Alabama Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	C5101	A. BUILDING _____ B. WING _____	02/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BEACON WOMEN'S CENTER	**1011 MONTICELLO COURT MONTGOMERY, AL 36117**

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L 000	INITIAL COMMENTS From 12/1/09 to 2/1/10, Department surveyors visited Beacon Women's Center ("the Center"), a Department licensed abortion or reproductive health center located at 1011 Monticello Court, in Montgomery, Alabama to conduct an on-site annual survey and to conduct four complaint investigations. The complaints were from patients who had received medical treatment at the Center. The Center was issued a probational license on 10/13/06 and operated under a consent agreement for one year due to the deficiencies written on the 8/3/06 annual survey. The following deficiencies were written on the survey conducted at the Center on 8/3/06 and are cited again on the 2009 annual survey: 1. Administration 2. Pharmaceutical Services 3. Physical Environment- Preventive Maintenance 4. Infection Control The following deficiencies were written on the survey conducted at the Center on 9/6/07 and are cited again on the 2009 annual survey: 1. Pharmaceutical Services The following deficiencies were written on the survey conducted at the Center on 7/18/08 and are cited again on the 2009 annual survey: 1. Administration 2. Patient Care 3. Pharmaceutical Services 4. Physical Environment- Preventive Maintenance 5. Infection Control During the 12/1/09 visit it was noted the medical	L 000		

Health Care Facilities

TITLE (X6) DATE

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

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equipment had not been inspected annually as required. The Administrator, Employee Identifier (EI) # 1, canceled the surgical abortions for the week of 12/1/09 and all patients were rescheduled.

On 12/10/09, Department surveyors returned to the Center to observe surgical abortions and to complete the annual and complaint surveys. After Department surveyors left the Center on 12/10/09, a new complaint was phoned in from another patient who received medical treatment from the Center. Department surveyors returned to the Center on 12/16/09 to investigate the new complaint.

On 12/28/09, another patient complaint was received against the Center. Department surveyors visited the Center again on 1/26/10 to investigate this complaint and follow up on concerns identified through the 12/16/09 survey. Surgical abortions were conducted on 1/28/10 by the Medical Director, EI # 7. Department surveyors were unable to conduct a controlled drug count during this visit. EI # 7 had the only key and forgot the key to the controlled drug cabinet. Center staff continued with the surgical abortions scheduled. Department surveyors secured the lock with tape and a label with their initials to prevent tampering with the controlled drug cabinet until they returned to the Center on 2/1/10 to conduct a controlled drug count with EI # 7 and EI # 2, the Center's Registered Nurse.

The following deficiencies were written as a result of the 2009 annual and complaint surveys.

420-5-1-.03 Patient Care
(1) Patient Care. All patient care must be rendered in accordance with all applicable

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federal, state, and local laws, these rules, and current standards of care, including all professional standards of practice. As with any surgical procedure, the physician performing the procedure is responsible for the procedure and for ensuring that adequate follow-up care is provided. In order to facilitate continuity of patient care, the facility physician shall contact and communicate with any physician rendering care for complications arising from the abortion as soon as he [or she] is informed of the existence of such complications. The facility shall develop and follow a policy and procedure for communication with outside physicians, such as emergency room physicians, so that all facility nurses and staff cooperate with any physician rendering
care for complications arising from an abortion.

This rule was not met as evidenced by:

Based on observation the Center failed to have medications available for patient comfort prior to surgical abortions being performed. This affected 17 of 17 scheduled surgical abortion procedures that were performed on 1/28/10.

Findings include:

The surveyors were on-site on 1/28/10 to observe Center staff on procedure day. At 2:10 PM Employee Identifier (EI) # 2, the Registered Nurse, was unable to access the controlled drug cabinet because EI # 7, the Medical Director, left the only key to the cabinet at his office in Selma. The controlled drug cabinet contained the Valium and Versed used to sedate patients prior to having a surgical abortion.

The 17 patients that were scheduled to have a

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L 000	Continued From page 3 procedure were given a choice to have their procedure completed without the use of sedation or their procedure could be rescheduled. All 17 of the scheduled surgical abortion procedures were performed by EI # 7 without the use of sedation. 420-5-1-.03 Patient Care (2) Policies and Procedures. The facility shall develop and follow detailed written policies and procedures that are consistent with all applicable federal, state, and local laws, these rules, and current standards of care, including all professional standards of practice. A comprehensive review of these policies and procedures shall be made annually, or whenever it appears that either a comprehensive or limited review is necessary to meet current legal requirements or standards of care. All necessary revisions shall be made and implemented promptly. (3) Patients' Rights. (a) The facility shall have written policies and procedures to ensure the patient the rights to dignity, privacy, and safety. This rule was not met as evidenced by: Based on state law, interviews and review of the policy protocol manual, the Center failed to develop policies and procedures that are consistent with applicable state law related to parental consent for abortions performed on unemancipated minors and mandatory reporting of suspected abuse or neglect of a minor child. In addition, the Center failed to have current policies and procedures available to Center staff to	L 000		

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provide safe and effective patient care. This had the potential to affect all patients that recieve services from the Center.

Findings include:

State laws

Section 26-21-3 of the Code of Alabama, which requires that the written consent of the parent or guardian be obtained before an abortion may be performed on an unemancipated minor, provides in part as follows:
" (a) Except as otherwise provided . . . no person shall perform an abortion upon an unemancipated minor unless he or she or his or her agent first obtains the written consent of either parent or the legal guardian of the minor . . .
(c) The person who shall perform the abortion or his or her agent shall obtain or be provided with the written consent from either parent or legal guardian stating the names of the minor, parent, or legal guardian, that he or she is informed that the minor desires an abortion and does consent to the abortion, the date, and shall be signed by either parent or legal guardian. The unemancipated minor shall verify on the same form, by her signature and in the presence of such person who shall perform the abortion or his or her agent, that said signature of the parents, parent or legal guardian is authentic. The consent shall be kept as a part of the minor's patient file for four years. "

The Alabama Child Abuse Reporting Act, section 26-14-3 of the Code of Alabama, reads in part as follows:
" (a) All hospitals, clinics, sanitariums, doctors, physicians, surgeons, medical examiners,

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L 000	Continued From page 5 coroners, dentists, osteopaths, optometrists, chiropractors, podiatrists, nurses, school teachers and officials, peace officers, law enforcement officials, pharmacists, social workers, day care workers or employees, mental health professionals, members of the clergy as defined in Rule 505 of the Alabama Rules of Evidence, or any other person called upon to render aid or medical assistance to any child, when the child is known or suspected to be a victim of child abuse or neglect, shall be required to report, or cause a report to be made of the same, orally, either by telephone or direct communication immediately, followed by a written report, to a duly constituted authority. " The Alabama Child Abuse Reporting Act, section 26-14-1 of the Code of Alabama, contains in part the following definitions: "(1) Abuse. Harm or threatened harm to a child's health or welfare. Harm or threatened harm to a child's health or welfare can occur through nonaccidental physical or mental injury, sexual abuse or attempted sexual abuse, or sexual exploitation or attempted sexual exploitation. 'Sexual abuse' includes the employment, use, persuasion, inducement, enticement, or coercion of any child to engage in, or having a child assist any other person to engage in, any sexually explicit conduct or any simulation of the conduct for the purpose of producing any visual depiction of the conduct; or the rape, molestation, prostitution, or other form of sexual exploitation of children, or incest with children as those acts are defined by Alabama law. ' Sexual exploitation ' includes allowing, permitting, or encouraging a child to engage in prostitution and allowing, permitting, encouraging or engaging in the obscene or pornographic photographing, filming or depicting of a child for commercial purposes.	L 000		

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(2) Neglect. Negligent treatment or maltreatment of a child, including the failure to provide adequate food, medical treatment, supervision, clothing or shelter.
(3) Child. A person under the age of 18 years ."

