Approved April 11, 2016

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FORM APPROVED

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0009	A. BUILDING: _____ B. WING _____	01/29/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF WINSTON SALEM	3000 MAPLEWOOD AVE STE 112 WINSTON-SALEM, NC 27103

(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
E 137	.0305(A) MEDICAL RECORDS 10A-14E .0305 (a) A complete and permanent record shall be maintained for all patients including the date and time of admission and discharge; the full and true name; address; date of birth; nearest of kin; diagnoses; duration of pregnancy; condition on admission and discharge; referring and attending physician; a witnessed, voluntarily-signed consent for each surgery or procedure and signature of the physician performing the procedure; and the physician's authenticated history and physical examination including identification of pre- existing or current illnesses, drug sensitivities or other idiosyncrasies having a bearing on the operative procedure or anesthetic to be administered. This Rule is not met as evidenced by: Based on policy review, medical record reviews and staff interview; the clinic staff failed to ensure the physician performing the surgical procedure signed and witnessed the voluntarily-consent for treatment for 1 of 7 patients having a surgical abortion (SAB) procedure. (Patient #21). The findings include: Review of the clinic's policy, "Surgical Abortion Policy" with a revision date of June 2012 revealed with SAB, the patient having the procedure and the physician performing the procedure each must sign the witnessed voluntary consent. Medical record review conducted January 29, 2016 with the HCM (Health Center Manager)	E 137	137 PPSAT requires that all physicians who perform abortions confirm patient informed consent. This is documented on the CO-015 NC Abortion Patient and Physician Informed Consent form. On February 29, 2016, the HCM reviewed this policy and protocol with the physician whose chart was cited in the inspection. In addition, the Affiliate Medical Director will review this with all physicians by March 31, 2016 and the HCM or designee will monitor daily to ensure both patient and physician signatures are present on consent forms prior to the procedure. This monitoring will continue for a minimum of 3 months and until 100% compliance is achieved.	2/29/16 3/31/16

Division of Health Service Regulation

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Alma Black — TITLE: President + CEO — (X6) DATE: April 5, 2016

STATE FORM 6899 — CVD211 — If continuation sheet 1 of 11

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E 137	Continued From page 1 revealed Patient #21 had a SAB performed on October 13, 2015. Review revealed the patient signed the consent. Further review revealed the physician performing the procedure failed to signed the consent. Interview with the HCM during medical record review revealed the physician performing the surgical procedure failed to sign the consent treatment.	E 137		
E 141	.0305(E) MEDICAL RECORDS 10A-14E .0305 (e) The facility shall maintain a daily procedure log of all patients receiving abortion services. This log shall contain at least patient name, estimated length of gestation, type of procedure, name of physician, name of RN on duty, and date and time of procedure. This Rule is not met as evidenced by: Based on medical record review, observation, and staff interview, the clinic staff failed to maintain an accurate daily procedure log for 3 of 23 days. The findings include: Review on 01/29/2016 of the clinic's procedure log dated 11/03/2015 revealed the estimated length of gestation (ELG) and time of procedure was not listed for 15 of 15 patients receiving services. Review of the procedure log dated 01/19/2016 revealed the ELG was not listed for 16 of 16 patients receiving services. Review of the procedure log dated 01/26/2016 revealed the ELG was not listed for 8 of 15 patients receiving services. Interview on 01/29/2016 at 1530 with the clinic's	E 141	At the time of inspection, it was identified that the HCM was keeping the incorrect version of patient logs. She was immediately trained in the requirements for AB log, and this has been filled out completely and correctly since that time. Regional Director has been monitoring this for compliance since inspection and all logs are accurate and complete. To avoid future confusion, PPSAT has created an EHR report that includes all state-required information. By April 31, 2016, all NC sites will run this report on each AB day and store the report as a paper AB Procedure Log. Regional Director will continue to monitor weekly until consistent compliance has been demonstrated.	1.29.16 4.31.16

