exchange information for treatment rooms and rating of insulation."</p>	T 400			

Attachment #1

7015

Statement of Ownership

The Ownership of Virginia Women's Wellness is that it is 100% owned by the professional corporation Professional Medical Services, P.C.

Ownership stake in corporations is held via shareholders through their ownership of shares of stock in the corporation. The shares of stock of Professional Medical Services, P.C. are owned by Quality Professional Solutions, Inc. (50%) and U.S. Medical Care, Inc. (50%).

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VDH/OLC

Virginia Women's Wellness – Addendum to Plan of Correction

Criminal background checks have been completed on the below listed employees / clinicians. All background checks listed no conviction data and have been inserted in to the individuals personnel file.

<u>Title</u>	<u>Date Criminal Background Check Processed</u>
Registered Nurse # 1	5/10/12
Registered Nurse # 2	5/10/12
Licensed Practical Nurse # 1	5/10/12
Licensed Practical Nurse # 2	5/10/12
Licensed Practical Nurse # 3	5/10/12
Licensed Practical Nurse # 4	5/10/12
Healthcare Team Member # 1	5/10/12
Healthcare Team Member # 2	5/10/12
Healthcare Team Member # 3	5/10/12
Healthcare Team Member # 4	5/10/12
Healthcare Team Member # 5	5/10/12
Healthcare Team Member # 6	5/10/12
Healthcare Team Member # 7	5/10/12
Healthcare Team Member # 8	5/10/12
Physician # 1	6/6/12

Attachment # 3 T155

Virginia Women's Wellness

We realize you as a patient have rights while at our facility and receiving medical care. Likewise you have responsibilities as a patient.

Your Rights As A Patient:

- ❖ You have the right to compassionate, caring, kind, considerate and respectful care regardless of age, race, religion, disabilities or source of payment.
- ❖ You have the right to personal privacy and confidentiality of personal and medical information.
- ❖ You have the right to understandable explanation of treatment and informed consent
- ❖ You have the right to make your wishes known regarding an Advanced Directive (Living Will or Power of Attorney). If you have a written Advanced Directive, a copy should be given to this healthcare facility, your family, and your doctor. These documents express your wishes for future care and name someone to speak for you should you be unable to speak for yourself. State information and forms for advanced directive can be found at <http://www.vdh.state.va.us/OLC/Downloadables/index.htm> and <http://www.vdh.state.va.us/OLC/documents/2008/pdfs/2005%20advanced%20directive%20form.pdf>
- ❖ You have the right to refuse treatment or seek other medical care.
- ❖ You have to right to know the charges for your visit to the office and medical care.
- ❖ You have the right to voice your concerns, questions or complaints. You can do so directly with our staff or if you wish to file a formal complaint, you can do so in writing or via telephone. The name, mailing address, and telephone number for the facility contact person and the OLC complaint unit are provided on the attached copy of this sheet. Complaints may be filed anonymously with the OLC. Complaints will be investigated, a resolution proposed, and complainant notified within 30 days from the date of receipt of the complaint.

Concerns, Questions or Complaints:

Director of Quality Assurance/Improvement
1 Alpha Avenue; Suite # 20
Voorhees, N.J. 08043
(800) 742-0230

and/ or

Virginia Department of Health
Facility of Licensure and Certification
9960 Mayland Drive, Suite 401
Richmond, VA 23233-1463
(800)955-1819

Your Responsibilities As A Patient:

- You are responsible to provide us with your complete, accurate, present, and past medical information.
- You are responsible for making an informed decisions and asking for clarification when necessary.
- Responsible to understand your role in your care and report unexpected changes in your condition.
- Responsible for following the treatment plan recommended and keeping your appointments.
- You are responsible for your actions if you refuse treatment or do not follow the treatment plan.
- You are responsible for respecting others privacy and abiding by facility rules and regulations.
- You are responsible to pay your financial obligations.

Patient Signature: _____

Date: _____

Attachment #4 T155

Virginia Women's Wellness

We realize you as a patient have rights while at our facility and receiving medical care. Likewise you have responsibilities as a patient.