Various Alabama criminal statutes address sex crimes against children. Among them are the following:
Section 13A-6-61 of the Code of Alabama, which provides as follows:
" (a) A person commits the crime of rape in the first degree if:
1) He or she engages in sexual intercourse with a member of the opposite sex by forcible compulsion; or
2) He or she engages in sexual intercourse with a member of the opposite sex who is incapable of consent by reason of being physically helpless or mentally incapacitated; or
3) He or she, being 16 years or older, engages in sexual intercourse with a member of the opposite sex who is less than 12 years old.
(b) Rape in the first degree is a Class A felony."

Section 13A-6-62 of the Code of Alabama, which provides as follows:
" (a) A person commits the crime of rape in the second degree if:
(1) Being 16 years old or older, he or she engages in sexual intercourse with a member of the opposite sex less than 16 and more than 12 years old; provided, however, the actor is at least two years older than the member of the opposite sex.
(2) He or she engages in sexual intercourse with a member of the opposite sex who is incapable of consent by reason of being mentally defective.
(b) Rape in the second degree is a Class B

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L 000	Continued From page 7 felony." Section 13A-6-67 of the Code of Alabama, which provides as follows: " (a) A person commits the crime of sexual abuse in the second degree if: (1) He subjects another person to sexual contact who is incapable of consent by reason of some factor other than being less than 16 years old; or (2) He, being 19 years old or older, subjects another person to sexual contact who is less than 16 years old, but more than 12 years old. (3) Sexual abuse in second degree is a Class A misdemeanor, except that if a person commits a second or subsequent offense of sexual abuse in the second degree within one year of another sexual offense, the offense is a Class C felony." The Center's policies and procedures were requested on 12/1/09 at 10:30 AM. An interview with the Registered Nurse, EI # 2, on 12/1/09 at 1:30 PM, revealed the staff did not keep a policy book; EI # 2 stated that the Administrator, EI # 1, was calling the corporate office in Atlanta, GA, for assistance. Policies and procedures were requested a second time from EI # 1 on 12/1/09 at 3:00 PM, and none were provided. On 12/2/09 at 9:00 AM, policies and procedures were again requested from EI # 1 and none were provided. On 12/2/09 at 12:30 PM, EI # 1 presented a book that contained the 2008 National Abortion Federation information and protocols. There were no Center specific policies in the manual. An interview with EI # 1 on 12/2/09 at 10:35 AM,	L 000		

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revealed that she was unaware of the Mandatory Reporting Law relating to minors.

On 12/10/09, EI # 8, the Executive Director in Atlanta, GA, faxed to EI # 1 a copy of the front sheet for the policy and procedure book reflecting the annual review by the Medical Director, Administrator and Executive Director. The last annual review was dated 1/2009. The surveyor asked EI # 1 for the policy and procedure manual and she could not provide it.

Policies and procedures were again requested from EI # 1 on 12/10/09 at 12:30 PM, and EI # 1 stated that she did not have anything different than the protocol book which contained the 2008 National Abortion Federation protocols.

On a return visit to the Center on 12/16/09 to investigate a complaint, EI # 1 was asked again for the Center's policies and procedures and EI # 1 was unable to provide any.

On a return visit to the Center on 1/26/10 to investigate a new complaint, EI # 8 was asked if the Center had policies and procedures. Employee Identifier # 8 gave the surveyors a manual with policies and procedures. This manual was not located by any of the Center staff on the previous on-site visits. Employee Identifier # 2, the Registered Nurse and now the Interim Administrator, was unaware the Center had policies and procedures on the previous on-site visits.

Patient Identifier # 23, a 14 year old, had a procedure on 12/23/09 to terminate a 16.5 week pregnancy. An undated progress note documented the 14 year old patient and her mother both verified the father of the unborn child

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was 16 years old. There was no documentation the agency reported this information which should have raised a reasonable person's suspicion of abuse.

During an interview with EI # 8 and EI # 2 on 1/27/10, both employees verified PI # 23 had not been reported as required by state statue. EI # 2 also verified she did not have a policy for when and to whom to report abuse or neglect.

In an interview on 2/1/10 at 9:41 AM, EI # 7, the Medical Director, was asked if he reported minors who came to the clinic for an abortion. EI # 7 asked what was meant by the surveyors question. The surveyor explained the reporting requirements to EI # 7. The Medical Director stated, "Oh yeah. I ask them but they (the minor patients) lie to you. If something comes up positive then I do. I ask them how old the father is." EI # 7 was asked if he documented this in the medical record. EI # 7 responded, "You say I need to write down even if there is nothing that comes up." EI # 7 was asked who he would report minors that were pregnant to and he stated, "Well first thing I would do is call DHR (Department of Human Resources) and find out from them who I need to report it to and go on down the line." EI # 7 asked the surveyor if minors had to be reported even if the father of the child was a minor. EI # 7 asked the surveyor, "So if mom is 12 and father is 15 then it will still have to be reported?" The surveyor responded that this was correct.

There was no documentation the Center reported a 14 year old who was pregnant by a 16 year old. Employee Identifiers # 1 and # 2 were unable to locate policies and procedures for the Center and EI # 2 acknowledged she had no policy for when

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or to whom to report abuse or neglect of a minor. The Center had no policies for parental consent and mandatory reporting consistent with state law. EI # 7, the Medical Director and physician performing surgical abortions, was unsure of the required reporting requirements.

420-5-1-.03(f) Patient Care Informed Consent
3. The physician who is to perform the abortion or the referring physician is required to perform an ultrasound before the abortion. The woman has the right to view the ultrasound before an abortion. The woman shall complete a required form to acknowledge that she either saw the ultrasound image or that she was offered the opportunity and rejected it.

4. She has the right to view a videotape prepared by the Department of Public Health and the ultrasound.

6. She cannot be forced or required by anyone to have an abortion. She is free to withhold or withdraw her consent for an abortion without affecting her right to future care or treatment and without the loss of any state or federally funded benefits to which she might otherwise be entitled.
(i) The patient shall complete and sign the form in Appendix A to these rules.
(ii) Prior to the performance of an abortion, the physician who is to perform the abortion or his or her agent shall receive the signed receipt of the certified mail dated 24 hours before the abortion, if mailed, and the signed forms that she has received the information of subsections (1) and (2) before the abortion, had the opportunity to view the video and the ultrasound, and provided her informed consent for an abortion. The abortion or reproductive health center shall retain the signed receipt, signed forms, and a printed

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L 000	Continued From page 11 copy of the ultrasound image in the woman's medical file for the time required by law, but not less than four years... The requirements of this rule were not met as evidenced by: Based on a review of medical records it was determined: 1. In 5 of the 19 medical records completed for surgical abortion procedures performed on 12/10/09, the woman failed to complete Appendix A to acknowledge that she either saw the ultrasound image or that she was offered the opportunity and rejected it. 2. On observation and review of the medical record of 17 surgical abortion procedures performed 1/28/10, only 9 patients had completed Appendix A. The Certification of Opportunity to View Ultrasound was signed by the patient but the form was not dated by the patient and is not marked whether she reviewed the ultrasound or rejected the opportunity. 3. The patients had not been provided the opportunity to view a video recording, "Did You Know" prepared by the Department of Public Health as part of the counseling. This had the potential to affect all patients served. Findings include: Refer to 420-5-1-.02 (8)(a) Records and Reports for medical record findings related to Patient Identifiers # 4, # 5, # 6, # 7 and #14 for surgical abortion procedures where the woman failed to complete Appendix A to acknowledge that she either saw the ultrasound image or that she was	L 000		

