STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	BO0004642	A. BUILDING: _____ B. WING _____	C 03/29/2019

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DELTA CLINIC OF BATON ROUGE, INC	756 COLONIAL DRIVE BATON ROUGE, LA 70806

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S 000	Initial Comments Complaint survey #LA0051232 Abbreviations: BP - blood pressure bpm - beats per minute cc - milliliter cm - centimeter D&C - Dilation and Curettage D&E - Dilation and Evacuation DON - Director of Nursing ga - gauge gm/dL - grams per deciliter H/H - Hemoglobin and Hematocrit Hct - Hematocrit Hgb - Hemoglobin IJ - Immediate Jeopardy IM - intramuscular inj - injection IV - intravenous LPN - Licensed Practical Nurse mcg - micrograms MD - Medical Doctor mg - milligram mil/uL - millions per microliter ml - milliliters NS - normal saline OAF- Outpatient Abortion Facility P&P - Policy & Procedure po - per os/by mouth POC - Products of Conception POR - Plan Of Removal PR - per rectum PRBC - Packed Red Blood Cells RBC - Red Blood Cells s/p - status post SPO2 - oxygen saturation u - unit V/S - Vital Signs yo - year old	S 000		

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S 137	4423 C - c -f - i-iv Staffing Requirements, Qualifications (i). identifying emergency medical equipment and medications that will be used to provide for basic life support until emergency medical services arrive and assume care; (ii). identifying and ensuring that a supply of emergency drugs for stabilizing and/or treating medical and surgical complications are maintained on the licensed premises; (iii). identifying and ensuring that each patient, before an abortion is performed or induced, is given by the physician performing or inducing the abortion, a telephone number of the hospital nearest to the home of the pregnant woman at which an emergency arising from the abortion would be treated; and This Rule is not met as evidenced by: Based on observations, review of records, and staff interviews, the Medical Director failed in the responsibility of identifying and ensuring that a supply of emergency medications and medical equipment for stabilizing and/or treating medical and surgical complications was maintained on the licensed premises. This failed practice affected 1 (Patient #1) of 3 (Patients #1, #2, and #3) sampled patients and had the potential of affecting 3 of 3 (Patients #1 - #3) sampled patients who had a surgical abortion procedure at the OAF. Findings: On 3/18/19 at 1:35 PM, S5Adm and S6Board	S 137		

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S 137	Continued From page 2	S 137		

Member verified that Patient #1 underwent a surgical abortion procedure on 3/15/2019 and experienced heavy blood loss at the time. The two staff continued and said the OAF failed to have available the necessary IV fluids to help stabilize the Patient at the time, 911 was called, and the Patient was transported out by ambulance to an acute care hospital for treatment.

During interview with S5Adm on 3/28/2019 at 11:05 AM, S5Adm presented a POR, done in response to another cited deficiency, which included the Policy and Procedure Managing Hemorrhage. The Interventions section of this Policy and Procedure documented medications and other supplies to be used in such procedures and documented interventions to be performed by Administrative, Nursing, and Physician staff. The Physician intervention for hemorrhage secondary to Uterine Atony and/or retained tissue/products of conception included in-part: Tamponade with sterile gauze and Bakri Balloon. When questioned about the use and availability of the Bakri Balloon as was documented on the Policy and Procedure, S5Adm affirmed that the OAF had no Bakri Balloon on site or available for use by a physician if needed. S5Adm said the OAF would have to order one.

On 3/28/19 at 12:20 PM, S5Adm presented two additional forms which were explained to be the list of emergency medications and supplies that the Medical Director approved to be kept on site. S5Adm explained that the form labeled as List of Emergency Equipment was the list of equipment the Medical Director approved to be kept on site. This form included a Crash KIT (crash cart). The next form labeled as STAT KIT ACLS was explained as the Medical Director's inventory list

