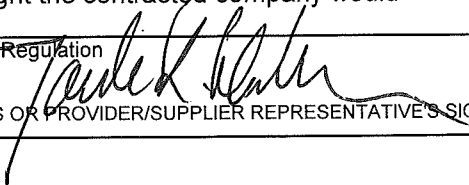


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NAME OF PROVIDER OR SUPPLIER  <b>A WOMAN'S CHOICE OF RALEIGH, INC</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>3305 DRAKE CIRCLE RALEIGH, NC 27607</b>		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE	
E 127	<p><b>.0206(4) ELEMENTS AND EQUIPMENT</b></p> <p>10A-14E . 0206 The physical plant shall provide appropriate elements and equipment to carry out functions of the facility with the following minimum requirements: (4) Each facility and its grounds shall be maintained to minimize hazards and enhance safety for staff and patients. Buildings systems and medical equipment must have preventative maintenance conducted as recommended by the equipment manufacturers' or installers' literature to assure satisfactory operation.</p> <p>This Rule is not met as evidenced by: Based on observation during tour of the clinic and staff interview, the facility failed to ensure annual preventative maintenance was completed on 1 of 2 steam autoclave units (Serial #ES007214).</p> <p>The findings include:</p> <p>Observation during tour of the clinic on 01/24/2013 at 1450 revealed two steam autoclaves currently in use. One of the two autoclaves (serial # ES007214) had a preventive maintenance sticker that recorded "expired 7/2012."</p> <p>Interview on 01/24/2013 at 1450 with Administration revealed they were unsure when the last preventive maintenance was done. The staff was unable to produce any evidence of preventive maintenance on this autoclave since July 2012. Further interview revealed the facility staff thought the contracted company would</p>	E 127	<p><i>Autoclave Preventative Maintenance will be done annually, we will use a PM log to keep track of when PM's should be done this will be monitored by office manager and Asst. office manager.</i></p> <p><i>Autoclave (Serial #ES007214) has been serviced on 2/10/13.</i></p> <p><i>See Attachment 1 &amp; 2</i></p>	2/18/13	

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



TITLE

Lab director

(X6) DATE

2/22/13

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E 127	Continued From page 1  ensure the preventive maintenance was done according to manufacture's recommendations. Interview confirmed the autoclave should have annual checks done and it was past due.	E 127		
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 clinic log reviews and staff interviews the clinic staff failed to maintain a daily procedure log containing the RN (Registered Nurse) on duty.  The findings include:  Review of the clinic daily procedure logs from September 1, 2012 to January 23, 2013 revealed no documentation of the name of the RN on duty.  Interview with administrative staff on 01/24/2013 at 1045 confirmed the log did not contain the name of the RN on duty.	E 141	RN will sign the top of the procedure log before any procedures are done, this will be checked by the office manager before clinic begins. see Attachment 3	2/18/13
E 157	.0311(A) SURGICAL SERVICES  10A-14E .0311 (a) Facilities. The operating room shall be maintained exclusively for surgical procedures and shall be so designed and maintained to provide an atmosphere free of contamination by pathogenic	E 157	Single dose vials will only be used for 1 patient, any medication left over will be wasted. Office manager or Asst. manager will count with RN at the beginning	2/18/13

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E 157	Continued From page 2  organisms. The facility shall establish procedures for infection control and universal precautions  This Rule is not met as evidenced by: Based on medication manufacturer's recommendations, observation during tour of the clinic, and staff interviews the facility failed to control the risk of infectious disease by failing to administer medication according to manufacturer's recommendations by using a single dose vial for multiple patients. The findings include: Review of an insert of manufacturers recommendations for "Fentanyl" (narcotic analgesic) revealed Fentanyl 250 mcgs (micrograms) per 5 mls (milliliters) is a "single use vial" that is intended for one patient . Further review of the manufacturers recommendations revealed the Fentanyl 250 mcgs per 5 mls vial "dosage should be individualized" and any remaining "unused contents" should be "destroyed." Review of the manufacturer's recommendations revealed Fentanyl 250 mcgs per 5mls is intended for use with one patient and should be discarded after use with a single patient. Observation during tour of the clinic on 01/24/2013 at 1425 revealed Fentanyl 250 mcgs per 5 mls single use vials were being administered to multiple patients. A single use vial of Fentanyl 250 mcgs per 5 mls was observed open with 2.5 mls of the content (Fentanyl) remaining in the vial. An interview with the clinic Registered Nurse (RN) on 01/24/2013 during tour revealed Fentanyl 250 mcgs per 5 mls single dose vials were opened and administered to multiple patients. RN # 1 said, "One vial (Fentanyl) can be used for three patients." RN #1 said, "when a (single dose) vial	E 157	<i>And end of clinic.</i>	

