STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AF-0005	A. BUILDING _____ B. WING _____	10/29/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A CAPITAL WOMENS HEALTH CLINIC	1511 STARLING DRIVE HENRICO, VA 23229

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T 000	Initial Comments An unannounced Biennial Licensure Inspection was conducted October 22, 2018 through October 23, 2018 and October 29, 2018 by two (2) Medical Facilities Inspectors from the Virginia Department of Health, Office of Licensure and Certification. The facility was not in compliance with the State Board of Health 12 VAC5-412, Regulations for Abortion Facilities.	T 000		
T 060	12 VAC5-412-180 A Personnel Each abortion facility shall have a staff that is adequately trained and capable of providing appropriate service and supervision to patients. The abortion facility shall develop, implement and maintain policies and procedures to ensure and document appropriate staffing by licensed clinicians based on the level, intensity, and scope of services provided. This RULE: is not met as evidenced by: Based on observations, staff interviews and review of facility documents, it was determined the facility failed to ensure that all staff were trained to provide appropriate services to patients. The findings included: Staff Member #1 (Alternate Administrator) had within his/her employee personnel file a job description for "Recovery Room Nurse". The job description evidenced, in part: Responsible for maintaining Recovery Room protocol and assuring patient safety and care. Reports to either the nursing supervisor or Administrator. Qualifications: 1. Current Virginia LPN (Licensed Practical Nurse) or RN (registered	T 060	This job title and description have been removed from Staff Member #1's responsibilities and file. We are no longer offering Conscious Sedation as an option for abortions.	1/8/19

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

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T 060	Continued From Page 1 Nurse) license. 2. Ability to work with diverse staff... Responsibilities: ...4. Monitor patients and records physical findings- bleeding, cramping, patient awareness, vitals ect...Charts appropriate information in patient's charts...8. Under physician standing orders or direct orders, provide and/or administer medications. 9. Is knowledgeable and able to use all emergency equipment. 10. Keeps daily count of narcotics used and is responsible for "daily count"..." On the bottom of the job description was a hand-written "addendum" which stated, "Effective July 8, 2015, (Name- Staff Member #1) has shown proficiency in the above tasks- after talking with (name of previous physician) (name) was allowed an exception from the requirements to be an LPN or RN and may work as a recovery room attendant (signature unrecognizable but was identified by Staff Member #1 as the signature of the previous medical director). Further review of the personnel record for Staff Member #1 revealed the staff member does not possess a license to practice nursing nor possesses a current CPR (cardiopulmonary resuscitation) certification. Staff Member #1 did have a "Certificate of Completion" for Administration of Moderate Sedation and Analgesics: Keeping the Patient Safe" completed on 10/16/18 which was approved by the Association of peri-operative Registered Nurses Incorporated. The Staff Member also had a "certificate of completion dated 9/18/18 from National Abortion Federation for "Managing Abortion Emergencies". On 10/29/18, the surveyor observed Staff Member #1 to be alone in the recovery room with 2 (two) patients from 10:53 a.m., until 11:03 a.m., while the Licensed Practical Nurse and Physician were	T 060		

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T 060	Continued From Page 2 in the procedure room with a patient receiving conscious sedation (Conscious sedation is an induced state of sedation characterized by minimally depressed consciousness such that the patient is able to continuously and independently maintain a patent (open) airway, retain protective reflexes (coughing, gagging) and remain responsive to verbal commands and physical stimulation.) via the intravenous (IV) route during the procedure. At 11:11 a.m., Staff Member #1 was again alone in the recovery room with 2 (two) patients, one of which was recovering from IV/conscious sedation, until 11:23 a.m., when the LPN returned from the procedure room. In an interview with Staff Member #1 on 10/29/18 at 1:05 p.m., regarding the recovery room monitoring, Staff Member #1 stated, "I had classes on anesthesia monitoring and safety from NAF." When asked whether the facility had a proficiency/competency for an unlicensed person to ensure their qualifications and proficiency, staff Member #1 stated, "I have the statement on my job description from (name of physician) that I'm qualified. We don't have any other training about that." The surveyor discussed the concerns related to the lack of documented proficiency training/competencies for an unlicensed person as well as the job description stating he/she had the ability to administer medications, count narcotics, and be able to operate emergency equipment which would have required a CPR or other demonstrated proficiency training. Staff Member #1 stated, "I did not even realize that medications were in there..." Concerns were discussed with Staff Member #1 on 10/29/18 at 3:15 p.m.	T 060		