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L 000	Continued From page 12 offered the opportunity and rejected it. Observation and Interview findings: An observation of the counseling provided to the patients on 1/27/10 at 10:58 AM, revealed EI # 2 provided 2 patients counseling. The counseling did not offer the patients the opportunity to view the video "Did You Know." The patients were guided through the paperwork and informed where to initial. The patients initialed the form which indicated the patients had been offered the opportunity to view the video, which was not a true statement. Every medical record reviewed by the surveyors between 12/1/09 and 1/28/10 had a form titled, " Certification of Voluntary and Informed Consent for Abortion". The patients were instructed to initial each area of the form of which the third area included the following, " That I have the right to view an ultrasound of my unborn child, as well as a video entitled ' Did You Know,' and I have been offered the opportunity to view both." During an interview with EI# 2 on 1/27/10 at 3:10 PM, she verified she had not offered the patients the opportunity to view the video and she had been instructed to give only the books. EI# 2 stated she had never offered the video to patients. Employee Identifier # 8 was interviewed on 1/28/10 at 12:30 PM, and verified the video was to be offered during the first visit counseling session. EI # 8 was asked where the patients would view the video. EI # 8 responded the video was watched in the back patient area. During this interview EI # 8 and a surveyor went to the back patient area. The back patient area did not have	L 000		

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L 000	Continued From page 13 a video machine. EI# 8 located the video machine in the front lobby where family members and friends waited for patients. EI# 8 informed the surveyor the video machine would be moved back to the back patient area for viewing the video. **** 420-5-1-.03 Patient Care (4)(f) Informed consent. Except in the case of a medical emergency, as defined in these rules, no abortion shall be performed or induced without the voluntary and informed consent of the woman upon whom the abortion is to be performed or induced. Except in the case of a medical emergency, as defined in these rules, consent to an abortion is voluntary and informed if and only if: 1. At least 24 hours before the abortion, the physician who is to perform the abortion, the referring physician, or a qualified person has informed and provided the woman in person, or by return receipt certified mail restricted delivery, and if by mail, again in person prior to the abortion, a copy of the printed materials developed by the Department of Public Health which list agencies that offer assistance, adoption agencies, development of the fetus, methods and risks of abortion and childbirth, father's obligations, alternatives to abortion and available methods of birth control. Mailing of the printed materials may be arranged by telephone. The requirements of this rule were not met as evidenced by: Based on an interview and review of medical	L 000		

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records it was determined in 3 of the 19 medical records completed for surgical abortion procedures performed on 12/10/09, that the 24 hour time frame was not followed for informed consent. This has the potential to affect all patients served.

Findings include:

1. Patient Identifier (PI) # 5 had a surgical abortion procedure performed on 12/10/09. On 12/16/09, a copy of PI # 5's medical record was provided to the surveyor. The record did not contain a copy of the Appendix A - Certification of Receipt of Abortion Information that documented, "I have received the printed materials entitled 'Did You Know'.... I understand that Alabama law requires that I be provided these materials at least 24 hours before I undergo an abortion, and I certify that this requirement of the law has been met for me." There was no way to determine if the patient had received this information 24 hours prior to the abortion procedure.

On a return visit to the Center on 1/28/10, the staff were not able to locate an Appendix A form. This form was not present in the medical record when reviewed by the surveyor on 12/16/09 or 1/28/10.The lack of information in the medical record indicated the physician performed the surgical abortion on 12/10/09 on the patient without legal consent.

In an interview on 1/28/10 at 12:55 PM, EI # 7, the Medical Director, was asked how he knew patients were given 24 hours' notice prior to a procedure that he performed. EI # 7 stated, "Everybody is suppose to have this done before they come to me." EI # 7 was asked what his

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responsibility, as the clinic physician, was in regard to making sure patients had received 24 hours' notice and had given their consent for a procedure. EI # 7 stated, "The consent form. I was not aware we had any body without a form. That's just a form lost. Like I said, I've not been checking behind them (the clinic staff). That's just an automatic thing (to assure there is a signed legal consent form on file prior to a procedure)." EI # 7 was asked how he knew patients had given their legal consent for a procedure he performed. EI # 7 stated, "I briefly look through the chart and see if they have the form. I must have missed it (the legal consent form for PI# 5)." EI # 7 was asked how he made sure he had met the legal requirements for a procedure he performed. EI # 7 stated, "I go through the chart...I assumed that was done. I guess I just missed some of those. When they come for pre-op it's suppose to be done (patients sign the consent form)." EI # 7 was asked if he understood the statute says a physician cannot perform an abortion without the 24 hours' notice given prior to the procedure and the patient's legal written consent. EI # 7 stated, "Right. I understand that I wasn't aware. That's suppose to be standard. I'm gonna make sure that's resolved. Something fell through the crack on that day." EI # 7 was given a copy of the state statute and asked if he had read the statute before. EI # 7 stated, "I think I read it when it first became law."

2. Patient Identifier (PI) # 19 had a surgical abortion procedure performed on 12/10/09. The Appendix A - "Certification of Receipt of Abortion Information" documented, "I have received the printed materials entitled 'Did You Know'.... I understand that Alabama law requires that I be provided these materials at least 24 hours before

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I undergo an abortion, and I certify that this requirement of the law has been met for me." The form was signed 12/2/09 but not marked as to whether the patient had received the information 24 hours prior to her procedure.

On a return visit to the Center on 1/28/10, the staff were not able to locate an Appendix A form. This form was not present in the medical record when reviewed by the surveyor on 12/16/09 or 1/28/10.The lack of information in the medical record indicated the physician performed the surgical abortion on 12/10/09 on the patient without legal consent.

3. Patient Identifier (PI) # 4, a minor patient, came to the Center for her first visit on 12/10/09. The patient had a surgical abortion procedure performed on 12/10/09.

On the Appendix A - Certification of Receipt of Abortion Information there was no documentation the patient had received the printed materials entitled "Did You Know" 24 hours prior to 12/10/09. The form signed 12/10/09 reads, "I understand that Alabama law requires that I be provided these materials at least 24 hours before I undergo an abortion, and I certify that this requirement of the law has been met for me." The patient signed and dated the form 12/10/09, the same day as the procedure.

On a return visit to the Center on 1/28/10, the staff were able to provide an Appendix A which had been signed at another Center on 12/7/09. This form was not present in the medical record when reviewed by the surveyor on 12/16/09 or 1/28/10. The information was found in the filing by staff on 1/28/10 and presented to the surveyor. The lack of information in the medical record

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L 000	Continued From page 17 indicated the physician performed the surgical abortion on 12/10/09 on the minor without legal consent. 420-5-1-.02(1)(a) Administration. Governing Authority. (a) Responsibility. The governing authority is the person or persons responsible for the management, control, and operation of the facility, including the appointment of persons to fill the minimum staffing requirements. The governing authority shall ensure that the facility is organized, equipped, staffed and administered in a manner to provide adequate care for each patient admitted. The requirements of this rule were not met as evidenced by: Based on observations, record reviews, and interviews, the Center's Governing Authority failed to ensure the Center was properly staffed to provide safe quality patient care. This had the potential to affect all patients served. Findings include: The Center had scheduled 25 procedures for 12/10/09. The surveyor confirmed on 12/16/09 at 9:00 AM, the Center staff and physician performed 19 surgical abortions and 7 follow-ups between 2:00 PM and 8:30 PM on 12/10/09. The staffing according to a written list received from Employee Identifier (EI) # 1, the Administrator, on 12/16/09 at 9:20 AM was 1 Registered Nurse(RN) for the recovery room, 1 medical assistant for the procedure room, 1 medical assistant for the sterilization room, and 1	L 000		

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L 000	Continued From page 18 clerical person working the front desk. The following observations were made on 12/10/09 while the Center was providing patient care. At 3:14 PM, 5 patients came to the recovery room to be premedicated by EI # 2, the Registered Nurse. The first post-operative patient came to the recovery room. Completion time of the procedure by the physician was documented as 3:14 PM. EI # 2 continued to pre-medicate the other patients who were standing in the room waiting for their surgical abortion. The first set of vital signs on the first patient, PI # 1, were taken at 3:22 PM with EI # 2 commenting to the surveyor the time difference was because she was administering medications to the other patients who were in the recovery room. EI # 2 then placed medication cups (containing Methergine 0.2 mg [milligram] and Ibuprofen 800 mg) at the chair side of 4 of the chairs in the recovery room. Envelopes with the patients' discharge medications, written discharge instructions and a complimentary pack of birth control pills were placed by the chairs. PI # 1 commented to the nurse she did not think the Valium (pre-op medication) did much good. PI # 1 was premedicated at 3:07 PM and her procedure time was 3:12 PM to 3:14 PM. There was not adequate time for the medication to be effective. Valium taken by mouth begins to take effect 30 minutes after it is taken. Refer to Mosby's Nursing Drug Reference book, 21st edition, Copy Right 2008.	L 000		