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E 157	Continued From page 3  (Fentanyl) is opened the prescribed dose is drawn from the vial and the remaining contents of the vial are stored for use with the next patient." An interview with the Office Manager during tour revealed a single dose vial of Fentanyl 250 mcgs per 5 mls was observed to be open with 2.5 mls of content remaining. The Nurse Manager stated, "the Fentanyl 250 mcgs per 5 mls single dose vials are being used for multiple patients." Interview revealed the Office Manager stated the Fentanyl 250 mcgs per 5 mls single dose vials were being administered to as many as three patients. Interview confirmed the manufacturer's recommendations for administration of Fentanyl 250 mcgs per 5 mls single dose vials were not being followed by the facility.	E 157		
E 158	.0311(B) SURGICAL SERVICES  10A-14E .0311 (b) Tissue Examination: (1) The physician performing the abortion is responsible for examination of all products of conception (P.O.C.) prior to patient discharge. Such examination shall note specifically the presence or absence of chorionic villi and fetal parts or the amniotic sac. The results of the examination shall be recorded in the patient's medical record. (2) The facility shall have written procedures, supplies and equipment available for gross and microscopic evaluation of abortion specimens. If placental or fetal tissue is not identified by gross examination, a microscopic examination must be done on the P.O.C. In cases where the microscopic evaluation is negative for	E 158	Physician will examine every P.O.C. after he completes the procedure. The physician will document in Gross description that he has examined the P.O.C. and also sign. Medical Staff members are aware that the physician must examine every P.O.C.	2/18/13

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E 158	<p>Continued From page 4</p> <p>chorionic villi and fetal parts, or the weight of the P.O.C. falls substantially below the appropriate weight range for the fetal age, a microscopic examination by a board certified or board eligible pathologist shall be done on the P.O.C.</p> <p>(3) The results of this examination, the findings of further patient evaluation and any subsequent treatment must be recorded in the patient's medical record.</p> <p>(4) The facility shall establish procedures for obtaining, identifying, storing and transporting specimens.</p> <p>(5) The facility shall establish a method for follow-up of patients on whom no villi are seen.</p> <p>This Rule is not met as evidenced by: Based on clinic policy review, medical record review and staff interview, the physician performing the surgical abortion failed to examine the products of conception (POC) prior to patient discharge for 16 of 18 patients that had a surgical abortion procedure done (#1, 2, 3, 4, 5, 6, 7, 9, 11, 12, 13, 14, 15, 16, 17, 18).</p> <p>The findings include:</p> <p>Review of the clinic's "Products of Conception Examination Procedure" policy (dated September 22, 2002) revealed "...7. Place the dish on top of the back light for visual examination. 8. Gently explore the contents of the dish to identify pregnancy tissue. 9. Record results on lab log.... 11. Label the dish with the patient's name so the physician can check contents.... 13. If there is still an absence of villi and sac, notify the</p>	E 158		

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E 158	<p>Continued From page 5</p> <p>physician and clinic administrator. 14. Keep this specimen in the dish until the physician has determined her/his course of action.... 18. If you find any unusual structures, hydropic (enlarged) villi, or multiple pregnancies, have the physician examine the entire specimen."</p> <p>1. Medical record review of Patient #1 revealed a 41 year-old female admitted on 01/22/2013 for a surgical abortion procedure. Record review revealed the patient had a Dilation and Evacuation for an intrauterine pregnancy of 12.3 weeks gestation. Record review revealed the examination of the products of conception (POC) included a documentation of weight, gestation age estimated by appearance, identification of an intact fetus, presense or absense of chorionic villi, visualization of fetal parts identified, sac seen and weather tissue was forwarded to pathology for further examination. Record review revealed this examination was performed by an office assistant.</p> <p>Interview on 01/24/2013 at 1445 with a nursing assistant revealed that she was responsible for gross examination of the POC after the procedure was completed. Interview revealed all the nursing assistants and medical office assistants had been trained to do this examination. The staff member stated "I would ask (physician name) if I suspected an abnormal finding." The staff member stated the physician only looks at the POC when asked to do so by staff. Interview revealed the physician was rarely called to look at the POC.</p> <p>Interview on 01/24/2013 at 1515 with administrative staff revealed "The doctor doesn't look at all of them (POC)." The staff member stated he only looks at the POC when staff alert</p>	E 158		

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E 158	<p>Continued From page 6</p> <p>him there is a problem. Interview confirmed that all certified nursing assistants/medical office assistant are responsible for the examination of the products of conception. Interview revealed if the physician examines the POC, then he makes a note of his findings in the "Gross Description" section of the medical record. Administrative staff confirmed there was no evidence that the physician examined the POC for Patient #1.</p> <p>2. Medical record review of Patient #2 revealed a 22 year-old female admitted on 1/22/2012 for a surgical abortion procedure. Record review revealed the examination of the products of conception (POC) included a documentation of weight, gestation age estimated by appearance, identification of an intact fetus, presense or absense of chorionic villi, visualization of fetal parts identified, sac seen and weather tissue was forwarded to pathology for further examination. Record review revealed this examination was performed by an office assistant.</p> <p>Interview on 01/24/2013 at 1445 with a nursing assistant revealed that she was responsible for gross examination of the POC after the procedure was completed. Interview revealed all the nursing assistants and medical office assistants had been trained to do this examination. The staff member stated "I would ask (physician name) if I suspected an abnormal finding." The staff member stated the physician only looks at the POC when asked to do so by staff. Interview revealed the physician was rarely called to look at the POC.</p> <p>Interview on 01/24/2013 at 1515 with administrative staff revealed "The doctor doesn't look at all of them (POC)." The staff member stated he only looks at the POC when staff alert</p>	E 158		