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E 141	Continued From page 2 Regional Director revealed deficiencies with the procedure log were identified October 2015 and a request to automatically populate the ELG following ultrasound results was submitted to the Regional Director of Patient Services. Interview revealed an internal auditing process was initated during the interim; however, the Regional Director stated, the clinic's Health Service Manager "did not receive the proper training and it was just poor training on my part." Interview revealed two logs are maintained, one at the reception desk and one in the procedure area of the clinic. Interview revealed the Health Service Manager was conducting audits on the incorrect log, skewing the overall data. Interview revealed that although an improvement initiative was implemented, "We continue to have deficiencies."	E 141		
E 149	.0306(D) PERSONNEL RECORDS 10A-14E .0306 (d) The governing authority shall be responsible for implementing health standards for employees, as well as contractual employees, which are consistent with recognized professional practices for the prevention and transmission of communicable diseases. This Rule is not met as evidenced by: Based on credential file reviews, physician schedule review, and staff interviews; the clinic staff failed to ensure annual registration with the North Carolina Board of Pharmacy (NCBOP) for 1 of 5 dispensing physicians (Physician #1) performing medical abortions (MAB). The findings include:	E 149	NC BOP Physician Dispensing License for physician #1 was applied for on February 2, 2016, and is now in place. PPSAT Director of Human Resources or designee tracks all credentialing and licensing centrally, with reminders sent to staff and managers when renewals are due. The HCM will work with the HR department to verify all physicians have up-to-date licenses on file at all times.	2.2.16

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E 149	Continued From page 3 Review of credential files conducted January 29, 2016 revealed Physician #1, was employed with the clinic on an as needed basis. Review revealed the physician's registration with the NCBOP as a dispensing physician expired December 31, 2015. Review of Physician #1's schedule conducted January 29, 2016 revealed the physician last worked at the clinic on January 2, 2016 and performed six (6) MABs. Interview conducted January 29, 2016 with the Health Center Manager (HCM) during credential file reviews revealed the physician would explain the MAB process to the patient. Further interview revealed the physician would dispense 200 mg (milligrams) of Mifeprex (medication used to terminate a pregnancy) for the patient to take in clinic followed by 200 mcg (micrograms) of Misoprostol (medication used to terminate a pregnancy) for the patient to take 24-48 hours at home, after discharge from the clinic. Interview conducted January 29, 2016 at 1658 with the Vice President of Patient Services revealed Corporate Human Resources failed to ensure Physician #1 had annual registration with the NCBOP.	E 149		
E 151	.0307 NURSING SERVICE 10A-14E .0307 (a) There shall be a minimum of one registered nurse with experience in post-operative or post-partum care who is currently licensed to practice professional nursing in North Carolina on duty in the clinic at all times when patients	E 151	PPSAT has modified its processes such that all medications used for abortion procedures are now drawn up by RN on duty. Medications, once drawn up by RN, are kept under RN's direct control until the medication is needed for a patient. The new process was reviewed with all RNs and staff during February 1, 2016 Health Center meeting. HCM will monitor this process during AB services.	2.1.16

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E 151	Continued From page 4 are in the facility. (b) There shall be supporting personnel sufficient to meet patient needs and to provide safe patient care. This Rule is not met as evidenced by: Based on clinic policy review, observation, and staff interview, the clinic staff failed to ensure medication preparation competency for 1 of 1 Health Care Assistants (HCAs) (Staff #2). The findings include: Review on 01/29/2016 of the clinic's "Infection Prevention Manual, Safe Injection Practices" policy with a review date of October 2013 revealed "All HCP (health care personnel) will be properly trained and privileged before performing any injection practices...." Observation on 01/29/2016 at 1300 revealed a filled syringe labeled 1% Lidocaine lying on the counter in the clinic's sterilization room labeled "Reprocessing Room #2." Observation revealed the syringe was labeled with Staff #2's initials along with the date and time. Observation revealed a multidose vial labeled 1% Lidocaine 10mg/ml (milligram/milliliter: unit of measurement) also sitting on the counter along side the filled syringe. Observation revealed that although the multidose vial and filled syringe were noted in an area patients are not allowed, the medication was not secured to prevent possible tampering or contamination. Interview on 01/29/2016 at 1600 with the clinic's Regional Director revealed all direct care staff receive training on safe injection practices, including Staff #2. Interview revealed that although all direct care staff receive training on safe injection practices, there is no formal competency evaluation performed. Interview	E 151		