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T 195	Continued From Page 3	T 195		
T 195	12 VAC5-412-220 B Infection Prevention Written infection prevention policies and procedures shall include, but not be limited to: 1. Procedures for screening incoming patients and visitors for acute infectious illnesses and applying appropriate measures to prevent transmission of community-acquired infection within the facility; 2. Training of all personnel in proper infection prevention techniques; 3. Correct hand-washing technique, including indications for use of soap and water and use of alcohol-based hand rubs; 4. Use of standard precautions; 5. Compliance with blood-borne pathogen requirements of the U.S. Occupational Safety & Health Administration; 6. Use of personal protective equipment; 7. Use of safe injection practices; 8. Plans for annual retraining of all personnel in infection prevention methods; 9. Procedures for monitoring staff adherence to recommended infection prevention practices; and 10. Procedures for documenting annual retraining of all staff in recommended infection prevention practices. This RULE: is not met as evidenced by: Based on observations, staff interview, and facility	T 195	1. All staff has been re-trained in proper use of personal protective equipment. 2. The ultrasound probe is now cleaned following the manufacturer's recommendation for disinfection. 3. All staff has been re-trained in proper cleaning and infection prevention techniques. 4. Pre-filled, sealed, and disposable eye wash products have been added to all procedure and scrub rooms as of 12/3/18.	12/17/18 12/03/18 12/17/18 12/03/18

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T 195	Continued From Page 4 document review, it was determined that facility staff failed to; 1. Ensure that staff deemed by the facility to have the potential for occupational exposure to blood and body fluids utilized personal protective equipment (PPE); 2. That manufacturer's recommendations for disinfection of semi-critical equipment were followed; 3. That staff followed procedures for proper cleaning of environmental surfaces in order to prevent transmission of dangerous pathogens, and; 4. That an eye wash station was immediately available to employees who had the potential for exposure to blood and body fluid splashes to the eyes, face, mucous membranes and/or chemicals which could expose workers to bloodborne pathogens, or cause serious eye irritation. The findings included: 1. Between 9:30 a.m. and 9:40 a.m., the surveyor observed a surgical procedure performed by SM #7, assisted by SM #5; SM #1 was also present as a breathing coach. SM's #1 and 5 wore scrub uniforms without PPE. SM#7 did not wear PPE over his/her scrubs, and did not wear eye or face protection, other than eyeglasses (which were not safety glasses as evidenced by the lack of side shields). At 1:40 p.m. on 10/29/18 the surveyor asked SM #1 if patients' HIV or hepatitis B (HBV) status was known at the time of the procedure; SM #1 stated "We don't know the HIV or HBV status of our patients, we use universal precautions". Universal	T 195		

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T 195	Continued From Page 5 precautions is an approach to infection control to treat all human blood and certain human body fluids as if they were known to be infectious for HIV, HBV and other bloodborne pathogens. (www.osha.gov) SM #1 was interviewed at 2:10 p.m. on 10/29/18, and a discussion was held related to SM #7's lack of PPE gown/eye and face protection observed during the performance of the surgical procedure as noted above. SM #1 stated "(Physician's name) says (he/she) doesn't need PPE because (he/she) doesn't anticipate exposure to blood/body fluids, and (he/she) wears glasses". OSHA (Occupational Safety and Health Administration) Fact Sheet entitled "Personal Protective Equipment (PPE) Reduces Exposure to Blood Borne Pathogens (BBP), accessed at www.osha.gov included the following information related to PPE: "When splashes, sprays, splatters, or droplets of blood or OPIM (other potentially infectious materials) pose a hazard to the eyes, nose or mouth, then masks in conjunction with eye protection (such as goggles or glasses with solid side shields) or chin-length face shields must be worn. Protection against exposure to the body is provided by protective clothing, such as gowns, aprons, lab coats, and similar garments. Surgical caps or hoods, and shoe covers or boots are needed when gross contamination is expected, such as during orthopedic surgery or autopsies. Exception to Use of Personal Protective Equipment: A worker may choose, temporarily and briefly, under rare and extraordinary circumstances, to forego use of personal protective equipment. It must be the worker's professional judgment that	T 195		