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E 158	Continued From page 7  him there is a problem. Interview confirmed that all certified nursing assistants/medical office assistant are responsible for the examination of the products of conception. Interview revealed if the physician examines the POC, then he makes a note of his findings in the "Gross Description" section of the medical record. Administrative staff confirmed there was no evidence that the physician examined the POC for Patient #2.  3. Medical record review of Patient #3 revealed a 29 year-old female admitted on 01/19/2013 for a surgical abortion procedure. Record review revealed the examination of the products of conception (POC) included a documentation of weight, gestation age estimated by appearance, identification of an intact fetus, presense or absense of chorionic villi, visualization of fetal parts identified, sac seen and weather tissue was forwarded to pathology for further examination. Record review revealed this examination was performed by an office assistant.  Interview on 01/24/2013 at 1445 with a nursing assistant revealed that she was responsible for gross examination of the POC after the procedure was completed. Interview revealed all the nursing assistants and medical office assistants had been trained to do this examination. The staff member stated "I would ask (physician name) if I suspected an abnormal finding." The staff member stated the physician only looks at the POC when asked to do so by staff. Interview revealed the physician was rarely called to look at the POC.  Interview on 01/24/2013 at 1515 with administrative staff revealed "The doctor doesn't look at all of them (POC)." The staff member stated he only looks at the POC when staff alert	E 158		



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E 158	<p>Continued From page 8</p> <p>him there is a problem. Interview confirmed that all certified nursing assistants/medical office assistant are responsible for the examination of the products of conception. Interview revealed if the physician examines the POC, then he makes a note of his findings in the "Gross Description" section of the medical record. Administrative staff confirmed there was no evidence that the physician examined the POC for Patient #3.</p> <p>4. Medical record review of Patient #4 revealed an 18 year-old female admitted on 01/11/2013 for a surgical abortion procedure. Record review revealed the examination of the products of conception (POC) included a documentation of weight, gestation age estimated by appearance, identification of an intact fetus, presense or absense of chorionic villi, visualization of fetal parts identified, sac seen and weather tissue was forwarded to pathology for further examination. Record review revealed this examination was performed by an office assistant.</p> <p>Interview on 01/24/2013 at 1445 with a nursing assistant revealed that she was responsible for gross examination of the POC after the procedure was completed. Interview revealed all the nursing assistants and medical office assistants had been trained to do this examination. The staff member stated "I would ask (physician name) if I suspected an abnormal finding." The staff member stated the physician only looks at the POC when asked to do so by staff. Interview revealed the physician was rarely called to look at the POC.</p> <p>Interview on 01/24/2013 at 1515 with administrative staff revealed "The doctor doesn't look at all of them (POC)." The staff member stated he only looks at the POC when staff alert</p>	E 158		

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E 158	Continued From page 9  him there is a problem. Interview confirmed that all certified nursing assistants/medical office assistant are responsible for the examination of the products of conception. Interview revealed if the physician examines the POC, then he makes a note of his findings in the "Gross Description" section of the medical record. Administrative staff confirmed there was no evidence that the physician examined the POC for Patient #4.  5. Medical record review of Patient #5 revealed a 26 year-old female admitted on 1/07/2013 for a surgical abortion procedure. Record review revealed the examination of the products of conception (POC) included a documentation of weight, gestation age estimated by appearance, identification of an intact fetus, presense or absense of chorionic villi, visualization of fetal parts identified, sac seen and weather tissue was forwarded to pathology for further examination. Record review revealed this examination was performed by an office assistant.  Interview on 01/24/2013 at 1445 with a nursing assistant revealed that she was responsible for gross examination of the POC after the procedure was completed. Interview revealed all the nursing assistants and medical office assistants had been trained to do this examination. The staff member stated "I would ask (physician name) if I suspected an abnormal finding." The staff member stated the physician only looks at the POC when asked to do so by staff. Interview revealed the physician was rarely called to look at the POC.  Interview on 01/24/2013 at 1515 with administrative staff revealed "The doctor doesn't look at all of them (POC)." The staff member stated he only looks at the POC when staff alert	E 158		