Your Rights As A Patient:

- ❖ You have the right to compassionate, caring, kind, considerate and respectful care regardless of age, race, religion, disabilities or source of payment.
- ❖ You have the right to personal privacy and confidentiality of personal and medical information.
- ❖ You have the right to understandable explanation of treatment and informed consent
- ❖ You have the right to make your wishes known regarding an Advanced Directive (Living Will or Power of Attorney). If you have a written Advanced Directive, a copy should be given to this healthcare facility, your family, and your doctor. These documents express your wishes for future care and name someone to speak for you should you be unable to speak for yourself. State information and forms for advanced directive can be found at <http://www.vdh.state.va.us/OLC/Downloadables/index.htm> and <http://www.vdh.state.va.us/OLC/documents/2008/pdfs/2005%20advanced%20directive%20form.pdf>
- ❖ You have the right to refuse treatment or seek other medical care.
- ❖ You have to right to know the charges for your visit to the office and medical care.
- ❖ You have the right to voice your concerns, questions or complaints. You can do so directly with our staff or if you wish to file a formal complaint, you can do so in writing or via telephone. Complaints may be filed anonymously with the OLC. Complaints will be investigated, a resolution proposed, and complainant notified within 30 days from the date of receipt of the complaint.

Concerns, Questions or Complaints:

*Director of Quality Assurance/Improvement
1 Alpha Avenue, Suite # 20
Voorhees, N.J. 08043
(800) 742-0230*

and/ or

*Virginia Department of Health
Facility of Licensure and Certification
9960 Mayland Drive, Suite 401
Richmond, VA 23233-1463
(800)955-1819*

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- You are responsible to provide us with your complete, accurate, present, and past medical information.
- You are responsible for making an informed decisions and asking for clarification when necessary.
- Responsible to understand your role in your care and report unexpected changes in your condition.
- Responsible for following the treatment plan recommended and keeping your appointments.
- You are responsible for your actions if you refuse treatment or do not follow the treatment plan.
- You are responsible for respecting others privacy and abiding by facility rules and regulations.
- You are responsible to pay your financial obligations.

PATIENT'S COPY

POLICY AND PROCEDURES MANUAL
Virginia facilities

5. Handling & Storage of Soiled Linens

No reusable linens are used in the facility.

6. Handling, Storage & Processing of Regulated Medical Waste

GENERAL INFORMATION AND IDENTIFICATION:

The Following classes of RMW are generated in the facility:

Class 2 Waste – Pathological Wastes

“Class 2” Human Pathological Wastes, including tissues, and fluids that are removed during surgery or other medical procedures, and specimens of body fluids and their containers.

Disposal - Class 2 waste is stored in appropriately labeled bags.

This waste will be collected and transported to the freezer for storage until future transport by RMW carrier.

Class 3 Waste – Human Blood and Blood Products

“Class 3” Liquid waste human blood: products of blood; items saturated and/or dripping with human blood; or items that were saturated and/or dripping with human blood that are now caked with dried human blood; including serum, plasma, and other blood components, and their containers, which are used or intended for use in either patient care testing and laboratory analysis or the development of pharmaceuticals. Intravenous administration tubing with visible blood and an angiocatheter attached are also included in this category.

Disposal - All Class 3 waste is to be bagged in red bags and shall be collected and transported to the designated RMW holding/preparation area within the center. Body fluids may be discarded in the sanitary sewer via pouring. Body fluids poured into a drain shall be poured during the flushing cycle of a hopper (toilet bowl for urine), and the receptacle discarded into RMW containers.

Note: Personnel performing this task (usually in Scrub) must utilize personal protective equipment, e.g. fluid resistant gowns, gloves, goggles or face shield.

Class 4 Waste – Sharps

“Class 4” Sharps that have been used in patient care or treatment, including hypodermic needles, syringes (with or without the attached needle), Pasteur pipettes, scalpel blades blood vials, needles with attached tubing and culture dishes (regardless of presence of infectious agents). Also included are other types of broken glassware that were in contact with infectious agents such as used slides and cover slips.

Disposal - “Class 4” Sharps are placed in sharps containers provided throughout all areas. All used sharps are to be collected and transported to the designated RMW holding/preparation area within the center.

REGULATED MEDICAL WASTE SPILL CLEANUP PROCEDURES

Cleaning of Autoclave

- * *Empty original distilled water out of the autoclave*
- * *Fill autoclave with cleaning solution and tap water*
- * *Run autoclave through one normal cycle*
- * *Drain autoclave again*
- * *Remove tray from inside autoclave*
- * *Use a brillo pad to scrub this part of the autoclave*
- * *Rinse autoclave sterilizing tunnel*
- * *Drain*
- * *Replace with clean distilled water*
- * *Run through one normal cycle*
- * *This task shall be performed monthly*

8. Disposal of Non-reusable Medical Equipment

All items marked disposable or single-use only are to be discarded after each Patient use. Any items soiled or blood tinged shall be disposed of in a proper bio-hazard container. Any disposables that are not blood tinged may be disposed of in regular trash.