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T 195	Continued From Page 6 using the personal protective equipment would prevent the delivery of health care or public safety services or would pose an increased hazard to the safety of the worker or coworker. When such a situation occurs, the employer is required to investigate and document the circumstances to determine if there is a way to avoid it from happening again in the future. Employers and workers should be aware that this is not a blanket exemption to the requirement to use PPE. OSHA expects that this will be an extremely rare occurrence...". The surveyor asked for the facility's policy related to the use of PPE, and was given "Part 1 Bloodborne Pathogens Standard", which included the following information in part: "Model Exposure Control Plan/Policy: ...The following exposure control plan (ECP) is provided to eliminate or minimize occupational exposure to bloodborne pathogens in accordance with OSHA standard 29 CFR 1910.1030, {Occupational Exposure to Bloodborne Pathogens} must comply with the procedures and work practices outlined in this ECP.....This ECP includes: Determination of employee exposure...those employees who are determined to have occupational exposure to blood or other potentially infectious materials (OPIM)...". Employee Exposure Determination: Job Title/Location: Medical Staff/Procedure room Recovery room nurse/Recovery room Nursing supervisor/Throughout clinic Administrator/Throughout clinic Laboratory technician/Lab Sterilization technician/Sterilization room Hand holder/Procedure room The types of PPE available to employees are as follows: gloves, eye protection, face masks,	T 195		

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T 195	Continued From Page 7 aprons,gloves, goggles...". The surveyor was also given the facility's policy entitled "Personal Protective Equipment", which included the following information , in part: "Scope: All facility personnel. Purpose: To both protect personnel from infection, and to prevent personnel from spreading infections among patients. Policy: Personal Protective Equipment (PPE) will be worn to protect staff from exposure to or contact with infectious agents. Procedure: ...Wear a gown to protect skin and clothing during procedures or activities where contact with blood or body fluids is anticipated. Do not wear the same gown for the care of more than one patient. Wear mouth, nose, and eye protection during procedures that are likely to generate splashes or sprays of blood or other body fluids". 2. The surveyor interviewed SM #1 and a discussion was held related to cleaning and disinfection of the probe used for transvaginal ultrasound procedures on 10/29/18 at 10:00 a.m. . SM #4 stated "I scrub the surgical instruments with a brush then soak them in Alconox, scrub again, then rinse. They use the Protex spray to clean the ultrasound probe after the condom is removed". SM #1 was interviewed on 10/29/18 at 2:00 p.m. related to cleaning of the ultrasound probe, and he/she stated "The vaginal probe is the only semi-critical equipment in the room. There are no specific instructions for cleaning, other than for semi-critical equipment. With gloves on, after the ultrasound, the condom is removed, any extra ultrasound (U/S) gel gets wiped off with a paper towel, the probe is sprayed down with Protex, and then it dries. Usually, on top of that, while setting up for the next patient, the cords and keyboard get	T 195		

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T 195	Continued From Page 8 wiped with 1:10 bleach. The probe doesn't come in contact with non-intact skin due to the condom. (Physician's name) does the abdominal probe during procedures". The keyboard gets wiped down with alcohol after the last patient, because it dries faster than bleach water, if U/S is in the procedure room". The surveyor asked for the directions for use for the U/S probe, as well as the facility's procedure for cleaning and disinfection, and was given the following documents: 1) "GE Transducer Cleaning and Disinfection Guidelines", and 2) "GE healthcare: Ultrasound Transducer Compatible Cleaning, Disinfection & Gel Products", which included a list of approved cleaning, disinfectant, and gel products, listed Protex disinfectant spray, and included the following information: "Please read these special instructions: 1. Follow the manufacturer's instruction for use for each cleaning, disinfectant or gel product. 2. The information provided in this website is for low level disinfection. For high level disinfection please refer to the FDA website (//www.fda.gov). The complete list of cleaning agents reflects all cleaners GE has tested our probes with for global use...". Staff Member #1 also provided the surveyor with a copy of the directions from the bottle of Protex. The label included the following information: ""Use Protex Disinfectant Spray: As a disinfectant on hard, nonporous surfaces; for disinfection of ultrasound transducers, probes, mammography compressor plates and other hard nonporous surfaces; to clean and disinfect tables, chairs and countertops...". "Directions for use...Disinfection/Virucidal/Fungicidal Directions: Spray 6-8 inches from surface, until surfaces are	T 195		