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E 158	Continued From page 10  him there is a problem. Interview confirmed that all certified nursing assistants/medical office assistant are responsible for the examination of the products of conception. Interview revealed if the physician examines the POC, then he makes a note of his findings in the "Gross Description" section of the medical record. Administrative staff confirmed there was no evidence that the physician examined the POC for Patient #5.  6. Medical record review of Patient #6 revealed a 22 year-old female admitted on 10/24/2012 for a surgical abortion procedure. Record review revealed the examination of the products of conception (POC) included a documentation of weight, gestation age estimated by appearance, identification of an intact fetus, presense or absense of chorionic villi, visualization of fetal parts identified, sac seen and weather tissue was forwarded to pathology for further examination. Record review revealed this examination was performed by an office assistant.  Interview on 01/24/2013 at 1445 with a nursing assistant revealed that she was responsible for gross examination of the POC after the procedure was completed. Interview revealed all the nursing assistants and medical office assistants had been trained to do this examination. The staff member stated "I would ask (physician name) if I suspected an abnormal finding." The staff member stated the physician only looks at the POC when asked to do so by staff. Interview revealed the physician was rarely called to look at the POC.  Interview on 01/24/2013 at 1515 with administrative staff revealed "The doctor doesn't look at all of them (POC)." The staff member stated he only looks at the POC when staff alert	E 158		

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E 158	<p>Continued From page 11</p> <p>him there is a problem. Interview confirmed that all certified nursing assistants/medical office assistant are responsible for the examination of the products of conception. Interview revealed if the physician examines the POC, then he makes a note of his findings in the "Gross Description" section of the medical record. Administrative staff confirmed there was no evidence that the physician examined the POC for Patient #6.</p> <p>7. Medical record review of Patient #7 revealed a 21 year-old female admitted on 9/08/2012 for a surgical abortion procedure. Record review revealed the examination of the products of conception (POC) included a documentation of weight, gestation age estimated by appearance, identification of an intact fetus, presense or absense of chorionic villi, visualization of fetal parts identified, sac seen and weather tissue was forwarded to pathology for further examination. Record review revealed this examination was performed by an office assistant.</p> <p>Interview on 01/24/2013 at 1445 with a nursing assistant revealed that she was responsible for gross examination of the POC after the procedure was completed. Interview revealed all the nursing assistants and medical office assistants had been trained to do this examination. The staff member stated "I would ask (physician name) if I suspected an abnormal finding." The staff member stated the physician only looks at the POC when asked to do so by staff. Interview revealed the physician was rarely called to look at the POC.</p> <p>Interview on 01/24/2013 at 1515 with administrative staff revealed "The doctor doesn't look at all of them (POC)." The staff member stated he only looks at the POC when staff alert</p>	E 158		

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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
E 158	<p>Continued From page 12</p> <p>him there is a problem. Interview confirmed that all certified nursing assistants/medical office assistant are responsible for the examination of the products of conception. Interview revealed if the physician examines the POC, then he makes a note of his findings in the "Gross Description" section of the medical record. Administrative staff confirmed there was no evidence that the physician examined the POC for Patient #7.</p> <p>8. Medical record review of Patient #9 revealed a 22 year-old female admitted on 12/03/2012 for a surgical abortion procedure. Record review revealed the examination of the products of conception (POC) included a documentation of weight, gestation age estimated by appearance, identification of an intact fetus, presense or absense of chorionic villi, visualization of fetal parts identified, sac seen and weather tissue was forwarded to pathology for further examination. Record review revealed this examination was performed by an office assistant.</p> <p>Interview on 01/24/2013 at 1445 with a nursing assistant revealed that she was responsible for gross examination of the POC after the procedure was completed. Interview revealed all the nursing assistants and medical office assistants had been trained to do this examination. The staff member stated "I would ask (physician name) if I suspected an abnormal finding." The staff member stated the physician only looks at the POC when asked to do so by staff. Interview revealed the physician was rarely called to look at the POC.</p> <p>Interview on 01/24/2013 at 1515 with administrative staff revealed "The doctor doesn't look at all of them (POC)." The staff member stated he only looks at the POC when staff alert</p>	E 158		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>AB0028</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>01/24/2013</b>
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E 158	<p>Continued From page 13</p> <p>him there is a problem. Interview confirmed that all certified nursing assistants/medical office assistant are responsible for the examination of the products of conception. Interview revealed if the physician examines the POC, then he makes a note of his findings in the "Gross Description" section of the medical record. Administrative staff confirmed there was no evidence that the physician examined the POC for Patient #9.</p> <p>9. Medical record review of Patient #11 revealed a 21 year-old female admitted on 12/05/2012 for a surgical abortion procedure. Record review revealed the examination of the products of conception (POC) included a documentation of weight, gestation age estimated by appearance, identification of an intact fetus, presense or absense of chorionic villi, visualization of fetal parts identified, sac seen and weather tissue was forwarded to pathology for further examination. Record review revealed this examination was performed by an office assistant.</p> <p>Interview on 01/24/2013 at 1445 with a nursing assistant revealed that she was responsible for gross examination of the POC after the procedure was completed. Interview revealed all the nursing assistants and medical office assistants had been trained to do this examination. The staff member stated "I would ask (physician name) if I suspected an abnormal finding." The staff member stated the physician only looks at the POC when asked to do so by staff. Interview revealed the physician was rarely called to look at the POC.</p> <p>Interview on 01/24/2013 at 1515 with administrative staff revealed "The doctor doesn't look at all of them (POC)." The staff member stated he only looks at the POC when staff alert</p>	E 158			