9. Maintenance & Repair of Equipment

All equipment shall be maintained and repaired in accordance with manufacturer recommendations. Annual preventative maintenance shall be performed by Tidewater Medical or another company with qualified medical technicians.

10. Cleaning of Environmental Surfaces

All environmental surfaces shall be thoroughly cleaned and maintained daily. Surfaces shall be cleaned with germicidal wipes or disinfecting solution. Terminal cleaning of the procedure rooms shall be performed monthly. Detailed cleaning of environmental surfaces as outlined below:

Front Lab: All surfaces are fully cleanable. All surfaces should be wiped with germicidal wipes and allow for 2 minutes drying time.

Attachment #7

POLICY AND PROCEDURES MANUAL

Virginia facilities

7175

Ultrasound Room: After each patient use, the entire examination table and pillow shall be wiped with germicidal wipes and allow for 2 minutes drying time. The disposable cover on the pillow shall be replaced after each Patient. Once the examination table is fully dry, it may be dressed with new paper covering. Abdominal ultrasound probes shall be cleaned with germicidal wipes and allow for 2 minutes drying time. Vaginal ultrasound probes shall be cleaned with germicidal wipes or T-spray with proper contact time before wiping.

Procedure / Examination Room: The specimen jar and all soiled instruments shall be passed through the window. When preparing for the next patient, jars and instruments shall be returned to the room via the doorway. After each patient use, the entire examination table and pillow shall be wiped with germicidal wipes and allow for 2 minutes drying time. The disposable covers on the stirrups and pillow shall be replaced after each patient. Once the examination table is fully dry, it may be dressed with new paper covering.

Scrub Room: The specimen jar and soiled instruments are received through the pass through window. The instruments are placed on a pad on the counter. The specimen is then examined, weighed and bagged. The instruments are then counted, washed in a mixture of enzymatic detergent and water and scoured with a stiff bristle brush. Instruments will soak in this mixture for 5 minutes before being thoroughly rinsed. Instruments are then placed in a covered container for transport to the autoclave room. The pad on the counter is replaced before receiving next packet of instruments. Specimen jars are stored in the scrub room and returned to the procedure room via the doorway not the pass through window.

Autoclave Room: Instruments are received in a covered container.

Instruments are removed from the container and are again washed in a mixture of water and enzymatic detergent, allowing for 5 minutes soak time. Instruments are then thoroughly rinsed. Instruments are wrapped in csr wrap or placed in autoclave pouches and ready to be processed in the autoclave at this point. After instruments are removed from the autoclave and allowed to dry, they are stored in the autoclave room or the procedure room for future use.

Alternatively, instruments are removed from the container and placed in a high level disinfectant for 20 minutes. After being removed from the solution, instruments are rinsed in distilled water. Instruments are wrapped in csr wrap or placed in autoclave pouches and ready to be processed in the autoclave at this point. After instruments are removed from the autoclave and allowed to dry, they are stored in the autoclave room or the procedure room for future use.

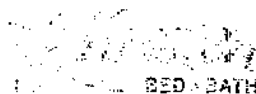
Recovery Room: After each patient use, the entire chair shall be wiped with germicidal wipes and allow for 2 minutes drying time. Once the chair is fully dry, it may be dressed with new disposable covering. At the end of each patient session the cushions shall be removed and the surfaces under the cushions shall be thoroughly cleaned and disinfected. All surfaces in the recovery room are to be wiped with germicidal wipes and allow for 2 minutes drying time.

Cloud Nine Wipeable Pillows 21"x27" (12)

Page 1 of 2

Attachment # 8

T 175



BED & BATH

1-800-432-7571

Live Customer Service is Available M-F - 9am - 5:30pm • SAT 11am - 4pm • EST

SHOPPING BAG 0

enter keyword or item #



Home | About Us | Shipping & Handling | Return Policy | FAQs | Policies | Contact Us

Ask us about our customized hygiene kit 1-800-432-7571

Home • Pillows • Wipeable/Reusable Healthcare Pillows by the Case • Cloud Nine Wipeable Pillows 21"x27" (12)

-- select from below --

CATEGORIES

- Bed Linens
- Pillows
- Mattress Covers & Pads
- Towels and Washcloths
- Shower Curtains
- Hygienic and Mesh Laundry Bags
- Bath Robes and Children's Cover-Ups
- Shower Things
- Personal Hygiene Kits, Amenities, & Ditty Bags
- Floor/Entrance Mats

OUR CUSTOMERS SAY...