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S 137	Continued From page 3 of emergency medications and supplies which were kept in the STAT KIT (crash cart). On 3/28/2019 at 12:27 PM, a comparison of the OAF's STAT KIT (crash cart) inventory with the STAT KIT ACLS (inventory list of emergency medications to be kept in the cart) was performed with S4LPN. S4LPN verified that the inventory list included two vials of Midazolam (Versed) 2mg injection and two vials of Adenosine 3mg/4 ml. S4LPN verified that the STAT KIT (crash cart) had no Midazolam (Versed) available and only one vial of Adenosine which was expired as of 02/2019. An interview and review of the OAF's presented Policy and Procedures and associated list of emergency medications and emergency supplies was conducted with S3MD/Medical Director on 3/29/2019 at 11:10 AM. S3MD affirmed that he was involved with the OAF's POR and Policy and Procedures. S3MD acknowledged that the OAF's lists of emergency medications and supplies were approved and said that they were the responsibility of the administrative staff to maintain. When asked about the potential use of a Bakri Balloon for an intervention in a patient who experienced hemorrhaging secondary to uterine atony and/or retained tissue/products of conception as was documented on the OAF's Policy and Procedure Managing Hemorrhage, S3MD said that he would not use a Bakri Balloon. S3MD was asked about the inventory list containing the OAF's emergency medications, the lack of Midazolam (Versed) and only one of two vials of Adenosine, which was expired, present on the crash cart. S3MD replied that he would not use Adenosine. S3MD said the Adenosine would be for the 911 response personnel to use. S3MD said the medications should be checked and	S 137		

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S 137	Continued From page 4 should not have been expired. S3MD said he was aware that the Midazolam (Versed) was on back-order and was not aware of another medication to use in place of the Midazolam (Versed). S3MD was asked about the OAF's supply of IV fluids for stabilizing and/or treating medical and surgical complications should such complications present. S3MD said in the case of Patient #1, he assumed the OAF's administrative staff ensured IV fluids were available for use. S3MD acknowledged that the OAF's lists of emergency medications and supplies were approved and said that they were the responsibility of the administrative staff to maintain.	S 137		
S 205	4435 A-B Intra-operative Procedures A. The outpatient abortion facility shall ensure that emergency medical equipment and supplies as required by the governing body, medical director and medical staff are available for intra-operative care and shall include, but are not limited to: 1. surgical or gynecologic table; 2. surgical instrumentation; 3. emergency drugs for stabilizing and/or treating medical and surgical complications as approved by the medical director; 4. oxygen; 5. intravenous fluids; and 6. sterile dressing supplies. B. The outpatient abortion facility shall ensure that the medical equipment required for an abortion shall be maintained and immediately available to the physician in the procedure and/or post-anesthesia recovery area to provide emergency medical care and treatment.	S 205		

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This Rule is not met as evidenced by:
Based on interviews and record reviews, the outpatient abortion facility failed to ensure that emergency medical equipment and supplies were available for intra-operative and/or post-op care. This is evidenced by failure of the facility to have emergency intravenous fluids available for 1 (#1) of 3 (#1, #2, #3) patients sampled having surgical abortion procedures. Patient #1 experienced excessive bleeding and a decreased blood pressure and had to be transferred to a local hospital without having been given IV fluids by the OAF to help stabilize her condition. This deficient practice resulted in an Immediate Jeopardy situation.

Findings:

An Immediate Jeopardy situation was found to exist and notification was made to S1DirOperations on 3/15/19 at 4:40 p.m. The immediate crisis was that patients undergoing surgical abortions did not have necessary IV fluids to help stabilize them in the event of complications during procedures or post-operatively. On 3/15/19 Patient #1 was admitted for a surgical abortion. She had a history of five previous Cesarean Sections (C-Section) and one miscarriage with heavy bleeding post operatively. During the surgical abortion procedure Patient #1 began to have a decrease in blood pressure, heavy bleeding and speaking incoherently. The OAF did not have any IV fluids to administer to help stabilize Patient #1. When the OAF checked to see if they had any fluids they realized there were no fluids available. The OAF had no system in place to replace/restock IV