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E 151	Continued From page 5 revealed that once the nurse demonstrates how to draw medications up, the HCA is then allowed to perform the same, independently, without documentation of observation or ongoing evaluation of competency.	E 151		
E 156	.0310 EMERGENCY BACK-UP SERVICES 10A-14E .0310 The facility shall provide intervention for emergency situations. These provisions shall include but are not limited to: (1) Basic cardio-pulmonary life support; (2) Emergency protocols for: (a) Venous access supplies, (b) Air-way support and oxygen, (c) Bag-valve mask unit with oxygen reservoir, and (d) Suction machine; (3) Emergency lighting available in the operating room; and (4) Ultrasound equipment. This Rule is not met as evidenced by: Based on review of the crash cart checklist, manufacturer's recommendations, observation, and staff interview, the clinic staff failed to ensure functional equipment was available for use during medical emergencies. The findings include: Review on 01/28/2016 of the clinic's "Monthly Emergency Box Inventory for Centers Providing Surgical Services" (emergency equipment checklist) revealed periodic checks of the suction machine and AED functionality are not required components of the monthly crash cart inspection. Review on 01/29/2016 of the manufacturer's recommendations for the AED "Set-up and	E 156	As of February 1, 2016, functional check of AED and oral suction machines has been added to the monthly WS Emergency Cart Checklist (see attached). This checklist is completed monthly by the clinician, who will demonstrate functionality by turning on the machines and confirming appropriate start-up.	2.1.16

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E 156	Continued From page 6 Check-out Procedure" revealed "...7. Check AED Plus unit periodically to ensure that green check symbol appears in status indicator window..." Observation on 01/28/2016 at 1300 of the clinic's crash cart revealed a suction machine and an AED (Automatic External Defibrillator). Interview on 01/28/2016 at 1300 with the clinic's Regional Director and Vice President (VP) of Patient Services revealed testing of the suction machine functionality is not a requirement. The AED was added to the emergency medical equipment in October to meet the new regulatory requirements." Interview revealed, "I know we aren't checking it (AED) and to be honest, we haven't looked at the manufacturer recommendations or developed a protocol. We are going to have to determine how often checks should be done. What does periodic mean? Maybe every six (6) months or maybe we need to do it every month. We will have to come together and decide on that." Interview revealed Management had not yet had time to implement protocols for checking the AED and added both the AED and suction machine functionality would become part of the emergency equipment inspections.	E 156		
E 165	.0314 CLEANING OF MATERIALS AND EQUIPMENT 10A-14E .0314 (a) All supplies and equipment used in patient care shall be properly cleaned or sterilized between use for different patients. (b) Methods of cleaning, handling, and storing all supplies and equipment shall be such as to prevent the transmission of infection	E 165		

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E 165	Continued From page 7 through their use. This Rule is not met as evidenced by: Based on clinic policy review, personnel record review, observation, and staff interview, the clinic staff failed to ensure safe Infection Control (IC) practices during disinfection of equipment. The findings include: Review of the clinic's "Infection Prevention Manual" last reviewed October 2013 revealed personal protective equipment (PPE) is required when performing invasive procedures and/or anytime there is potential exposure to blood or body fluids. Review revealed PPE is required when cleaning and disinfecting medical instruments and/or equipment. Review on 01/29/2016 of Staff #1's personnel record revealed no evidence of IC training or High Level Disinfection (HLD) process. Observation on 01/29/2016 at 1215 revealed Staff #1 in the clinic's disinfection room (Reprocessing Room #1) with disposable lab coat, disposable shoe covers, face shield with mask, and gloves. Observation revealed a second disposable lab coat hanging on the back of the reprocessing room door, along with three, yellow cloth-like aprons. The disposable lab coat hanging on the door was also used during the disinfection observation. Observation revealed there was no additional PPE available for use aside from that being worn. Observation on 01/29/2015 at 1215 revealed Staff #1 verbally designated one side of the sink as "dirty" and the other as "clean." Observation revealed dirty medical instrumentation passed over "clean/disinfected" waiting to be wrapped for the sterilization process. Continued observation revealed Staff #1 did not remove the disposable shoe covers prior to leaving the processing area and placed the face shield with the face mask on	E 165	PPSAT requires and provides initial and annual infection prevention training. As of February 15, 2016, all correct PPE is available directly in the processing room, including liquid-repellent disposable gowns, gloves, shoe covers, and face masks. All non-disposable gowns/aprons have been removed from the facility. The HCM and employees are trained on the correct use of PPE and annual reviews of infection prevention practices are done with all staff. WS staff reviewed the Infection Prevention Manual again on February 1, 2016. Review of PPE included training on appropriate disposal after one use and prior to leaving dirty areas as well as employee requirement to use appropriate PPE (see PPSAT PPE use guidelines). Appropriate use of PPE by physicians is monitored at least annually as part of clinical evaluations. In addition, PPSAT is in process of revising the Infection Prevention Manual. This will be in place by July 1, 2016 and will include initial and annual documentation of competencies in infection control procedures. Compliance with required training is also monitored by the PPSAT training department.	2.15.16 2.1.16 7.1.16