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E 158	Continued From page 14  him there is a problem. Interview confirmed that all certified nursing assistants/medical office assistant are responsible for the examination of the products of conception. Interview revealed if the physician examines the POC, then he makes a note of his findings in the "Gross Description" section of the medical record. Administrative staff confirmed there was no evidence that the physician examined the POC for Patient #11.  10. Medical record review of Patient #12 revealed a 24 year-old female admitted on 12/12/2012 for a surgical abortion procedure. Record review revealed the examination of the products of conception (POC) included a documentation of weight, gestation age estimated by appearance, identification of an intact fetus, presense or absense of chorionic villi, visualization of fetal parts identified, sac seen and weather tissue was forwarded to pathology for further examination. Record review revealed this examination was performed by an office assistant.  Interview on 01/24/2013 at 1445 with a nursing assistant revealed that she was responsible for gross examination of the POC after the procedure was completed. Interview revealed all the nursing assistants and medical office assistants had been trained to do this examination. The staff member stated "I would ask (physician name) if I suspected an abnormal finding." The staff member stated the physician only looks at the POC when asked to do so by staff. Interview revealed the physician was rarely called to look at the POC.  Interview on 01/24/2013 at 1515 with administrative staff revealed "The doctor doesn't look at all of them (POC)." The staff member stated he only looks at the POC when staff alert	E 158		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>AB0028</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>01/24/2013</b>
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E 158	<p>Continued From page 15</p> <p>him there is a problem. Interview confirmed that all certified nursing assistants/medical office assistant are responsible for the examination of the products of conception. Interview revealed if the physician examines the POC, then he makes a note of his findings in the "Gross Description" section of the medical record. Administrative staff confirmed there was no evidence that the physician examined the POC for Patient #12.</p> <p>11. Medical record review of Patient #13 revealed a 35 year-old female admitted on 12/24/2012 for a surgical abortion procedure. Record review revealed the examination of the products of conception (POC) included a documentation of weight, gestation age estimated by appearance, identification of an intact fetus, presense or absense of chorionic villi, visualization of fetal parts identified, sac seen and weather tissue was forwarded to pathology for further examination. Record review revealed this examination was performed by an office assistant.</p> <p>Interview on 01/24/2013 at 1445 with a nursing assistant revealed that she was responsible for gross examination of the POC after the procedure was completed. Interview revealed all the nursing assistants and medical office assistants had been trained to do this examination. The staff member stated "I would ask (physician name) if I suspected an abnormal finding." The staff member stated the physician only looks at the POC when asked to do so by staff. Interview revealed the physician was rarely called to look at the POC.</p> <p>Interview on 01/24/2013 at 1515 with administrative staff revealed "The doctor doesn't look at all of them (POC)." The staff member stated he only looks at the POC when staff alert</p>	E 158		



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E 158	<p>Continued From page 16</p> <p>him there is a problem. Interview confirmed that all certified nursing assistants/medical office assistant are responsible for the examination of the products of conception. Interview revealed if the physician examines the POC, then he makes a note of his findings in the "Gross Description" section of the medical record. Administrative staff confirmed there was no evidence that the physician examined the POC for Patient #13.</p> <p>12. Medical record review of Patient #14 revealed a 21 year-old female admitted on 11/02/2012 for a surgical abortion procedure. Record review revealed the examination of the products of conception (POC) included a documentation of weight, gestation age estimated by appearance, identification of an intact fetus, presense or absense of chorionic villi, visualization of fetal parts identified, sac seen and weather tissue was forwarded to pathology for further examination. Record review revealed this examination was performed by an office assistant.</p> <p>Interview on 01/24/2013 at 1445 with a nursing assistant revealed that she was responsible for gross examination of the POC after the procedure was completed. Interview revealed all the nursing assistants and medical office assistants had been trained to do this examination. The staff member stated "I would ask (physician name) if I suspected an abnormal finding." The staff member stated the physician only looks at the POC when asked to do so by staff. Interview revealed the physician was rarely called to look at the POC.</p> <p>Interview on 01/24/2013 at 1515 with administrative staff revealed "The doctor doesn't look at all of them (POC)." The staff member</p>	E 158		

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E 158	<p>Continued From page 17</p> <p>stated he only looks at the POC when staff alert him there is a problem. Interview confirmed that all certified nursing assistants/medical office assistant are responsible for the examination of the products of conception. Interview revealed if the physician examines the POC, then he makes a note of his findings in the "Gross Description" section of the medical record. Administrative staff confirmed there was no evidence that the physician examined the POC for Patient #14.</p> <p>13. Medical record review of Patient #15 revealed a 25 year-old female admitted on 11/27/2012 for a surgical abortion procedure. Record review revealed the examination of the products of conception (POC) included a documentation of weight, gestation age estimated by appearance, identification of an intact fetus, presense or absense of chorionic villi, visualization of fetal parts identified, sac seen and weather tissue was forwarded to pathology for further examination. Record review revealed this examination was performed by an office assistant.</p> <p>Interview on 01/24/2013 at 1445 with a nursing assistant revealed that she was responsible for gross examination of the POC after the procedure was completed. Interview revealed all the nursing assistants and medical office assistants had been trained to do this examination. The staff member stated "I would ask (physician name) if I suspected an abnormal finding." The staff member stated the physician only looks at the POC when asked to do so by staff. Interview revealed the physician was rarely called to look at the POC.</p> <p>Interview on 01/24/2013 at 1515 with administrative staff revealed "The doctor doesn't</p>	E 158		