"Currently I have an order from you another dozen pillows as I do every year about this time. I wanted to thank you for your company. It is the only one online, or anywhere that will sell ... read more"

[View All / Submit Testimonial](#)

VISIT OUR SISTER SITE



VISIT OUR SISTER SITE



VISIT OUR SISTER SITE



CLICK TO ENLARGE

Cloud Nine Reusable Pillows 21"x27" (12)

Item #: pf51107-050

Regular Price \$79.95

Quantity: 1

☐ SEND PAGE TO A FRIEND**ADD TO SHOPPING BAG**

DESCRIPTION

The Pillow Factory® family of reusable and wipeable pillows feature the SRC® core system as well as high quality fluid resistant and fluid proof covers which can be easily wiped clean.

SRC® adds support and resiliency to resist wear, crumbling and breakdown while providing superior patient support and comfort. Use after use, these pillows retain about 65% of their original height, resulting in better value per patient day.

- 21"x27" - 21 oz.
- Color: Blue
- Medium loft
- Sold by the case; 12 pillows in each case
- Maximum comfort
- Soft and quiet
- Made in the USA
- 100% recycled fiberfill is environmentally responsible
- Treated Olefin exterior

Features:

- Stain Resistant
- Fluid Resistant
- Flame Resistant
- Breathable
- Non-Allergenic

*Standard lead time for Pillow Factory items is 10 business days so allow up to 3 weeks for delivery. In most cases these wipeable pillows are made to order. If you need this item before a certain date let us know in the comments section of the order.

RECENTLY VIEWED



POPULAR ITEM

Cloud Nine Wipeable Pillows 21"x27" (12)
\$79.95

RELATED ITEMS

Microvent Pillows with Vinyl Cover 20"x27" (12)
Comfort Care™ Wipeable Pillows 21"x27" (12)

Cloud Nine Wipeable Pillows 21"x27" (12)
Comfort Care™ Wipeable Pillows 13"x17" (24)

Comfort Care™ Wipeable Pillows 19"x25" (12)
Easy Care® Wipeable Pillows 19"x25" (12)

POLICY AND PROCEDURES MANUAL**Virginia facilities**

C. In the Virginia facilities, all drugs maintained in the facility for daily administration shall not be expired and shall be properly stored in enclosures of sufficient size with restricted access to authorized personnel only. All medications used for multiple Patients will be drawn from multi-use bottles. If a bottle or vial is labeled for single use, it will be used for only one Patient and any unused portions will be discarded. When using multi-dose vials or bottles, the calculation of remaining medication left in the vial or bottle will be made by subtracting the amount drawn from the starting volume of unopened vial or bottle. Drugs shall be maintained at appropriate temperatures in accordance with definitions in 18VAC110-20-10.

D. The mixing, diluting or reconstituting of drugs in the Virginia facilities for administration shall be in accordance with regulations of the Board of Medicine (18VAC85-20-400 et seq.). Mixing, diluting or reconstituting of drugs will be performed by a Physician, Registered Nurse or by a trained HCTM with a second check being performed by a Registered Nurse or Physician. This mixing, diluting or reconstituting shall take place on a designated sanitary work space.

E. Records of all drugs in Schedules I-V 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.

XIII. Equipment and Supplies.

The facility shall maintain medical equipment and supplies appropriate and adequate to care for patients based on the level, scope and intensity of services provided, including but not limited to:

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.

Virginia Women's Wellness Quality Assurance Program

This document outlines the Quality Assurance Program of Virginia Women's Wellness. The purpose of this program is to implement an ongoing, comprehensive, integrated, self-assessment program of the quality and appropriateness of care and services provided at Virginia Women's Wellness, including data collection, assessment, evaluation and improvement. This program includes the following components:

- I. Data Collection. Data are collected from a number of sources for the Quality Assurance Program. These include, but are not limited to, the following data:
 - a. Staffing patterns and performance and supervision are evaluated on an ongoing basis.
 - b. An annual review of a random sample of medical records shall be conducted.
 - c. Documentation of Patient Satisfaction through follow-up telephone surveys of patients shall be conducted.
 - d. Documentation of Patient Satisfaction through review of patient's hand-written comments on follow-up appointment forms shall be done.
 - e. Complaints are received, documented, and reviewed through written mail, e-mails, calls to Administration, calls to the Call Center, calls to the Facility, and calls to the OLC.
 - f. Infections, complications and adverse events are documented on the Complication Log.
 - g. Staff concerns regarding patient care are received and reviewed.
- II. The collected data are reviewed, evaluated, and assessed by the Quality Improvement Committee which shall meet informally as needed to address any identified problems or concerns. In addition, the full Q/I Committee shall meet on a formal basis, no less than annually, to review, analyze and evaluate the quality of care and to offer suggestions for improvement.
- III. The Quality Improvement Committee shall review all measures implemented to resolve problems or concerns that have been identified.
- IV. The results of the Quality Improvement Committee shall be reported to the Governing Body at least annually and shall include the deficiencies identified and recommendation for corrections and improvements. This report shall be acted upon by the Governing Body and the Facility.
- V. All corrective actions shall be identified and evaluated.
- VI. Any deficiencies identified by the Quality Improvement Committee that jeopardize patient safety shall be reported immediately to the Governing Body.