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E 165	Continued From page 8 the shelf. Observation revealed staff did not follow safe IC practices to prevent the spread of infection. Observation on 01/29/2016 at 1455 revealed Staff #1 and Staff #2 in the clinic's Reprocessing Room #1 (disinfection room) cleaning medical equipment. Observation revealed Staff #1 was at the sink with a cloth-like apron, disposable shoe covers, face shield with mask and gloves washing medical equipment. Observation revealed Staff #1 failed to don disposable, no absorbent PPE. Interview on 01/29/2016 at 1215 with Staff #1 revealed the yellow cloth-like aprons are not used during the "cleaning/disinfection" process and Staff #1 was not sure why the cloth-like aprons were hanging on the back of the door. Interview revealed disposable lab coats/gowns "are usually kept in here." Interview revealed Staff #1 got the disposable lab coat and face shield with the mask worn during observations at 1215 from the shelf over the reprocessing sink had not considered contamination of the mask worn during the cleaning/disinfection process. Interview on 01/29/2016 at 1715 with the clinic's Regional Director and Vice President (VP) of Patient Services during the exit conference revealed Regional Director questioned whether it was not the employee's responsibility to ensure proper use of Personal Protective Equipment (PPE). Interview revealed the clinic's Regional Director stated "I thought we (clinic administration) only had to provide PPE and it's up to the employee to decide to wear it or not." Interview revealed, "A lot of our docs don't use masks during procedures. We do not monitor the use of PPE."	E 165	PPSAT has created a standard flow for all dirty supplies and instruments through the processing room to ensure that there is no contamination of clean instruments. (See the attached flow sheet.) All staff will be trained on this flow by March 31, 2016, and this visual representation will be prominently posted within the processing room for easy reference. This will be monitored daily by the HCM or designee on clinic days.	3.31.16
E 166	.0315 HOUSEKEEPING	E 166		

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E 166	Continued From page 9 10A-14E .0315 Abortion clinics shall meet the standards for sanitation as required by the Division of Environmental Health in the rules and regulations governing the sanitation of private hospitals, nursing and rest homes, sanitariums, sanatoriums, and educational and other institutions, 10 NCAC 10A, with special emphasis on the following: (1) There must be cleaning of such a frequency as to maintain the floors, walls, woodwork and windows in a manner to minimize the spread of dust particles in the atmosphere. Accumulated waste material must be removed at least daily. (2) The premises must be kept free from rodents and insect infestation. (3) Bath and toilet facilities must be maintained in a clean and sanitary condition at all times. (4) Linen which comes directly in contact with the patient shall be provided as needed for each individual patient. No such linen shall be interchangeable from one patient to another before being properly cleaned, sterilized, or laundered. This Rule is not met as evidenced by: Based on observation and staff interview, the clinic failed to separate biohazardous waste from patient scrubs, staff's personal belongings, and unused supplies allocated for another clinic and to empty accumulated waste on a daily basis. The findings include: Observation on 01/28/2016 at 1145 revealed a small storage room with three (3) large, full sharps containers and two (2) mid-size full sharps containers marked with biohazardous signage,	E 166	As of February 1, 2016, the HCM has designated the cited closet for janitorial supplies. The scrubs, which are used for staff only, are now being stored in the clinician office. No other staff personal items are being kept in that closet and it has a sign clearly identifying it as the "Janitor's Closet." This closet is being used to store the janitorial supplies, including the trash can and other excess cleaning supplies. On February 1, 2016, center staff were retrained that used biohazard containers, once full, are not to be stored in any location other than the processing room. HCM is ensuring that trash is taken out nightly and monitoring the clinic regularly to ensure the proper storage of supplies and confirm that there is no opportunity for cross-contamination between biohazard containers and clean supplies or staff personal items.	2.1.16