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E 158	<p>Continued From page 18</p> <p>look at all of them (POC)." The staff member stated he only looks at the POC when staff alert him there is a problem. Interview confirmed that all certified nursing assistants/medical office assistant are responsible for the examination of the products of conception. Interview revealed if the physician examines the POC, then he makes a note of his findings in the "Gross Description" section of the medical record. Administrative staff confirmed there was no evidence that the physician examined the POC for Patient #15.</p> <p>14. Medical record review of Patient #16 revealed a 24 year-old female admitted on 9/08/2012 for a surgical abortion procedure. Record review revealed the examination of the products of conception (POC) included a documentation of weight, gestation age estimated by appearance, identification of an intact fetus, presense or absense of chorionic villi, visualization of fetal parts identified, sac seen and weather tissue was forwarded to pathology for further examination. Record review revealed this examination was performed by an office assistant.</p> <p>Interview on 01/24/2013 at 1445 with a nursing assistant revealed that she was responsible for gross examination of the POC after the procedure was completed. Interview revealed all the nursing assistants and medical office assistants had been trained to do this examination. The staff member stated "I would ask (physician name) if I suspected an abnormal finding." The staff member stated the physician only looks at the POC when asked to do so by staff. Interview revealed the physician was rarely called to look at the POC.</p> <p>Interview on 01/24/2013 at 1515 with administrative staff revealed "The doctor doesn't</p>	E 158		

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E 158	<p>Continued From page 19</p> <p>look at all of them (POC)." The staff member stated he only looks at the POC when staff alert him there is a problem. Interview confirmed that all certified nursing assistants/medical office assistant are responsible for the examination of the products of conception. Interview revealed if the physician examines the POC, then he makes a note of his findings in the "Gross Description" section of the medical record. Administrative staff confirmed there was no evidence that the physician examined the POC for Patient #16.</p> <p>15. Medical record review of Patient #17 revealed a 30 year-old female admitted on 9/18/2012 for a surgical abortion procedure. Record review revealed the examination of the products of conception (POC) included a documentation of weight, gestation age estimated by appearance, identification of an intact fetus, presense or absense of chorionic villi, visualization of fetal parts identified, sac seen and weather tissue was forwarded to pathology for further examination. Record review revealed this examination was performed by an office assistant.</p> <p>Interview on 01/24/2013 at 1445 with a nursing assistant revealed that she was responsible for gross examination of the POC after the procedure was completed. Interview revealed all the nursing assistants and medical office assistants had been trained to do this examination. The staff member stated "I would ask (physician name) if I suspected an abnormal finding." The staff member stated the physician only looks at the POC when asked to do so by staff. Interview revealed the physician was rarely called to look at the POC.</p> <p>Interview on 01/24/2013 at 1515 with administrative staff revealed "The doctor doesn't</p>	E 158		

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E 158	<p>Continued From page 20</p> <p>look at all of them (POC)." The staff member stated he only looks at the POC when staff alert him there is a problem. Interview confirmed that all certified nursing assistants/medical office assistant are responsible for the examination of the products of conception. Interview revealed if the physician examines the POC, then he makes a note of his findings in the "Gross Description" section of the medical record. Administrative staff confirmed there was no evidence that the physician examined the POC for Patient #17.</p> <p>16. Medical record review of Patient #18 revealed a 19 year-old female admitted on 9/08/2012 for a surgical abortion procedure. Record review revealed the examination of the products of conception (POC) included a documentation of weight, gestation age estimated by appearance, identification of an intact fetus, presense or absense of chorionic villi, visualization of fetal parts identified, sac seen and weather tissue was forwarded to pathology for further examination. Record review revealed this examination was performed by an office assistant.</p> <p>Interview on 01/24/2013 at 1445 with a nursing assistant revealed that she was responsible for gross examination of the POC after the procedure was completed. Interview revealed all the nursing assistants and medical office assistants had been trained to do this examination. The staff member stated "I would ask (physician name) if I suspected an abnormal finding." The staff member stated the physician only looks at the POC when asked to do so by staff. Interview revealed the physician was rarely called to look at the POC.</p> <p>Interview on 01/24/2013 at 1515 with administrative staff revealed "The doctor doesn't</p>	E 158		