~~See~~ attachment # 11

ABORTION PROCEDURE RECORD

T340

Name: _____ Date: _____

Birth Date: _____ Age: _____ LMP: _____ Chart Number: _____

PRE-OPERATIVE LABORATORY TEST RESULTS:

VITAL SIGNS: BP: _____ / _____ Pulse: _____ Temp: _____ Wt: _____ Ht: _____

Rh (+ or -): _____ Hct: _____ Glu/Pro: _____ / _____ HSPT (+ or -): _____

LSPT (+ or -): _____ Signature of Lab Tech.: _____

Date: _____ TOP or D&E at _____ weeks LOCAL/TWILIGHT

PRE-OPERATIVE VITAL SIGNS:

B/P: _____ / _____ Pulse: _____ O2 Saturation: _____ Time: _____ am/pm Staff's Initials: _____

_____ I have discussed with the patient the abortion she has requested, and I believe she is sufficiently
MD initial mature and intelligent to understand the nature and consequences of her condition and the procedure.

PRE-EVACUATION EXAM:

Vagina ☐ WNL ☐ Other: _____

Cervix ☐ WNL ☐ Other: _____

Adnexa ☐ WNL ☐ Other: _____

Uterus ☐ WNL ☐ Other: _____

☐ ANT ☐ MID ☐ POST SIZE: _____ weeks ☐ Other: _____

PRE-OP MEDS: ☐ Midazolam _____ mg IV
☐ Fentanyl _____ mcg IV ☐ Other _____ mg IV

Intra-operative vitals signs:

B/P: _____ / _____ Pulse: _____ O2 Saturation: _____ Time: _____ am/pm Staff's Initials: _____

The patient was continuously monitored using pulse oximetry, blood pressure reading, and visual observation. Her medical condition and vital signs ☐ did ☐ did not remain within normal limits at all times during the procedure.

Procedure Time started: _____ am/pm Time ended: _____ am/pm

Paracervical block administered with 20cc 1% Lidocaine, 4 units Vasopressin, 4 units Pitocin

Cervix Dilated to _____ mm.

Cannula type: _____ mm _____ flexible _____ rigid

Sharp Curettage: ☐ YES ☐ NO

Estimated Blood Loss: _____ cc Procedure Tolerated: _____

Physician's Comments:

Attachment # 12

T375

~~XXXXXXXXXX~~
~~XXXXXXXXXX~~
Virginia Beach, Va

Invoice for Work: 12B0610

June 10, 2012

Address for Work to Be Done:

Women's Wellness
224 Groveland Road
Virginia Beach, Va 23452

Work done:

Sand and Refinish Armrest on four (4) chairs - in recovery room.

Amount Due: \$ 400.00

Thanks,

~~XXXXXXXXXX~~
~~XXXXXXXXXX~~
~~XXXXXXXXXX~~

A Hachment #13

SALES
NEWPORT NEWS, VIRGINIA 23601

T 375

Phone :

Fax :

INVOICE

Date : 05/31/12
Due Date: 06/30/12

No. : 212595
Page: 1

PMS
PROFESSIONAL MEDICAL SERVICES
VIRGINIA BEACH WELLNESS CENTER
224 GROVELAND ROAD
VA BEACH VA 23452

Ship To/Remarks

Via YIM	FOB	Terms 0/ 0/ N30	Your#	Our#	Rep. JB
Description Item Number	Ordered Measure	Shipped Backordered	Unit Price Discount %	Extended	
REUPHOLSTER EXAM TABLE TOPS Item #: TMSS	3.0	3.0	400.0000	1200.00	

THANK YOU VERY MUCH FOR YOUR BUSINESS

REMIT TO: PROFESSIONAL MEDICAL SERVICES
NEWPORT NEWS, VIRGINIA 23601

Sub-Total : 1200.00
Tax : 60.00
Total : 1260.00
Net To Pay: 1260.00

T380

5/16/2012

Done-By

~~CONFIDENTIAL~~
Newport News VA 23601

Tech

Attachment # 15

Virginia Emergency Disaster Preparedness Plan

T385

Evaluation Report

Year: 2012

1. How effective was the Emergency Preparedness Plan? (Attach a copy of supportive data, including drill evaluation/ checklist.)