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S 205	Continued From page 6 fluids that were used and/or to check to ensure IV fluids were available prior to the start of a surgical abortion procedure in the event of a complication. Patient #3 was currently having a surgical abortion procedure and Patient #2's surgical abortion procedure was to follow after Patient #3's was completed. Review of Patient #1's OAF medical record revealed she had arrived at the facility on 3/15/19 for a surgical abortion procedure. Further review revealed she had previously had 5 Cesarean Sections and 1 miscarriage. Review of Patient #1's OAF Operative Notes revealed the surgical abortion procedure began at 12:18 p.m. and ended at 1:02 p.m. Documentation revealed after Patient #1's placenta was extracted she began to have heavy supra-cervical bleeding. Patient #1's blood loss during the procedure was documented as 250cc-350cc. Patient #1's blood pressure was documented as 148/90 with a pulse of 92 bpm at the beginning of the procedure at 12:19 p.m. Patient #1's blood pressure upon transfer to a local hospital at 2:15 p.m. was documented as 100/70 with a pulse of 104 bpm. S3MD documented that, "Patient #1's affect was not to my satisfaction and I felt she needed fluids or blood." S3MD also documented Emergency Medical Services (local ambulance) had been called. There was no documentation that IV fluids had been administered. Review of Patient #1's OAF Recovery Room record revealed at 1:06 p.m. her blood pressure was documented as being 90/55. Further review revealed in the nurse's notes Patient #1 was documented as being semiconscious with a moderate amount of blood loss resulting in 911	S 205		

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S 205	Continued From page 7 being called by S2DON. In an interview on 3/15/19 at 4:17 p.m. with S1DirOperations, she said there had been an ambulance at the facility earlier in the day. She said Patient #1 had lost a heavy blood volume after her procedure. S1DirOperations said S3MD had been concerned over Patient #1's blood volume loss. She also said Patient #1 had a history of heavy bleeding after a previous miscarriage. She said Patient #1 also had 5 previous cesarean sections. In an interview on 3/15/19 at 4:20 p.m. with S2DON, she said Patient #1 had been transferred out to a local hospital at about 2:15 p.m. to receive IV fluids and possibly blood. She said Patient #1 had a significant blood loss during her procedure. When asked if they give blood at the OAF she said no. When asked if they give fluids at the OAF, she said normally they did but they did not realize they had ran out of IV fluids until Patient #1 needed them. She said they typically have 3 bags of 1 Liter Normal Saline in the crash cart but there was none when she checked. She said there was no current process for restocking the fluids when they were used. S2DON said Patient #1's blood pressure had dropped to 78/56 at one point and her pressure was 100/70 when she was transferred to a hospital. In an interview on 3/15/19 at 4:30 p.m. with S1DirOperations, she said Patient #3 was currently in the middle of a surgical abortion procedure and Patient #2 was to have a surgical abortion procedure after Patient #3. When asked the process for checking the crash cart for fluids she replied it was checked regularly but she was not sure how often.	S 205		

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S 205	Continued From page 8 In an interview on 3/15/19 at 4:35 p.m. with S2DON, she said the crash cart was checked for expiration dates monthly, but she did not know what the system was for replacing the normal saline bags of IV fluids when some had been used. A copy of the facility's policy for replacing emergency fluids was requested 3 times but none was provided. As of 3/15/19 at 5:45 p.m. the IJ remained in place. S1DirOperations was instructed and acknowledged that the OAF was not to perform any surgical abortion procedures until the IJ had been removed. An onsite revisit was conducted on 03/18/2019 at 1:35 p.m. S5Adm and S6Board Member presented the first POR dated 03/15/2019 which included in-part: the OAF will keep an adequate amount of IV fluids and necessary IV start kits on hand. ..the nurse on duty will check the stock of IV fluids during first work day of the week to ensure that proper amounts of IV fluids are readily available on site. S5Adm verified that the POR did not address what was an adequate amount of IV fluids or supplies to be kept on site and did not include input from any nursing or medical staff. A second POR was presented on 3/18/2019 at 2:20 p.m. This POR indicated in-part: that the OAF would keep a minimum of 3-1000 ml of 0.9% Sodium Chloride and 3-500 ml of 0.9% Sodium Chloride and all necessary IV start kits. S5Adm verified that the second POR did not include any input from any nursing or medical staff, did not address the quantity of IV start kits to have on site, or show any method of how the	S 205		