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E 158	Continued From page 21  look at all of them (POC)." The staff member stated he only looks at the POC when staff alert him there is a problem. Interview confirmed that all certified nursing assistants/medical office assistant are responsible for the examination of the products of conception. Interview revealed if the physician examines the POC, then he makes a note of his findings in the "Gross Description" section of the medical record. Administrative staff confirmed there was no evidence that the physician examined the POC for Patient #18.	E 158		
E 163	.0313(C) POST-OPERATIVE CARE  10A-14E .0313 (c) Any non-ambulatory patient shall be accompanied by an attending medical or nursing staff member during any transfer within or outside the facility.  This Rule is not met as evidenced by: Based on patient record review, policy manual review, and administrative staff interview, the clinic failed to ensure a staff member accompanied a patient to the hospital for 2 of 2 patients transferred to a hospital (#1 and 2).  The findings include:  Review of the "Transfer Protocol" on 1/24/2013 revealed the statement "Any patient having an adverse condition known or suspected to have occurred during or after abortion procedure will be transferred to a designated hospital for evaluation or admission." Further review of the "Transfer Protocol" revealed "after the physician recognizes the need for emergency transfer, he (the physician) orders the clinic administrator to call for EMS (Emergency Medical Service) . Review of the "Transfer Protocol" revealed the	E 163	Medical Staff member will accompany patient during any hospital transfer. All medical staff members are aware of this policy. Each medical staff member has a copy of this policy in their employee file. See Attachment 4	2/18/13

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E 163	Continued From page 22  physician "stays with the patient " until the arrival of EMS. Continued review of the "Transfer Protocol" revealed upon arrival the "EMS team will stabilize the patient for transfer and the physician directs them (EMS team) to transfer the patient to the designated hospital emergency room." Review of the "Transfer Protocol" revealed there was no plan for any staff member, administrator, or physician to accompany the patient when being transferred to the designated hospital emergency room.  1. Patient #1 was admitted 9/1/2013 at 10:10 AM for a surgical abortion. The patient was admitted to the recovery area at 11:45 AM where it was determined the patient had heavy bleeding during the pad check. Emergency medical personnel were called and the patient was transported to a local hospital. There was no evidence a staff member accompanied the patient to the hospital.  Interview with the agency director on 1/9/13 at 12:10 PM confirmed a staff member did not accompany the patient to the hospital.  2. Patient #2 was admitted 1/7/12 at 10:55 AM for a surgical abortion. The patient was admitted to the recovery area at 13:35 PM where it was determined the patient had heavy bleeding during the pad check. Emergency medical personnel were called and the patient was transported to a local hospital. There was no evidence a staff member accompanied the patient to the hospital.  Interview with the agency director on 1/9/13 at 12:10 PM confirmed a staff member did not accompany the patient to the hospital.	E 163		
E169	.0402 FILE	E169	<i>Any physician working at the clinic will have</i>	<i>2/25/13</i>

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E169	<p>Continued From page 23</p> <p>10A-14E .0402 An individual file for each physician practicing in the clinic shall be maintained. Each file shall contain the information outlined in Rule .0401 of this Section.</p> <p>This Rule is not met as evidenced by: Based on a physician file reviews and staff interviews, the clinic failed to provide a current physician credential file for 1 of 3 practicing physicians employed in the clinic (Physician A).</p> <p>The findings include:</p> <p>A physician file review on 01/24/2013 for Physician A revealed that no current physician file was available. The review revealed there was no evidence of an application, work experience or license available for review.</p> <p>Review of the clinic procedure log revealed Physician A had performed abortion procedures at the clinic on 09/08/2012.</p> <p>An interview with the clinic office manager on 01/24/2013 at 1845 revealed that no current physician file could be found during the survey for Physician A. The interview revealed that the physician was currently on staff at the clinic and there was no current license or application found on site for Physician A. Interview revealed Physician A's credentialing file was located offsite in Florida with the clinic owner.</p> <p>Reference Investigation #NC00084154.</p>	E169	<i>An employee file on the premises at all times.</i>	



Autoclave Preventative Maintenance Log

Month	Autoclave #	PM's Done(y/n)	Autoclave #	PM's Done(y/n)	Date/Distributor
January					
February					
March					
April					
May					
June					
July					
August					
September					
October					
November					
December					

Attachment 1

PSS World Medical, Inc.  
 1816 WEST POINTE DR  
 SUITE B  
 CHARLOTTE NC 28214

Phone: (704) 916-3800  
 Fax: (704) 916-3995



Permit	Exp
204	12/31/13

# PACKING SLIP

Order Number	43962748	Date	02/16/13
Bill To:	329171 WOMEN'S CHOICE OF RALEIGH 3305 DRAKE CIRCLE RALEIGH NC 27607		
Bill To:	(919) 781-6934		
Ship To:	(919) 781-6934		
Accounting Notes			