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At 3:27 PM, the second patient, PI # 2, entered to the recovery room by wheelchair and was transferred to the chair with the help of the medical assistant. The completion time of the procedure by the physician was documented as 3:26 PM. The patient came into the room telling EI # 2, the Registered Nurse, that she could not take birth control pills because she had a history of blood clots. EI # 2 instructed her to take her two pills at the chair side at 3:32 PM and then the first vital signs were checked at 3:37 PM. This was 11 minutes after PI # 2 entered the recovery room. The patient's blood pressure was 98/82 with a pulse rate of 118, by automatic blood pressure cuff readings. The blood pressure was rechecked with a reading of 109/81 and pulse rate of 116. The blood pressure cuff used on PI # 2 had been used on PI # 1 and had not been cleaned nor had EI # 2, the Registered Nurse, washed her hands between the two patients after she had touched the patients with her bare hands.

At 3:39 PM the third patient, PI # 3, was brought to the recovery room by wheelchair. Employee Identifier #3, the medical assistant who escorted PI # 3 to the recovery room, asked EI # 2 if she was okay. No response was given from EI # 2 and EI # 3 left the recovery room area.

EI # 2 then transferred the blood pressure cuff from PI # 2 back to PI # 1 to recheck her vital signs. The blood pressure cuff had not been cleaned nor had the nurse washed her hands between the two patients after direct contact with her bare hands to the patients' skin.

Employee Identifier # 3 returned to the recovery room with a second blood pressure cuff and applied it to PI # 2 and checked her vital signs

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which were, B/P 109/80 and pulse rate of 113. A third wrist blood pressure cuff was brought in and applied to the wrist of PI # 3 which had an automated reading of 148/102.

At 3:50 PM, PI # 1 was told to go in the restroom and re-dress, to leave the sanitary pad open and face up in the red bagged trash can where the EI # 2 could check the amount of blood on the pad.

EI # 2 cleaned the torn recliner chair that PI # 1 had occupied with Clorox spay and wiped it down with gloved hands. The Chux pad was changed after the seat of the recliner was dry.

EI # 2 asked PI # 2 if she told the doctor about her history of blood clots and the patient answered that she, " Put it on that paper." (The patient was referring to the history and physical section of the form completed by the patient.)

PI # 2 had her blood pressure checked at 3:55 PM. The blood pressure was 108/78 and pulse rate was 114. Her temperature was checked with the automatic thermometer applied to the bare skin of the forehead and it was 98.5 Fahrenheit. PI #2 was sent to the bathroom to redress with instructions to place her sanitary pad open and face up in the red bagged trash can where EI # 2 could assess the amount of blood on the pad and to call the nurse before she was completely dressed to come in to give her Rhogam injection.

Employee Identifier # 3, a medical assistant, came into the room and removed the wrist cuff from PI # 3 and left the recovery room with the wrist cuff without cleaning it.

PI # 2 came out of the bathroom completely dressed, EI # 2 reminded her she had to give her

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an injection. The patient returned to the bathroom for the injection then came back out. EI # 2 looked in the red bagged trash can and called to PI # 2 asking her where she put her pad. PI # 2 returned to the bathroom and showed EI # 2 the used sanitary pad was in the regular trash.

PI # 2 was discharged. As she started to leave she placed the sample pack of birth control pills in the nurse's hand and said that she was not going to take them with her history of blood clots.

Of the 3 recovery room patients observed, the Center staff failed to clean medical equipment that came in direct contact with patients' skin and wash their hands after direct patient contact per CDC (Centers for Disease Control and Prevention) guidelines.

The thermometer which was used to check the temperature of the patients with the other vital signs was placed against the bare skin of the forehead. It was never cleaned.

The observation of how the patients' bleeding was assessed led the surveyor to question the accuracy of whose pad EI # 2 was looking at as the procedure day went on and there were 19 procedures to be done. EI # 2 stated that the pad on top always belonged to the last person in the bathroom.

At 4:00 PM, EI # 1, the Administrator, came back to the recovery room to assist EI # 2. EI # 1 checked PI # 3's vital signs which were B/P 109/67 and pulse rate of 84. The surveyor asked EI # 1 about the number of blood pressure cuffs available. EI # 1 stated the Center had 3, 1 for the laboratory, and tried to keep 2 in the recovery room. EI # 1 was told there was only 1 in the

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L 000	Continued From page 22 recovery room. Employee Identifier # 1 left the recovery room and returned at 4:10 PM with an anxious patient crying stating that her blood sugar was low since she had not been able to eat all day and she was a diabetic. EI # 2 left to find the patient a peppermint hard candy and to consult with the physician about treatment for this patient. There were 6 additional patients escorted to the recovery room by EI # 3 while EI # 2 was out speaking to the physician. EI # 2 returned with a soda and told the patient to drink about half of it and eat a pack of crackers. EI # 2 pre-medicated her and told her she would be the next on the table. EI # 2 medicated a second patient and sent her along with the diabetic patient back to change clothes for their surgical abortion. At 4:25 PM, there were still 4 patients standing in the recovery room waiting to be medicated for their procedures and PI # 3 was still sitting in the chair. PI # 3's vital signs were taken and were B/P 104/68 and pulse rate of 85. The patient was ambulated to the bathroom to change clothes. At 4:30 PM, EI # 2 was medicating a patient who did not have a driver and would only be able to receive 1 Aleve tablet. The patient spoke up and said she was allergic to Aleve. EI # 2 flipped to the front of the chart to see if allergies were listed. EI # 2 then sent EI # 1, an unlicensed staff member, to speak with the physician for an order for Tylenol. During this time the surveyor could hear PI # 3 in the bathroom vomiting and coughing. EI # 2, the Registered Nurse, went to the door and asked PI # 3 if she was all right. PI # 3 stated, "Yes just throwing up." PI # 3 came out of the bathroom	L 000		

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and EI # 2 asked her if she wanted to stay a little longer and PI # 3 stated that she would. EI # 2 helped PI # 3 back to the chair she had been sitting in and re-checked her vital signs with the contaminated blood pressure cuff. At 4:50 PM, PI # 3 returned to the bathroom and vomited again. At 5:00 PM, PI # 3 remained in the recovery room, she had been in the recovery room 1 hour and 20 minutes.

After the first 3 procedures were completed the physician started doing follow ups and no other patients came to the recovery room. EI # 2, the Registered Nurse, did not have adequate help to observe post surgical patients, patients who were medicated awaiting their procedure, treat crises (low blood sugar, vomiting, hypertension), clean chairs, document the patient's condition and clinical findings, give discharge instructions and answer questions from the patients.

During an interview on 12/16/09 at 11:21 AM with EI # 2, the Registered Nurse who worked the recovery room, the surveyor asked if the staff working 12/10/09 was the usual amount of staff. She stated, "Yes,usually." She was then asked by the surveyor if that number was sufficient for meeting patient care needs. She stated, "No."

During an interview with EI # 1 on 12/16/09 at 11:48 AM, the surveyor asked if the staffing on 12/10/09 was the normal staffing. She stated, "It is." EI # 1 said the Center tries try to find extra help, but they (potential help) are looking for more than just one day a week to work.