The drill was effective and it was evaluated for efficiency.

2. How often are drills conducted?

Bi-annually

3. Is contact information page 5 accurate?

Yes, [redacted] the Administrator is designated as responsible for Fire and Safety Program.

4. Evaluation of Staff Emergency Training: types of emergency preparedness training that occurred, number and percentage of staff who received training, is staff adequate to handle emergency, and is emergency supplies, equipment available.

The staff was trained and participated in an in-service training and demonstration. The staff also effectively completed a drill and necessary supplies and equipment was available. Fire extinguisher demonstration performed.

5. How effective is the plan in preparing the clinic for internal and external disasters?

The drill was completed well and the plan was effective in evacuating the building safely. The plan also will be effective for external disasters.

CONCLUSIONS AND RECOMMENDATIONS FOR THE PLAN FOR THE NEXT YEAR

What are the most important recommended areas of emergency preparedness to address?

Ensure every employee is aware of the meeting place and how to operate the PA system.

Report completed by [redacted]

Title Compliance Officer Date 5/4/12



ADT Always There

ADT COMMERCIAL SALES AGREEMENT

TOWN NO.
0070-NORFOLK, VA

CUSTOMER NO.

JOB NO.

PO NO.

ESTIMATE NO.
1-LSNWWAttachment # 16
CUSTOMER
COPY

DATE: 6/11/2012

ADT Security Services, Inc. ("ADT")

Enclosed is the
2550 Elsmere Ave, Suite J
Norfolk, VA 23513
Tele. No. (757) 852 5048

Virginia Women's Wellness
d/b/a:
("Customer")
Customer Billing Information
224 Groveland Road,
Virginia Beach, VA 23452
Attn: Michelle Nelson
Tele. No. (757) 306-4706

Customer Premises Serviced
224 Groveland Road,
Virginia Beach, VA 23452
Attn: Michelle Nelson
Tele. No. (757) 306-4706

This ADT Commercial Sales Agreement is between Customer and ADT effective as of the date signed by Customer. By entering into this Agreement, ADT and Customer agree to the Terms and Conditions contained in this Agreement. The Equipment and/or Services, collectively the System(s) covered under this Agreement is/are listed in the attached Schedule(s) of Protection / Scope of Work ("SOW").

I. THE FOLLOWING DOCUMENTS ARE ATTACHED TO THIS AGREEMENT AND ARE INCORPORATED BY REFERENCE:

- (a) Hazardous Substance Checklist and Customer Letter
- (b) Scope of Work / Schedule(s) of Protection
- (c) Terms and Conditions
- (d) Additional Terms and Conditions
- (e) State Specific Forms, if applicable (e.g., local permit applications)
- (f) Customer Installation Acceptance Form (specific to Equipment/Services purchased)
- (g) If multiple locations, see attached schedule

II. Charges and Fees: Customer agrees to pay the Sum of \$0.00 ("Installation Charge") with \$0.00 payable upon acceptance of this Agreement ("Installation Charge Deposit") plus any applicable "Fees" and sales taxes. ADT may invoice Customer for progress billings based upon Equipment and/or System components delivered or stored, and/or Services performed before completion of the System/Equipment installation, activation of the System, connection to the CMC, or any other Service(s). All outstanding Installation Charges and/or Fees shall be due and payable upon completion of the installation of the Equipment/System and as a precondition to activation of System and, if applicable, connection to ADT's Central Monitoring Center ("CMC") or any other Service(s). Any changes in the STATEMENT OF WORK / SCHEDULE OF PROTECTION made by the Customer after execution of this Agreement must be agreed to ADT and the Customer in writing and may be subject to additional charges and/or fees. Any equipment ordered by Customer by e-mail or telephone order shall be subject to terms and conditions of the Agreement and may be subject to shipping, handling, and/or restocking fees. For the Service(s) provided as indicated in this Agreement, Customer agrees to pay Service Charges in the amount of \$3,025.92 per annum (the "Annual Service Charge"), payable in advance plus applicable state and/or local taxes for 5 year(s) (the "Initial Term") effective from the date such Service is operative under this Agreement. Until Customer has paid ADT the Installation Charge and Fees in full, Customer grants to ADT a security interest in the Equipment and all proceeds thereof to secure such payment. After the Initial Term this Agreement shall automatically renew on an Annual basis unless terminated by either party upon written notice at least thirty (30) days prior to the anniversary date. ADT shall have the right to increase Annual Service Charge(s) after one (1) year. For termination prior to the end of the Initial Term, Customer agrees to pay, in addition to any outstanding Fees and charges for Service(s) rendered prior to termination, 90% of the Annual Service Charge(s) remaining to be paid for the unexpired term of the Agreement as liquidated damages but not as a penalty. Additionally, Customer agrees to pay any assessments, taxes, fees or charges imposed by any governmental body, telephone, communication, or signal transmission company such as false alarm, permitting or connection fees, or administration fees or service charges assessed by ADT related to changes in applicable laws and/or AHJ requirements, the need to reprogram alarm controls/devices to comply with area code, signal transmission, numbering or other changes relating to the installed Equipment and/or Service(s) provided under this Agreement ("Fees").