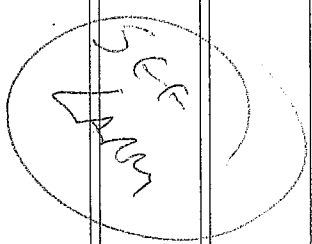
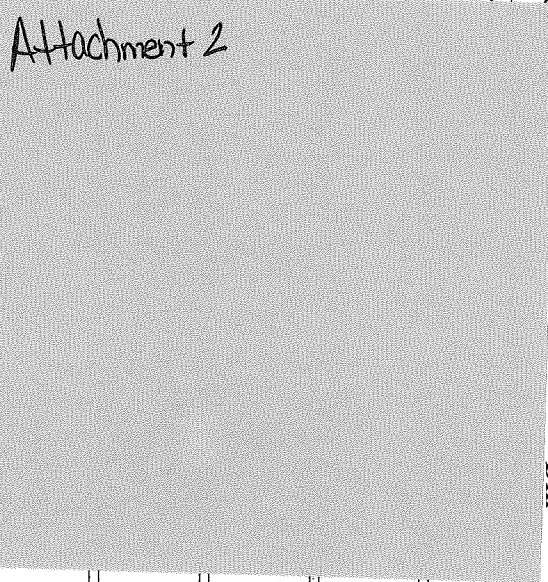
Invoice Number	79358227	Date	02/18/13
Ship To:	329171 WOMEN'S CHOICE OF RALEIGH 3305 DRAKE CIRCLE RALEIGH NC 27607		
HALME JOURKO KALERVO MD	24771	10/23/13	
Customer PO Number EBOVY			

Batch / Tote	/ 0
Time	5:14:52
Page	Page 1 of 1
Sales Rep Name	GRAY, ROGER
Order Entered By	LSANTOS
Ship Via	Truck 31

Shipping Instructions:



PSS #	Qty	Uom	Shipped	B/O	MFG #	Description	Bin	JDE Lot #	Expiration Date
11277	35	EA	35	0	LBR/21	LA			
180929	1	EA	1	0	RPR/CLNR-HRDWR	CI			
8	1	EA	1	0	RPR/RPL LSTD PARTS /S				
8	1	EA	1	0	RPR/053-0391-01	D			
8	1	EA	1	0	RPR/053-0527-00	D			
8	1	EA	1	0	RPR/SN ES007214				
					RITTER M11-001 AUTOCLAVE				



*Autoclave in for yearly preventive maintenance service. Replaced listed parts, performed system breakdown cleaning. Calibrated logic pcb, lube m parts. Electrical safety and over all performance tested. Final performance tested to mfg specifications.*

**OUR PURPOSE:** Strengthen the clinical success and financial health of caregivers by solving their biggest problems.  
**OUR MISSION:** Improve caregivers' financial performance by 20%.

Box: \_\_\_\_\_ Tote: \_\_\_\_\_ Bag: \_\_\_\_\_ Refr: \_\_\_\_\_

**8227**

NURSE

**AB LAB SHEET**

Doctor \_\_\_\_\_

Date/Time \_\_\_\_\_

HCG+ Control Lot # \_\_\_\_\_

Exp. \_\_\_\_\_ \*

Rh+ Control Lot # \_\_\_\_\_

Exp. \_\_\_\_\_ \*

HCG - Control Lot # \_\_\_\_\_

Exp. \_\_\_\_\_ \*

Rh - Control Lot # \_\_\_\_\_

Exp. \_\_\_\_\_ \*

Controls Done Initials \_\_\_\_\_

Controls Done Initials \_\_\_\_\_

#	Patient Name	2 min	25 iu	IC	Time	HCT	Rh	U/S	poc wt	evi	sac	fpi	fwd
1													
2													
3													
4													
5													
6													
7													
8													
9													
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11													
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28													
29													
30													

Attachment 3

Wampole HCG 2 Min

Antigen Lot # \_\_\_\_\_

Exp. \_\_\_\_\_

Antiserum Lot # \_\_\_\_\_

Exp. \_\_\_\_\_

Anti-D Gamma Clone

Lot # \_\_\_\_\_

Exp. \_\_\_\_\_

\* = RESULT

## A Woman's Choice of Raleigh Emergency Transfer Protocol

Any patient having an adverse condition or complication known or suspected to have occurred during or after abortion procedure will be transferred to WakeMed Hospital for evaluation or admission.

After the physician recognizes the need for emergency transfer, he orders the clinic administrator to call for EMS (Emergency Medical Team), either calling 911 or, preferably, 919-661-2504 to arrive ASAP. The physician stays with the patient in the procedure room (or recovery room if applicable) until arrival of EMS.

The administrator also calls 919-350-8000 to reach WakeMed Emergency Room Supervisor and have her talk to the physician directly. The physician identifies the patient by name and further demographics and a brief description of the patient's condition are given. The physician will then be connected to the chief resident or attending in Gynecology service for description and discussion of the patient's condition.

The EMS team will help stabilize the patient for transfer and the physician directs them to transfer the patient to WakeMed Emergency Room. A copy of patient's chart is given to the team to be taken to the E.R. personnel. A member of the clinic's medical staff will accompany the patient on the transfer to the Hospital. The physician also will discuss the situation with the person who accompanied the patient to the clinic, usually the designated driver.