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S 205	Continued From page 9 OAF determined the minimum amount of IV fluids to maintain on site. As of 3/18/19 at 3:00 p.m. the IJ remained in place. S5Adm verified that the OAF was instructed not to perform any surgical abortion procedures until the IJ had been removed. Review of the transporting ambulance run report dated 03/15/2019, revealed the following in-part: Patient #1's name: Primary Impression: Vaginal Hemorrhage Secondary Impression: Hypotension Chief Complaint: Weakness Signs & Symptoms: Genitourinary - Abnormal uterine and vaginal bleeding. Cardiovascular-Hypotension. Generalized Symptoms - Weakness. On scene: 14:11:03 At Patient: 14:12:16 14:13: Assessment- Physician reports that he was performing a D&E procedure on the patient and was able to extract the fetus but could not stop the vaginal bleeding and called 911 V/S monitored on scene. Pt is found hypotensive. Pt was moved over to stretcher. IV was established on scene. Pt was administered NS in route. BP increased in route. 14:16: Patient alert, blood pressure 88/59, pulse 109, respirations 16, SPO2 97% room air. 14:17: 16 ga, right antecubital, Normal Saline (0.9% NaCl), total fluid 300 ml, pt. response improved. Review of Patient #1's Hospital Records revealed in-part: Arrival 3/15/19 at 14:54 Arrival Mode: Ambulance Chief Complaint = Bleeding	S 205		

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S 205	Continued From page 10 Hospital Report: Due to likely incomplete abortion and persistent moderate vaginal bleeding, I called ___ resident, to consult ___ OBGYN service for possible surgery ... Signed by MD 3/15/19 at 15:37 History and Physical in-part: GYN Faculty I saw and evaluated Patient in (the Hospital). Impression: 28 yo s/p attempted dilation and evacuation of 15 weeks pregnancy with continued vaginal bleeding, guarded condition. Plan: 1. s/p D&E - continued vaginal bleeding, approximately 300 cc + 800 after the procedure. Given 400 mcg Cytotec PO + 800 mcg PR given at the OAF, with continued bleeding. Tachycardia to 120's, + (positive) orthostatics, H/H 7/24. Patient symptomatic. Counseled about options, will proceed to OR for suction D&C for suspected retained POC. Signed 3/15/19 at 16:46 by MD. Operative Report: Date of Procedure March 15, 2019 Preoperative Diagnosis: retained POC status-post dilation and evacuation for elective abortion. Operation: Exam under anesthesia, Suction dilation and curettage, ultrasound guided. Specimen: Products of Conception. Drains: Foley catheter, uterine tamponade balloon containing 50 cc of saline. Estimated Blood Loss: 400 cc. Complications: Bleeding, Methergine 0.2 mg IM given intraoperatively along with one unit of packed red blood cells. Operative Progress Note: Procedure: Signed by supervising MD on 3/15/2019 at 19:19 I was present and scrubbed for exam under	S 205		

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anesthesia and suction D&C.
Cervix examined and without lacerations, approximately 1-2 cm dilated. Active bleeding was noted from os, suction and sharp curettage was done multiple times. US performed intra-operatively which helped to confirm intact uterus and homogenous appearing endometrial stripe.
Methergine 0.2 mg IM given intra-operatively, along with 1u PRBCs. Bleeding improved, but due to continued minimal bleeding from os, balloon placed in uterus with 50 ml saline and urinary catheter inserted into bladder.

Operative Report:
Surgery: 03/16/2019
Preoperative Diagnosis: Persistent hemorrhage following D&E and status -post D&C for retained POC, cesarean section times five, suspicion for placenta accrete (accreta).
Operation: Total abdominal hysterectomy and bilateral salpingectomy.
Anesthesia: General endotracheal
Estimated blood loss: 500 ccs.
Specimens: Uterus, cervix and bilateral fallopian tubes.
Indications: in part- Despite medical management as well as the tamponade balloon, the patient had persistent hemorrhage so it was decided at this time that the patient would undergo a hysterectomy and bilateral salpingectomy for persistent postoperative hemorrhage with suspicion for placenta accrete (accreta) due to the patient's history of five cesarean sections in the past.