III. ENTIRE AGREEMENT; CUSTOMER ACCEPTANCE: This Agreement, together with all of its written Amendments, Riders, Scope of Work and/or Exhibits, constitutes the entire agreement between the Customer and ADT relating to the subject matter hereof and supersedes any prior or contemporaneous oral or written agreements and understandings. The terms and conditions of this Agreement will prevail over any conflicting, inconsistent or additional terms and/or conditions contained in any purchase order, agreement, or other document issued by Customer. In signing this Agreement, Customer is not relying on any advice, advertisements, or oral representations of ADT and agrees to be bound to the terms and conditions contained in all the pages of the Agreement. Customer agrees that any representation, promise, condition, inducement or warranty, express or implied, not included in this Agreement will not be binding upon ADT, and that the terms and conditions in this Agreement apply as printed without alteration or qualification, except as specifically modified by a written agreement. Any changes in the Statement of Work or scope of the work requested by the Customer after the execution of this Agreement may result in additional cost to the Customer and any such changes/additions must be authorized in writing by both the Customer and ADT. Customer's failure to accept and sign this Agreement within ninety (90) days of the date shown above may result in price increases. Customer acknowledges that: (a) ADT has explained the full range of protection, equipment, and services available to Customer; (b) additional protection over and above that provided herein is available and may be obtained from ADT at an additional cost to the Customer; (c) Customer desires and has contracted for only the Equipment and/or Service(s) itemized in this Agreement; (d) the Equipment/Service(s) specified in this Agreement are for Customer's own use and not for the benefit of any third party; (e) Customer owns the premises in which the Equipment is being installed or has the authority to engage ADT to carry out the installation in the premises; and (f) Customer will comply with all laws, codes and regulations pertaining to the use of the Equipment/Service(s).

ATTENTION IS DIRECTED TO THE WARRANTY, LIMIT OF LIABILITY AND OTHER CONDITIONS CONTAINED IN THE SECTIONS ENTITLED "TERMS AND CONDITIONS" AND "ADDITIONAL TERMS AND CONDITIONS". THIS AGREEMENT REQUIRES FINAL APPROVAL OF AN ADT AUTHORIZED MANAGER BEFORE ANY EQUIPMENT/SERVICES MAY BE PROVIDED. IF APPROVAL IS DENIED, THIS AGREEMENT WILL BE TERMINATED AND ADT'S ONLY OBLIGATION TO CUSTOMER WILL BE TO NOTIFY CUSTOMER OF SUCH TERMINATION AND REFUND ANY AMOUNTS PAID IN ADVANCE.

IF MAINTENANCE SERVICE IS DECLINED, CUSTOMER MUST INITIAL
HERE _____

IF A 5-DAY FAMILIARIZATION PERIOD IS REQUESTED, CUSTOMER MUST INITIAL
HERE _____

Presented by:

(Signature of ADT Sales Representative)

Sales Agent: Dave
Sales Representative Registration Number (if applicable): 999999

Accepted By:

(Signature of Customer's Authorized Representative)

(Name Printed)

Title:

Date Signed:

Attachment # 17

T390



ADT COMMERCIAL SALES AGREEMENT

TOWN NO.
0070-NORFOLK, VA

CUSTOMER NO.

JOB NO.

PO NO.

ESTIMATE NO.
14SNVW

ADT Always There™

STATEMENT OF WORK / SCHEDULE OF PROTECTION

IV. STATEMENT OF WORK / SCHEDULE OF PROTECTION ("SOW"): ADT agrees to install or cause to be installed the Equipment and furnish the Service(s), collectively the System, on the terms and conditions set out in this Agreement.