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E 166	Continued From page 10 large (approximate 20 gallon) trash can with a full, tied trash bag with another small bag on top, a shipping box just behind the sharps containers, alongside the trash can with three (3), unopened gallons of Cidex (disinfectant) in the shipping box sitting atop a close biohazard box, scrub pants and shirts hanging beside the trash can, and staff personal belongings (purses) sitting atop items in the floor, and coats hanging on the wall. Interview on 01/28/2016 at 1145 with the clinic's Regional Director revealed the sharps containers "should not be there" and the accumulated waste "should have been emptied last night." Interview revealed the shipping box containing three (3) gallons of Cidex were to be sent to another clinic and "just haven't been sent yet." Interview revealed the scrub pants and shirts are for patient use as needed and that staff also use the room to store personal belongings. Interview revealed biohazardous waste is picked up monthly with 12/15/2015 as the last date of service. Interview revealed that due to limited space, improvisions had to be made and clinic staff "have to use what we do have."	E 166		

Monthly Emergency Box Inventory for Centers Providing Surgical Services

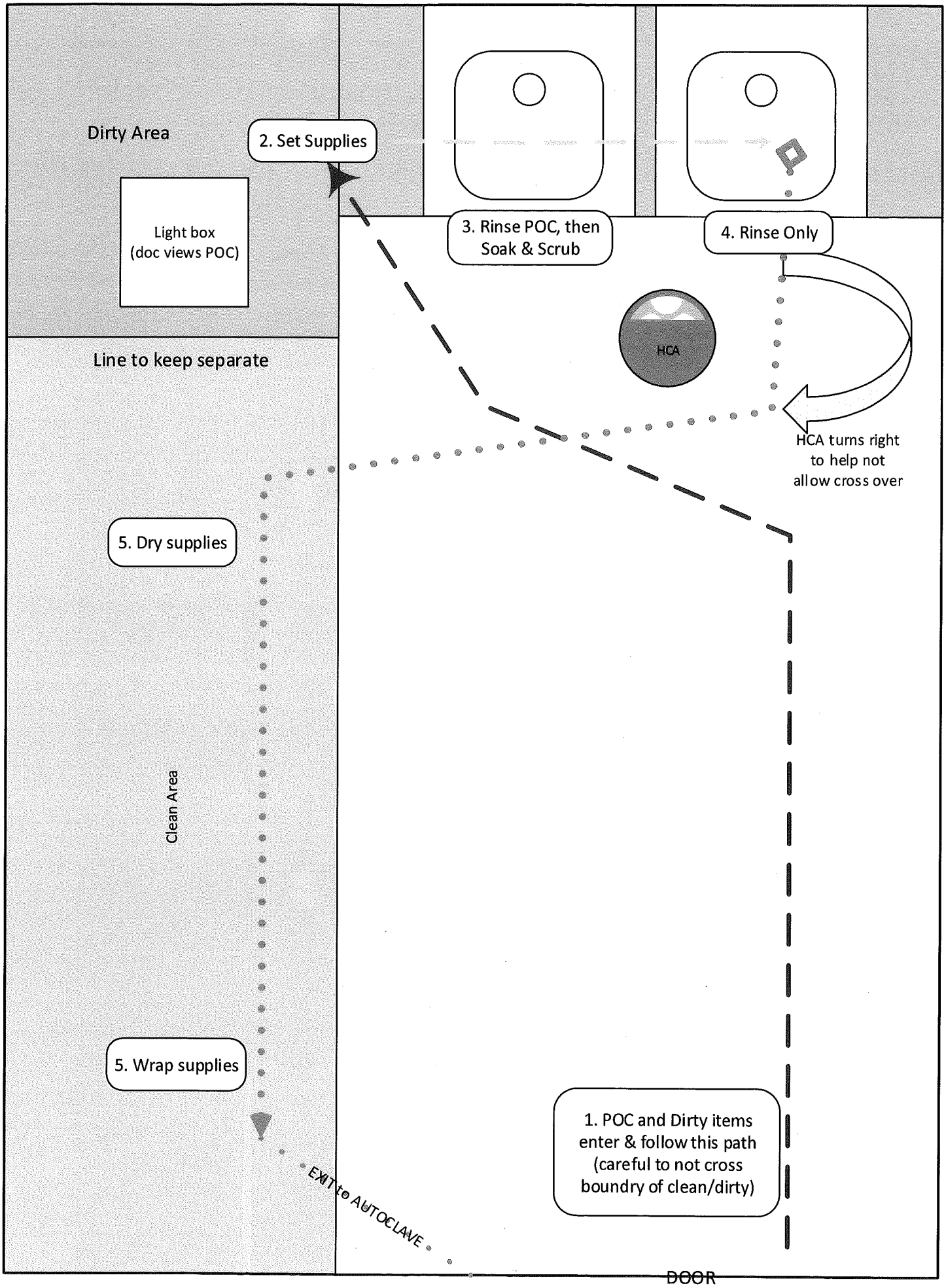
Center Name	Year
Affiliate Name	Phone
Address and City	Zip