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T 195	Continued From Page 9 thoroughly wet. Do not breathe spray. Treated surfaces must remain wet for 10 minutes. Wipe dry with a clean cloth, sponge, or mop or allow to air dry...Kills HIV-1 and HBV and HCV on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS) or Hepatitis B Virus (HBV) or Hepatitis C Virus (HCV). Special instructions for cleaning and decontamination against HIV-1 or HBV or HCV on surfaces/objects soiled with blood/body fluids...Cleaning procedure: Blood and other body fluids containing HIV or HBV or HCV must be thoroughly cleaned from surfaces and objects before application of Protex Disinfectant Spray; Contact time: Leave surface wet for 1 minute (60 seconds) for HIV-1 and 10 minutes for HBV and HCV. Use a 10 minute contact time for disinfection against all other viruses, bacteria and fungi claimed...". SM #1 was interviewed again after reading the information noted above. A discussion was held related to the Protex directions for use (DFU) provided to the surveyor, as listed above. SM #1 stated "No, we don't know HIV/HBV status of the patient's, we use universal precautions. No, we don't have a procedure, we just go by directions on the Protex". The surveyor read over the Protex DFU with SM #1, pointing out the directions related to pre-cleaning to prevent transmission of HIV-1, HCV, and HBV. SM #1 stated "Are you saying we have to clean before we use the	T 195		

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T 195	Continued From Page 10 Protex?" The surveyor asked for the policy related to cleaning the transvaginal ultrasound probe, and was given the facility's "Sterilization Policy", which stated the following in part: "...Semicritical items contact mucous membranes or non-intact skin. Semicritical items minimally require high-level disinfection using chemical disinfectants. High-level disinfection traditionally is defined as complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores. The TDA definition of high-level disinfection is a sterilant used for a shorter contact time to achieve a 6-log (10) kill of an appropriate Mycobacterium species. Cleaning followed by high-level disinfection should eliminate enough pathogens to prevent transmission of infection. This facility only uses one for {sic} of a semicritical item, which is the vaginal probe. The vaginal probe will never be used without a probe cover, first and foremost. Secondly, the vaginal probe will be treated with an appropriate high-level disinfectant between patients, after the removal and disposal of the probe cover...". 3. Between 9:30 a.m. and 9:40 a.m. the surveyor observed a surgical procedure. After the procedure, SM #5 cleaned the exam table with liquid in a spray bottle which was labeled 1:10 bleach solution; however, the counter top, suction machine, and flexible exam light used during the procedure were not cleaned. The facility's sterilization policy was reviewed, and included the following information: "Noncritical items are those that come in contact with intact skin but not mucous membranes. Intact skin acts as an effective barrier to most microorganisms; therefore, the sterility of items coming in contact with intact skin is "not critical." {sic} In this	T 195		

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T 195	Continued From Page 11 guideline, noncritical items are divided into noncritical patient care items and noncritical environmental surfaces 43,44. Examples of noncritical patient-care items are bedpans, blood pressure cuffs, crutches and computers 45. In contrast to critical and some semicritical items, most noncritical reusable items may be decontaminated where they are used and do not need to be transported to a central processing area. Virtually no risk has been documented for transmission of infectious agents to patients through noncritical items 37 when they are used as noncritical items and do not contact non-intact skin and/or mucous membranes. Noncritical environmental surfaces include exam room tables and any/all hard and flat surfaces in patient areas. Noncritical environmental surfaces frequently touched by hand potentially could contribute to secondary transmission by contaminating hands of health-care workers or by contacting medical equipment that subsequently contacts patients. Non critical surfaces should be cleaned at least weekly or when spills occur, and when these surfaces are visibly soiled. In these circumstances, a bleach solution of 1:10 should be used. Reference: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008, CDC". 4. At 10:00 a.m. on 10/29/18, Staff Member (SM) #4 was observed cleaning instruments used during surgical procedures with Alconox (a concentrated, anionic detergent used for manual cleaning) prior to autoclave sterilization. SM #4 was wearing PPE. The Material Safety Data Sheet (MSDS) for Alconox includes the following information in part: "Emergency eye wash fountains and safety	T 195		

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T 195	Continued From Page 12 showers should be available in the immediate vicinity of use or handling." As stated earlier, Protex is used for the cleaning of transvaginal probes. The MSDS for Protex states the following related to contact with eyes: "Eye contact: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice." At 2:20 p.m. on 10/29/18 the surveyor observed the facility's double bottle refillable emergency wash station located on the back of the door of the room where the autoclave was located. The bottles were empty, and not ready for use if needed. Concerns were discussed with SM #1, the alternate administrator, throughout the course of the survey, and again on 10/29/18 at 3:15 p.m.	T 195		
T 280	12 VAC5-412-250 D Anesthesia Services An abortion facility administering moderate sedation/conscious sedation shall maintain the following equipment, supplies and pharmacological agents, as required by 18 VAC 85-20-360 B: 1. Appropriate equipment to manage airways; 2. Drugs and equipment to treat shock and anaphylactic reactions; 3. Precordial stethoscope; 4. Pulse oximeter with appropriate alarms or an equivalent method of measuring oxygen	T 280	We are no longer offering Conscious Sedation as an option for abortions.	01/08/19