- A. Ownership of System and/or Equipment: ADT Owned - ADT may remove or upon written notice to the Customer, abandon in whole or in part, all devices, instruments, appliances, cabinets, and other materials associated with the system, upon termination of this agreement, without obligation to repair or redecorate any portion of the Customer's premises upon such removal, and the removal or abandonment of such materials shall not be held to constitute a waiver of the right of ADT to collect any charges which have been accrued or may be accrued hereunder.
- B. Services to be Provided ("Services")

Alarm monitoring and Notification Services:

Burglar Alarm and Fire Alarm Monitoring PROVIDED, Monitoring with Additional Group Service PROVIDED

Video Surveillance Services (attach Rider Form #####):

No Service Selected

Managed Access Control Services:

No Service Selected

Video Equipment:

No Service Selected

Quality Service Plan(QSP)/Maintenance; Preventive Maintenance/Inspection:

Maintenance Quality Service Plan and 1 Fire Alarm Inspection PROVIDED

Additional Services:

Transmission - Digital Two Line

- C. Equipment to be Installed ("Equipment"): ADT will install, or cause to be installed, the Equipment as set forth in this SOW in Customer's designated facility(ies). As used herein, "installation" means: (i) affixing all Equipment and materials provided by ADT at such locations within the facility(ies) as are designated by Customer; (ii) providing and pulling cables/wires required to connect the Equipment to Customer's Communications Facilities and making such connections; (iii), in the case of a Digital Communicator installation, mount Equipment and plug into RJ31X phone jack previously installed by Customer; (iv) in the case of radio installation, mount radio Equipment and program Equipment with number furnished by Customer; (v) providing and installing software/firmware required by the Equipment; (vi) performing testing as required to establish that the ADT Equipment is connected, is functioning according to its specifications, and is communicating over Customer's Communications Facilities; and (vii) providing user-level training to Customer's designated representative in the use of such Equipment.

Qty	Product Name	Location
1	FIRE/BURG PKG W/D7412GV3	
1	ALPHA IV COMM CNTR, WHITE	
1	V-F COMMAND CENTER	
7	POPII II UL, LOW CURRENT	
1	POPEX ZONE EXPANDER	
1	TRANSFORMER KIT UL APPROV	
9	12V4W ZNX SMK SINGLE BASE	
7	SMOKE DET HEAD PHOTOELEC	
2	HEAT DETECTOR	
5	PIR MOTION SENSOR 50 FT POPII	
5	Surface Contact	
1	SIREN/2 TONE/ INDOOR - AQEMCO SENSORS	
2	Battery 12V 7AH (1)	
600	18/4c, SOL, Unshielded, CMP/F-PLP, Plenum, Red, 500' Reel	
2	Hold-up Hand Button	
1	Permit Fees	
1	Inspections - Fire or Card Access	
30	Wire Mold to run wire upstairs & to several devices.	

- D. Scope of Work: This Section is intended for installation use only. Any language contained in this Section that attempts to modify the Terms and Conditions of this Agreement shall be void and of no effect.

Contract Notes:



ADT Always There

ADT COMMERCIAL SALES AGREEMENT

TOWN NO.
0070-NORFOLK, VA

CUSTOMER NO.

JOB NO.

PO NO.

ESTIMATE NO.
1LSNMMW

Attachment #18

ADDITIONAL TERMS AND CONDITIONS

T390

ADT Security Services, Inc. ("ADT")

2550 Elmsmore Ave, Suite J
Norfolk, VA 23513
Tele. No. (757) 852-5048Virginia Women's Wellness
d/b/a:

("Customer")

Customer Billing Information

224 Groveland Road,
Virginia Beach, VA 23452
Attn: Michaela Nolepp
Tele. No. (757) 306-4705

DATE: 6/11/2012

Customer Premises Served

224 Groveland Road,
Virginia Beach, VA 23452
Tele. No. (757) 306-4706

Notwithstanding anything in the Agreement to the contrary, ADT and Customer agree as follows:

Terms and Conditions

AHJ Approval. For fire alarm systems required by law, the protection listed on this Agreement may be subject to approval by the local Authority Having Jurisdiction (AHJ). Any changes required by the AHJ may result in additional charges to the Customer.

A/C Power. Customer will supply the necessary 110VAC power as required by ADT.

Telephony. Customer is responsible for providing telephone company connectivity at control panel location.

Annual Service Charge - First Three Years. ADT agrees to honor the Annual Service Charge for Central Station Monitoring Services specified in this Agreement for the first three years of the Agreement.

All other terms and conditions of the Agreement, except those expressly modified herein, shall remain in full force and effect.

Presented by:

(Signature of ADT Sales Representative)

Sales Agent: DJS

Sales Representative Registration Number (if applicable):

Accepted By:

(Signature of Customer's Authorized Representative)

(Name Printed)

Title:

Date Signed:

RECEIVED
JUL 26
VDH/OLC