Hospital Laboratory Services Report:
Patient #1's lab values were as follow: in-part:
3/15/2019 at 15:54:
RBC = 2.90 with Reference at 4.2 to 5.40 mil/uL

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S 205	Continued From page 12 Hgb = 7.3 with Reference at 12.0 - 16.0 gm/dL Hct = 23.8 with Reference at 37.0 - 47.0 % Notes: in-part = Normocytic anemia consistent with blood loss/hemolysis. The hospital record indicated that the patient received a total of 4 units of blood as of 3/17/2019. The documented units of blood was administered as follows: 1. 3/15/19 at 17:36 2. 3/15/19 at 19:39 3. 3/17/19 at 12:40 4. 3/17/19 at 15:42 As of 3/18/2019 at 5:00 PM, Patient #1 remained an in-patient at the area Hospital. On 03/29/2019, an onsite survey was conducted at the OAF. At 3:30 p.m. S1DirOperations, S2DON, and S5Adm were notified of the accepted POR for the IJ situation. The surveyor confirmed that the OAF completed the following to remove the immediate jeopardy. The OAF, with involvement from S2DON and S3MD/Medical Director, developed a plan in-part as follows to ensure that: -The requisite number of IV fluids and IV start kits were available to nursing, determined on a daily basis by the number of patients scheduled for surgical procedures. -Designated staff were to fulfill the daily task of reconciliation of patients scheduled for surgical procedures and availability of IV fluids and IV start kits in accordance with the on-site work schedule of the DON. -Train all necessary staff for response to emergencies requiring IV resuscitation. -The development of the P&P; Pharmaceutical	S 205		

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S 205	Continued From page 13 Services Audit And Ordering - IV Start Kit And IV Fluids for auditing and maintaining the necessary amounts of emergency supplies to be available in the OAF. -Identified specific labeled containers in specific locations where IV fluids and IV start kits were to be maintained. -Trained staff and had staff view the location of the specific containers where IV fluids and IV start kits were located. -Developed daily and monthly check lists for designated nursing staff to check the quantities of IV fluids and IV start kits in the 3 designated storage areas. -A determination that the OAF shall maintain on site: 25 sets of IV fluids Sodium Chloride, 10 sets of IV fluids Dextrose, and 10 sets of IV fluids Lactated Ringers shall be on site daily and the same amount shall be kept in reserve. Maintenance of this inventory shall be the responsibility of the DON and has been reviewed and approved by the Medical Director. DON or clinic Administrator will be responsible for replenishing any used quantities using the same day or next day supplies ordering per protocol.	S 205		
S 259	4451 H Pharmaceutical Services H. The outpatient abortion facility shall order and maintain a supply of emergency drugs for stabilizing and/or treating medical and surgical complications on the licensed premises as authorized by the medical director.	S 259		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	BO0004642	A. BUILDING: _____ B. WING _____	C 03/29/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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S 259	Continued From page 14 This Rule is not met as evidenced by: Based on observations, review of records, and staff interviews, the OAF failed to order and maintain a supply of emergency drugs for stabilizing and/or treating medical and surgical complications on the licensed premises as authorized by the medical director. This deficient practice had the potential to affect 3 (Patients #1 - #3) of 3 (Patients #1 - #3) sampled patients who underwent a surgical abortion procedure at the OAF. Findings: During an interview on 3/28/19 at 12:20 PM, S5Adm presented a form which was explained to be the list of emergency medications and supplies that the Medical Director approved to be kept on site. S5Adm explained that the form labeled as STAT KIT ACLS was the Medical Director's inventory list of emergency medications and supplies which were kept in the STAT KIT (crash cart). On 3/28/2019 at 12:27 PM, a comparison of the OAF's STAT KIT (crash cart) inventory with the STAT KIT ACLS (inventory list of emergency medications to be kept in the cart) was performed with S4LPN. S4LPN verified that the inventory list included two vials of Adenosine 3mg/4 ml. S4LPN verified that the STAT KIT (crash cart) had only one vial of Adenosine which was expired as of 02/2019. An interview and review of the OAF's list of emergency medications and emergency supplies was conducted with S3MD/Medical Director on 3/29/2019 at 11:10 AM. S3MD acknowledged that the OAF's lists of emergency medications and supplies were approved and said that they were	S 259		

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S 259	Continued From page 15 the responsibility of the administrative staff to maintain. S3MD was asked about the STAT KIT ACLS (inventory list) containing the OAF's emergency medications and about only one of two vials of Adenosine, which was expired, present on the crash cart. S3MD replied that he would not use Adenosine. S3MD said the Adenosine would be for the 911 response personnel to use. S3MD said the medications should have been checked and should not have been expired.	S 259		