During an interview with EI # 2, the Interim Administrator as of 1/8/10 and the Center Registered Nurse, at 12:50 PM on 1/28/10 she confirmed that the documentation was not

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L 000	Continued From page 24 complete because she could not complete the documentation and provide patient care at the same time. EI # 2 stated she was too busy with patient care to get it all done. The Center failed to have adequate staff available in the recovery room to address the abnormal vital sign readings, assist a patient that was vomiting and assure patients received adequate discharge instructions. Refer to 420-5-10.03(8)2 Infection Control Refer to 420-5-1-.02(8)(a) Records and Reports	L 000		
L 100	ALABAMA LICENSURE DEFICIENCIES THE FOLLOWING ARE LICENSURE DEFICIENCIES AND REQUIRE A PLAN OF CORRECTION. This Rule is not met as evidenced by: 420-5-1-.02(5) Personnel (b) Personnel Files. There shall be a personnel file for each employee which shall include: 1. Job Description. A written job description that describes the duties and responsibilities, position title, authority and qualifications for each employee. The requirements of this rule were not met as evidenced by: Based on review of personnel files and interviews, it was determined that the Center failed to have signed and dated job descriptions for five of five employees.	L 100		

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L 100	Continued From page 25 Findings include: A review of five personnel files on 12/1/09 to include the Director of Nursing, three medical assistants and a financial analyst, revealed no signed and dated job descriptions. On 12/2/09 at 8:00 AM, a job description with the five employees' names at the top was presented to the surveyors for review. The job descriptions had not been signed and dated by the employees to indicate they had been reviewed. An interview was conducted with EI # 2, the Registered Nurse, on 12/2/09 at 8:35 AM. The surveyor presented a copy of a job description to EI # 2 to review. EI # 2 stated that she did not perform several duties listed and that she had not reviewed, signed or dated a copy of her job description. **** 420-5-1-.02 (8)(a) Records and Reports. Medical Records to be kept. An abortion facility shall keep adequate records, including procedure schedules, histories, results of examinations, nurses' notes, records of tests performed and all forms required by law. The requirements of this rule were not met as evidenced by: Based on a review of medical records, observation and interview it was determined that 16 of the 19 medical records were not completed for surgical abortion procedures conducted on 12/10/09.	L 100		

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L 100	Continued From page 26 The medical records failed to have documentation by the physician and nurse to indicate that patient care was rendered and consents and state required forms were completed according to standards of practice. The Center failed to have a completed recovery room log for 12/10/09 as observed on 12/16/09. Findings include: Alabama Board of Nursing, Standards of Practice Chapter 610-X-6-.06 Documentation Standards (1) The standards for documentation of nursing care provided to patients by registered nurses and licensed practical nurses are based on principles of documentation regardless of the documentation format. (2) Documentation of nursing care shall be: (a) Legible to include signature. (b) Accurate. (c) Complete. Complete documentation includes reporting and documenting on appropriate records a patient's status, including signs and symptoms, response, treatments, medications, other nursing care rendered, communication of pertinent information to other health team members, and unusual occurrences involving the patient. (d) Timely. (i) Charted at the time or after the care, including medications, is provided... (ii) Should the registered nurse or licensed practical nurse add documentation that was omitted, the documentation shall reflect " late entry" including a date and time the late entry was made as well as the date and time the care was provided. (iii) A mistaken entry in the record by a licensed nurse shall be corrected by a method that does not obliterate, white-out, or destroy the entry.	L 100		

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L 100	Continued From page 27 1. Patient Identifier (PI) #1 was the first patient to have had a surgical abortion procedure on 12/10/09. According to the record, the procedure was completed at 3:14 PM and she came to the recovery room at 3:22 PM. EI # 2, the Registered Nurse, stated to the surveyor who was observing on 12/10/09 that the time would be off because she had just started the record at 3:22 PM. The Discharge Criteria time was blank, the discharge time, patient's signature, RN signature, and after care instructions were not completed on the Recovery Room (RR) form. 2. Patient Identifier (PI) # 2's surgical abortion procedure was completed at 3:26 PM and was admitted to the RR at 3:37 PM, eleven minutes later. The vital signs taken in the RR documented the patient was tachycardiac through her RR stay until discharge at 4:07 PM. There was no documentation the physician was notified that PI # 2 was tachycardiac. The patient received a Rhogam injection, but the amount administered was not documented as to a Full or Mini dose. The patient told EI # 2 from the time she entered the RR she could not take birth control pills because she had a problem with blood clots. EI # 2 asked the patient if she told the physician and PI # 2 stated that she put it on the form(referring to the history and physical form the patient completed). On discharge the surveyor observed the patient take the birth control pills out of her bag with her discharge medications and give them to EI # 2. There was no documentation EI # 2 spoke with the physician concerning the patient's inability to take birth control pills. 3. Patient Identifier (PI) # 3 was admitted to the RR at 3:38 PM after the surgical abortion. The first blood pressure taken by EI # 2 was 148/102	L 100		

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L 100	Continued From page 28 as observed by the surveyor. On 12/16/09, the surveyor asked EI # 2 why she did not record the elevated blood pressure. Employee Identifier # 2 stated that she started recording blood pressure readings after the first abnormal blood pressure was obtained. The patient status section of the Discharge Criteria was blank. The time on the discharge was documented as 4:50 PM. The surveyor asked EI # 2 about the discharge time since the patient was still in the chair when the surveyor left the building at 5:00 PM. EI # 2 looked at the surveyor and said," You know how crazy it was back here, I was doing the best I could." 4. Patient Identifier (PI) # 4, a minor patient, came to the Center for her first visit on 12/10/09. The patient had a surgical abortion procedure that same day. The recovery room (RR) record documented her entering the RR at 4:44 PM. This patient was not in the RR when the surveyor left the premises at 5:00 PM. On the Appendix A - Certification of Receipt of Abortion Information, there was no documentation the patient had received the printed materials entitled " Did You Know" dated 12/10/09. The form reads, "I understand that Alabama law requires that I be provided these materials at least 24 hours before I undergo an abortion, and I certify that this requirement of the law has been met for me." The patient signed and dated the form 12/10/09, she did not have the information the required 24 hours prior to the abortion procedure. On a return onsite visit to the Center on 1/28/10, the Center staff provided an Appendix A which had been signed at another Center 12/7/09. This form was not present in the medical record when	L 100		

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L 100	Continued From page 29 reviewed by the surveyor on 12/16/09 or 1/28/10. The Appendix A form was reportedly found in the filing by staff on 1/28/10 and presented to the surveyor. The lack of information in the medical record indicated the physician performed the surgical abortion 12/10/09 on the minor without the required consent form being in the medical record. This same form, the Certification of Opportunity to View Ultrasound, was signed and dated 12/10/09 by the patient, but it was not marked whether she reviewed the ultrasound or rejected the opportunity. 5. Patient Identifier (PI) # 5 had a surgical abortion procedure on 12/10/09. The record given to the surveyor on 12/16/09 did not contain a copy of the Appendix A - Certification of Receipt of Abortion Information documented I have received the printed materials entitled " Did You Know". The form reads, "I understand that Alabama law requires that I be provided these materials at least 24 hours before I undergo an abortion, and I certify that this requirement of the law has been met for me." A copy of this information was not with the record. Appendix A page 2 the Certification of Voluntary and Informed Consent for Abortion was not present with the record. There was no way to determine if the patient had received this information 24 hours prior to the abortion procedure. On a return visit to the Center on 1/28/10, the staff were not able to locate an Appendix A form. This form was not present in the medical record when reviewed by the surveyor on 12/16/09 or 1/28/10. The lack of information in the medical record indicated the physician performed the surgical abortion on 12/10/09 on the patient	L 100		