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(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	Continued From Page 13 saturation; 5. Continuous electrocardiograph; 6. Devices for measuring blood pressure, heart rate and respiratory rate; 7. Defibrillator; and 8. Accepted method of identifying and preventing the interchangeability of gases. This RULE: is not met as evidenced by: Based on observation and staff interview, it was determined the facility failed to; 1. Maintain a continuous electrocardiograph for the monitoring of patients receiving conscious sedation and; 2. Failed to have appropriate equipment (ambu bag) accessible for the management of the patient's airway. The findings included: 1. During a review of the facility's emergency equipment on 10/23/18 at 9:30 a.m., the survey team was not able to locate a continuous electrocardiograph monitor (cardiac/heart monitor) in the facility. On 10/29/18 at 10:50 a.m. when observing the set-up and monitoring of the procedure room for patient's receiving conscious sedation (IV- intravenous sedation), there was no cardiac monitor available. Two (2) patients were scheduled for and received conscious sedation during their procedure (Patient #13 and Patient #15).	T 280		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AF-0005	A. BUILDING _____ B. WING _____	10/29/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A CAPITAL WOMENS HEALTH CLINIC	1511 STARLING DRIVE HENRICO, VA 23229

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T 280	Continued From Page 14 On 10/29/18 at 3:00 p.m. the survey team discussed the observation with Staff Member #1 (Alternate Administrator). Staff Member #1 stated, "We do not have a heart (cardiac) monitor, but we do have an AED (Automated External Defibrillator) but we have never used it and it does not print out anything." According to the American Heart Association AED Implementation (cpr.heart.org), the AED is used in the event of an emergency and not as a monitoring device. It will automatically analyze the heart rhythm (no picture or strip) of the victim and inform the rescuer, whether shocks are indicated. A shock is only indicated if the victim's heart is in ventricular fibrillation. If you get a "no shock" message from the AED it can mean one of three things: the victim that you thought was pulseless does indeed have a pulse, the victim has now regained a pulse, or the victim is pulseless but is not in a "shockable" rhythm (i.e. not ventricular fibrillation- a very rapid uncoordinated fluttering contractions of the ventricles of the heart resulting in loss of synchronization between the heart heat and the pulse beat. Merriam Webster's Medical Dictionary). On 10/29/18 at 11:30 a.m., Staff Member # 7 (Physician/Medical Director) stated, "No. We don't have continuous monitoring. We don't need it. We have an AED." 2. During the inspection of the facility emergency equipment on 10/23/18 at 9:30 a.m., the survey team was not able to locate an ambu bag in the area for emergency equipment. On 10/29/18 at 3:15 p.m. in a discussion of the observations/findings with Staff Member #1 (Alternate Administrator), Staff Member #1 stated, "I think we have an ambu bag somewhere; I just have to find it." Staff Member #1 picked up a packaged hand-held suction device and asked, "Is this it?" At 3:30 p.m., Staff Member #1 stated, "I	T 280		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AF-0005	A. BUILDING _____ B. WING _____	10/29/2018

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T 280	Continued From Page 15 found the bag. I had to search for it. It was in (Name of Administrator Staff Member #2) office. (He/She) must have had it in (his/her) office when we had the NAF survey a few weeks ago." The survey team discussed with Staff Member #1 the concern that the staff was not aware of the location of the bag and that during procedures on 10/29/18, the staff would not have had access to the bag, should it have been needed in an emergency situation. Concerns were discussed with SM #1, the alternate administrator, throughout the course of the survey, and again with SM #1 on 10/29/18 at 3:15 p.m. An electrocardiograph is an instrument for recording the changes of electrical potential occurring during the heartbeat (cardiac/heart monitor). Conscious sedation is an induced state of sedation characterized by minimally depressed consciousness such that the patient is able to continuously and independently maintain a patent (open) airway, retain protective reflexes (coughing, gagging) and remain responsive to verbal commands and physical stimulation. Ambu-bag is used for artificial respiration and is a device consisting of a bag that is squeezed by hand. (Definitions from Merriam-Webster's Medical Dictionary New Edition, Merriam Webster Incorporated)	T 280		

1/8/19

A Capital Women's Health Clinic
1511 Starling Drive • Richmond, Virginia 23229
Telephone (804) 754-1928
1-800-254-4479

January 8, 2019

Dear Dr. Middlebrooks,

Enclosed is our plan of correction following the Biennial Licensure Inspection in October of 2018.

Sincerely,

Diane Derzis,

Administrator
A Capital Women's Health Clinic