Medication and Suggest Amounts		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Ammonia Capsules Also in surgical rooms	6												
Atropine Sulfate 0.4 mg/ml Expires: Expires:	4												
Diphenhydramine (Benadryl) 50 mg caps/tabs Expires: Expires	6												
Diphenhydramine (Benadryl) IM 50 mg/ml Expires: Expires:	4												
Misoprostol (Cytotec) 200mcg Per tab Expires:	1 btl												
Epinephrine 1:1000 (1 mg/ml) 1 ml vial Expires: Expires:	4												
Epinephrine 1:10,000 Prefilled carpujet Expires: Expires:	4												
Methylergonovine (Methergine) 0.2mg/ml vial Expires:	10												
Naloxone (Narcan) 0.4 mg/ml Expires: Expires:	2												
Oxytocin (Pitocin) 10units/ml Expires: Expires:	10												

Medication and Suggest Amounts		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Flumazenil (Romazicon) 10 mg/ml Expires: Expires:	1												
Diazapam (Valium) 10mg per tablet Expires:	1												
Diazapam (Valium) 10mg/2ml vial or 5mg/ml vial Expires:	2												
Pitressin (Vasopressin) 20 units/ml Expires: Expires:	10												
Other Med:													
Safety Needles/Syringes													
3cc syringes with 21g needles	5												
TB syringes (sc Epi 1:1000)	5												
Anglocaths – 18, 20, 22	5 ea												
IV tubing	5 set												
IV solutions – LR/NS Expires:	2 bags												
Other Supplies													
Sterile 4 x 4 gauze	4												
Tape													
Non-Rebreather Face Mask	2												
Nasal cannula	2												
One-way valve mask	1												
Oxygen tank with liter meter >3/4 full	1												
1 airway set (at MD discretion)	1												
Adult Bag Valve Mask with reservoir	1												
Alcohol preps	10												
Exam gloves (ensure availability of latex-free)	10												
AED functioning	1												
Oral suction machine functioning	1												

Note: All emergency medications must be ordered 2 months prior to expiration date.

Signature	Date


Dirty Area
2. Set Supplies
Light box
(doc views POC)
3. Rinse POC, then
Soak & Scrub
4. Rinse Only
HCA
Line to keep separate
HCA turns right
to help not
allow cross over
5. Dry supplies
Clean Area
5. Wrap supplies
1. POC and Dirty items
enter & follow this path
(careful to not cross
boundry of clean/dirty)
EXIT to AUTOCLAVE
DOOR