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L 100	Continued From page 30 without legal consent. On this same form the Certification of Opportunity to View Ultrasound is not available to indicate whether the patient reviewed the ultrasound or rejected the opportunity. In an interview on 1/28/10 at 12:55 PM, EI # 7, the Medical Director, was asked how he knew patients were given 24 hours' notice prior to a procedure that he performed. The Medical Director stated, "Everybody is supposed to have this done before they come to me." The Medical Director was asked what his responsibility, as the clinic physician, was in regard to making sure patients received 24 hour notice and had given their consent for a procedure. The Medical Director stated, "The consent form I was not aware we had any body without a form. That's just a form lost. Like I said, I've not been checking behind them (the clinic staff). That's just an automatic thing (to assure there is a signed legal consent form on file prior to a procedure)." The Medical Director was asked how he knew patients had given their legal consent for a procedure he performed. The Medical Director stated, "I briefly look through the chart and see if they have the form. I must have missed it (the legal consent form for PI# 5)." The Medical Director was asked how he made sure he had met the legal requirements for a procedure he performed. The Medical Director stated, "I go through the chart...I assumed that was done. I guess I just missed some of those. When they come for pre-op it's supposed to be done (patients sign the consent form)." The Medical Director was asked if he understood the statute says a physician cannot perform an abortion without the 24 hours' notice given prior to the procedure and the patient's legal written consent. The Medical Director stated, "Right. I	L 100		

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L 100	Continued From page 31 understand that I wasn't aware. That's suppose to be standard. I'm gonna make sure that's resolved. Something fell through the crack on that day." The Medical Director was given a copy of the state statute and asked if he had read the statute before. The Medical Director stated, "I think I read it when it first became law." The ultrasound performed by Center staff on 12/2/09 on PI # 5's first visit to the Center showed 2 separate CRL(crown rump lengths) measurements with a comment section entry of twins, respective gestation 6.0/6.1 weeks. An ultrasound was completed 12/10/09 at 1:12 PM with a CRL of 11 centimeters (cm) and a gestational age of 7.1 weeks. There was no documentation present in the record regarding the first ultrasound indicating 2 separate CRL and measurements; the presence of twins. 6. Patient Identifier (PI) # 6 had a surgical abortion procedure on 12/10/09. Appendix A, the Certification of Opportunity to View Ultrasound is signed by the patient, but not dated by the patient and it is not marked whether she reviewed the ultrasound or rejected the opportunity. The physician documented in the comment section of the procedure record, Pitocin 1 cubic centimeter (cc). There was no indication if this was given intravenous(IV) by the physician or the time it was administered. EI # 2, the Registered Nurse, was asked about the Pitocin on 12/16/09. Employee Identifier # 2 stated that the physician will sometimes give Pitocin IV after the procedure if patients are 14.5 weeks or greater.	L 100		

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L 100	Continued From page 32 7. Patient Identifier (PI) # 7 had a surgical abortion procedure on 12/10/09. The recovery room record failed to document completion of the following sections: discharge criteria time, the discharge time and the date on the recovery room record. Appendix A, the Certification of Opportunity to View Ultrasound, is signed and dated 12/1/09 by the patient, but it is not marked whether she reviewed the ultrasound or rejected the opportunity. 8. Patient Identifier (PI) # 8 had a surgical abortion procedure on 12/10/09. The Discharge Criteria time was blank. The Discharge time was not recorded and the dose of Rhogam Mini/Full was not marked. The patient arrived in the recovery room at 5:39 PM and her first vital signs which were at 5:41 PM, recorded a temperature of 100.3 degrees Fahrenheit. There was no documentation the physician was notified of the elevated temperature. The pre-op medication Valium 10 mg and Aleve 220 mg was administered at 4:13 PM by EI # 2, the RN, but no route of medication administration was documented. 9. Patient Identifier (PI) # 10 had a surgical abortion procedure on 12/10/09. The pre-op medication Valium 10 mg and Aleve 220 mg was administered at 4:37 PM by EI # 2, the RN, but no route of medication administration was documented. 10. Patient Identifier (PI) # 11 had a surgical abortion procedure on 12/10/09. The Discharge time was not documented on the recovery room record.	L 100		

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L 100	Continued From page 33 11. Patient Identifier (PI) # 12 had a surgical abortion procedure on 12/10/09. There was no procedure time documented by the physician on the procedure record. 12. Patient Identifier (PI) # 13 had a surgical abortion procedure on 12/10/09. The recovery room record failed to document completion of the discharge criteria and the time. 13. Patient Identifier (PI) # 14 had a surgical abortion procedure on 12/10/09. The pre-op medication Valium 10 mg and Aleve 220 mg, was administered at 4:33 PM by EI # 2, the RN, but no route of medication administration was documented. On Appendix A, the Certification of Opportunity to View Ultrasound, was signed by the patient, but was not dated by the patient and is not marked whether she reviewed the ultrasound or rejected the opportunity. 14. Patient Identifier (PI) # 15 had a surgical abortion procedure on 12/10/09. The pre-op medication Valium 10 mg, and Aleve 220 mg, was administered at 5:21 PM by EI #2, the RN but no route of medication administration was recorded. 15. Patient Identifier (PI) # 18 had a surgical abortion procedure on 12/10/09. The recovery room record failed to document completion of the Discharge Criteria. The time was blank. There was no discharge time on the recovery room form. 16. Patient Identifier (PI) # 19 had a surgical abortion procedure on 12/10/09. The Appendix A - Certification of Receipt of Abortion Information, documented I have received the printed materials	L 100		

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L 100	Continued From page 34 entitled " Did You Know". The form read, "I understand that Alabama law requires that I be provided these materials at least 24 hours before I undergo an abortion, and I certify that this requirement of the law has been met for me." The form was signed 12/2/09 but not marked as to whether the patient had received the information. On Appendix A page 2 the Certification of Voluntary and Informed Consent for Abortion was blank at the top of the form. There was no date or documentation of the identity of the staff member that informed the patient of the information. The dose of Rhogam Mini/Full was not marked. The pre-op medication Valium 10 mg and Aleve 220 mg was administered 5:21 PM by EI # 2, the RN, but no route of medication administration was documented. Summary: The medical records maintained by the Center failed to have documentation by the physician and nurse to indicate that patient care was rendered and consents and state required forms were completed according to standards of practice. The Center failed to have a completed recovery room log for 12/10/09 as observed on 12/16/09. EI # 2, the Registered Nurse, was asked for the recovery room log on 12/16/09 at 9:00 AM. After 30 minutes, EI # 2 admitted she had not completed a recovery room log and stood at the front desk and filled out the log from the charts as the surveyors copied records. During the 12/16/09 visit to the Center, documentation was reviewed from the three records of the patients who were in the recovery	L 100		

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L 100	Continued From page 35 room observed by the surveyor on 12/10/09. The recovery room log was incomplete. The narcotic count sheet had been rewritten, and documentation on the patient's charts were incomplete. On 1/27/10, during an interview with EI # 2 she was provided with all of the medical records and questions regarding these records. EI # 2 was unable to provide any further information and confirmed the documentation was not complete. During an interview with EI # 2 on 1/28/10 at 12:50 PM, she confirmed that the documentation was not complete because she could not complete the documentation and provide patient care at the same time. EI # 2 stated she was too busy with patient care to get it all done. **** 420-5-1-.03 Patient Care (6)(f) Emergency Kit or Emergency Drugs 1. Each abortion clinic shall maintain upon the advice and written approval of the facility's medical director an emergency kit or stock supply of drugs and medicines for treating the emergency needs of patients. 2. The kit or medicine shall be stored in such a manner as to be inaccessible to unauthorized personnel while allowing quick retrieval by authorized personnel. The requirements of this rule were not met as evidenced by: Based on observations and interview, it was determined that the Center failed to ensure	L 100		

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L 100	Continued From page 36 emergency drugs were available for authorized personnel use. This had the potential to affect all patients served by the Center. Findings include: During the initial tour conducted in the recovery room on 12/1/09 at 8:30 AM, the Center's emergency drugs were not accessible to Center staff or the surveyors due to their cabinets being locked with padlocks. An interview with EI # 2, the Registered Nurse, on 12/2/09 at 10:35 AM, revealed the physician had the keys to all the drug storage. No other Center staff, including EI # 2 , have a key to access the medications. An interview was conducted with the Medical Director, EI # 7,on 12/10/09 at 2:30 PM. The surveyor asked EI # 7 about the availability of medications in an emergency situation when he was not present in the building. EI # 7 stated that he thought the Executive Director said something about that and they would work out some kind of system. During a tour on 12/10/09 at 2:35 PM, EI # 2 was asked where the oxygen tank for emergency use was. EI # 2 stated that she would look for it. The surveyor asked EI # 2 at 3:00 PM if she had found the oxygen tank and she stated that she had not. The oxygen was not located during the time the surveyors were present in the Center on 12/10/09. Failure to have access to emergency drugs and oxygen poses a serious risk to patient safety in the event of an emergency.	L 100		

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L 100	Continued From page 37 **** 420-5-1-.04(5)(d) Supplies Medications and supplies which have deteriorated or reached their expiration dates shall not be used for any reason. All expired or deteriorated items shall be disposed of promptly and properly. Each facility shall examine all stored medications and supplies no less frequently than once a month and shall remove from its inventory all deteriorated items and all items for which the expiration date has been reached. The facility shall maintain a log recording each such examination, and a description of each item or group of items removed from inventory and the reason for such removal. The requirements of this rule were not met as evidenced by: Based on observation and interview, it was determined that the Center failed to remove supplies and medication which had expired from inventory. This had the potential to affect all patients served. Findings include: During a tour of the Center on 12/1/09 at 2:10 PM, the surveyors observed: Gentamycin 80 mg (milligrams)/ml (milliliter) 1 vial with an expiration date of 12/01/08 and 6 Ammonia inhalers with an expiration date of 7/09 in the recovery room cabinet. On 12/10/09 at 2:55 PM, EI # 7, the Medical Director, unlocked the emergency drug storage unit in the recovery room for the surveyor to	L 100		

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L 100	Continued From page 38 review. The surveyor observed locked with the emergency drugs a total of ten, 10 ml syringes of Calcium Chloride 10% with an expiration date of 11/09. On 12/10/09 in the recovery room, EI # 2 was asked about the Calcium in the emergency kit being expired and she replied that she kept a list in her office in the book on the shelf. The list contained all of the drugs kept in the emergency kit and the dates those drugs expired. The surveyor viewed the book in the presence of EI # 2 and it did document that the Calcium expired in November 2009. EI # 2 then stated that she had not checked the emergency kit for December or she would have seen it. The surveyor observed the contents of the cabinet next to the sterilizer room to find 10 Iron tablets that had an expiration date of 6/2009. **** 420-5-1-.04(4)(c) Physical Environment (4) Treatment Facilities. (c) Recovery Room. One or more recovery rooms containing sufficient beds for recovering patients shall be provided. Reclining type vinyl upholstered chairs may be substituted in lieu of beds. Other items for the patients' comfort may be provided in the room. The requirements of this rule were not met as evidenced by: Based on observation and interview during tour of the Center, chairs in the recovery room were noted to be an infection control risk with foam showing on each chair. This has the potential to	L 100		

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L 100	Continued From page 39 affect all patients served. Findings include: Observed in the recovery room were 8 recliner chairs of which all 8 had the covers on the seat partly torn loose and unattached. Several other chairs had splits in the back of the chairs with white foam visable. During an interview with EI # 2 on 12/2/09 at 8:35 AM, she was asked how she assured the chairs were not an infection control risk. EI # 2 stated that the chairs were wiped down with clorox solution between patients. The cleaning of the vinyl chairs with splits in the upholstery and the seat covers loose and unattached would prevent adequate infection control. During an interview with EI # 1 on 12/16/09 at 11:48 AM, the surveyor asked her regarding the chairs in the recovery room needing reupholstering. She stated that they were hard to clean, we need new chairs not just reupholstered. She also stated that," I will definitely ask about that again." **** 420-5-1-.04(5)(b) Equipment and Supplies (b) Preventive Maintenance. There shall be a schedule of preventive maintenance developed for all equipment in the facility integral to patient care to assure satisfactory operation thereof. This schedule shall cover at least the following equipment: 1. Ultrasound: All ultrasound machines must be tested and calibrated by a trained, qualified	L 100		

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L 100	Continued From page 40 technician in accordance with the manufacturer's recommendations. In no event shall testing and calibration be done less than annually. 2. Autoclave: All autoclaves must be tested and maintained at least annually by a trained, qualified technician in accordance with the manufacturer's recommendations, except that necessary routine weekly cleaning, maintenance, and inspection may be performed by properly trained clinic staff or a trained, qualified technician in accordance with the manufacturer's recommendations. Dated chemical indicators shall be used with every load to ensure sterilization. Biological indicator testing must be performed every 40 service-hours, and the results of the biological indicator testing must be logged. (c) The facility must maintain a record for all equipment containing the following information: manufacturer, make, and model of the equipment; date of purchase of the equipment; any dates on which the equipment was removed from service for repair or maintenance and, if applicable, date equipment was returned to service; date and description of all tests, maintenance, or repairs performed on the equipment, including all routine inspection and maintenance performed by clinic personnel; the names and qualifications of the company and technician performing the tests, maintenance, or repairs; and the results of any tests, maintenance, or repairs. In addition, all manufacturer literature and information must be maintained in this record. If any of this information is not available for equipment purchased prior to October 2006, the fact of the missing information shall be noted in the equipment record, and, if there is no record of	L 100		

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L 100	Continued From page 41 proper maintenance in the last year, the equipment must be immediately tested and, if necessary, calibrated or repaired. The requirements of this rule were not met as evidenced by: Based on observations, review of emergency equipment logs and interviews it was determined that the Center failed to ensure equipment was in operable condition for use. This had the potential to affect all patients served. Findings include: During a tour of the facility on 12/1/09, the surveyors noted the biomedical stickers on the autoclave and the ultrasound equipment in the treatment rooms had an expiration date of 11/09. The clinic had two treatment rooms with room #1 labeled as "not in use." An interview with EI # 1, the Administrator, on 12/2/09 at 8:40 AM, revealed the person responsible for maintenance of the equipment had been due to come on 11/30/09. EI # 1stated she called and attempted to set up an appointment on 11/17/09, however the maintenance company was unavailable until 11/30/09. EI # 1 stated she left three messages for the maintenance company representative on 11/30/09 with no response and until he could come they would have to cancel clinic and reschedule the 12/2/09 week's appointments. The Emergency Defibrillator Test Log form instructions read, "The Defibrillator is tested prior to surgery on all procedure days by the Recovery Room RN (Registered Nurse). If the test fails, the administrator will be notified immediately."	L 100		

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L 100	Continued From page 42 A review of the log, dated November 2009, revealed the last date of testing was 11/14/09. The Center had performed surgical procedures on 11/19/09, 11/21/09 and 11/25/09 without prior testing of the defibrillator to ensure it was properly functioning in case of an emergency. An interview with EI # 2, the only Registered Nurse who works in the recovery room, on 12/2/09 at 8:25 AM, confirmed there was no documentation of defibrillator testing since 11/14/09. On 12/10/09 at 12:30 PM the Emergency Defibrillator Test Log was reviewed again during a complaint investigation. The form revealed dates of testing performed on 11/14/09, 11/19/09, 11/21/09 and 11/25/09. The last three entries had not been documented on 12/2/09 and were not documented as late entries. On 12/16/09 at 9:25 AM, the Emergency Defibrillator Test Log was reviewed again. The form revealed dates of testing performed on 12/12/09 with blank spaces left between 11/25/09 and the 12/12/09. On 12/10/09, the Center failed to document the equipment was checked and procedures were completed on this day. On 12/10/09 at 12:05 PM the surveyors met with the EI # 1, the Administrator, and requested the machine maintenance verification. A review of the Medical Equipment Solutions preventive maintenance forms revealed dates of service as 12/7/09. All equipment that was inspected by the maintenance company employee had documentation that it passed functional verfication.	L 100		

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L 100	Continued From page 43 There were no logs listing all the equipment checked on 12/7/09. On 12/10/09 at 12:15 PM, the following equipment was observed with orange stickers indicating the equipment was in satisfactory working condition according to the medical equipment inspector: Powerheart Automated External Defibrillator (AED) unit- preventive maintenance sticker dated 6/09 for next inspection. Microscope Bristolscope- preventive maintenance sticker dated 6/10 for next inspection. HemoCue Blood Analyzer-preventive maintenance sticker dated 6/10 for next inspection. Laboratory Centrifuge- preventive maintenance sticker dated 6/10 for next inspection. Rotomix - preventive maintenance sticker dated 6/09 for next inspection. Ultrasound System (observed locked in laboratory closet) with preventive maintenance sticker dated 6/10. According to the form completed this machine was not in working order. Ultrasound System (Room 1 with sign on door "not in use") with sticker dated 6/10. (Administrator stated it had a fuzzy screen when checked by maintenance). Ultrasound System - preventive maintenance sticker dated 6/09.(This was in room 2 procedure room). Suction Pump/Berkley Med Systems - no sticker present. (This was in exam room 2 which was being used for procedures). Suction Pump (Room 1 with sign on door "not in use") with sticker dated 6/10. Ritter Speedclaw - preventive maintenance sticker dated 6/10.	L 100		

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L 100	Continued From page 44 On 12/10/09 at 2:10 PM, EI # 7, the Medical Director, was observed checking the Ultrasound machine in Room 1 which had a sign on the door that read "not in use", meaning the entire room was closed. The surveyor asked EI # 7 if the machine was working. He stated that it was not, after the machine had been in use the equipment would get hot and no longer function properly. The surveyor commented to EI # 7 that the maintenance sticker applied Monday 12/7/09 documented it was in service and was to be rechecked in 6/2010. EI # 7 stated, " He didn't (the medical equipment inspector) know what he was talking about, he checks for safety not preventive maintenance or repair." The Center failed to assure all of the labeled equipment was properly functioning. The Center failed to assure the preventive maintenance stickers were dated accurately and the nonfunctioning equipment was labeled not for patient use. **** 420-5-1.03(8) Infection Control (a) Infection Control Committee. 1. There shall be an infection control committee composed of a physician and registered professional nurse who shall be responsible for investigating, controlling, and preventing infections in the facility. 3. There shall be continuing education provided to all staff on causes, effects, transmission, prevention, and elimination of infection at least annually.	L 100		

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L 100	Continued From page 45 The requirements of this rule were not met as evidenced by: Based on interview and review of the infection control manual, it was determined that the Center failed to have an active infection control committee responsible for investigating infections. This had the potential to affect all patients served. Findings include: The Center could not provide the surveyors with policies and procedures for Infection Control while the surveyors were on-site. An interview with EI # 2, the Registered Nurse, on 12/2/09 at 8:35 AM, confirmed no policies were available for review and revealed there were no action plans to address any problems with infection control which had been identified. **** 420-5-1.03(8)2 Infection Control 2. There shall be procedures to govern the use of sterile and aseptic techniques in all areas of the facility. The requirements of this rule were not met as evidenced by: Based on observation and interview it was determined that the Center failed to have procedures for use in the recovery room related to infection control and aseptic technique for patient care and protection. The staff failed to wash their hands and clean equipment between patients. This had the potential to affect all	L 100		

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L 100	Continued From page 46 patients served in the Center. Findings include: The Centers for Disease Control and Prevention, Volume 51 published 10/25/02, Guidelines for Hand Hygiene in Health-Care Settings. Recommendations: These recommendations are designed to improve hand-hygiene practices of HCWs(health care worker) and to reduce transmission of pathogenic microorganisms to patients and personnel in healthcare settings. Recommendations: 1. Indications for handwashing and hand antisepsis. C. Decontaminate hands before having direct contact with patients. F. Decontaminate hands after contact with a patient's intact skin (e.g. when taking a pulse or blood pressure...) I. Decontaminate hands after contact with inanimate objects (including medical equipment) in the immediate vicinity of the patient. J. Decontaminate hands after removing gloves. On 12/10/09 at 3:00 PM, the surveyor was present in the Center's recovery room to observe post-operative patient care. All 8 recliner chairs had covers on the seat partly torn loose and unattached. Several chairs had splits in the back of the chairs with white foam visable. All 8 of the recliners seats had Chux pads placed in the bottoms in preparation for the patient. On 12/10/09 at 3:14 PM, the first patient, PI # 1, entered the recovery room. PI # 1 had her vital signs taken. After PI # 1 had her vital signs taken the medical equipment was not cleaned.	L 100		

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L 100	Continued From page 47 At 3:27 PM, the second patient, PI # 2, entered the recovery room by wheelchair, transferred to the chair with the help of EI # 3, Medical Assistant # 1. The blood pressure cuff used on PI # 2 had been used on PI # 1 and had not been cleaned nor had EI # 2, the Registered Nurse, washed her hands between the two patients after she had touched the patients were her bare hands. At 3:39 PM, the third patient, PI # 3, was brought to the recovery room by wheelchair. EI # 2 then transferred the blood pressure cuff from PI # 2 back to PI # 1 to recheck her vital signs. The blood pressure cuff had not been cleaned nor had the nurse washed her hands between the two patients after direct contact with her bare hands to the patients skin. Employee Identifier # 3 returned to the recovery room with a second blood pressure cuff and applied it to PI # 2 and checked her vital signs. A third wrist blood pressure cuff was brought in and applied to the wrist of PI # 3. The blood pressure cuffs had not been cleaned between uses on multiple patients. At 3:50 PM, PI # 1 was told to go in the restroom and re-dress, to leave the sanitary pad open and face up in the red bagged trash can where the EI # 2 could check the amount of blood on the pad. EI # 2 cleaned the torn recliner chair that PI # 1 had occupied with Clorox spay and wiped it down with gloved hands. The Chux pad was changed after the seat of the recliner was dry. PI # 2 had her blood pressure checked at 3:55 PM. Her temperature was checked with the automatic thermometer applied to the bare skin of the forehead and it was 98.5 Fahrenheit. PI #2	L 100		

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L 100	Continued From page 48 was sent to the bathroom to redress with instructions to place her sanitary pad open and face up in the red bagged trash can where EI # 2 could assess the amount of blood on the pad and to call the nurse before she was completely dressed to come in to give her Rhogam injection. Employee Identifier # 3 came into the room and removed the wrist cuff from PI # 3 and left the recovery room with the wrist cuff without cleaning it. PI # 2 came out of the bathroom completely dressed, EI # 2 reminded her she had to give her an injection, the patient returned to the bathroom for the injection then came back out. EI # 2 looked in the red bagged trash can and called to PI # 2 where did you put your pad. PI # 2 returned to the bathroom and showed EI # 2 the used sanitary pad was in the regular trash. At 4:00 PM, EI # 1, the Administrator, came back to the recovery room to assist EI # 2. EI # 1 checked PI # 3's vital signs. The surveyor asked EI # 1 about the number of blood pressure cuffs available. EI # 1 stated the Center had three, one for the laboratory and tried to keep two in the recovery room. EI # 1 was told by the surveyor there was only one BP cuff in the recovery room. At 4:25 PM, there were still four patients standing in the recovery room waiting to be medicated for their procedures and PI # 3 was still sitting in the chair. PI # 3's vital signs were taken, the equipment was not cleaned after its use. The patient was ambulated to the bathroom to change clothes. At 4:50 PM, EI # 2 helped PI # 3 back to the chair she had been sitting in and rechecked her vital	L 100		

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L 100	Continued From page 49 signs with the contaminated blood pressure cuff. The surveyors also made observations of post-operative care provided in the recovery room on 1/28/10. The 19 patients who underwent surgical abortion procedures on 1/28/10 received care from staff who failed to clean the blood pressure equipment between patient contacts and did not routinely wash their hands between patient contacts. Of the three recovery room patients observed, the Center staff failed to clean medical equipment that came in direct contact with patients skin and wash their hands after direct patient contact per Centers for Disease Control and Prevention (CDC) guidelines. The thermometer which was used to check the temperature of the patients with the other vital signs was placed against the bare skin of the forehead. It was never cleaned. The blood pressure cuffs were never cleaned and the staff failed to wash their hands between contact with the patients. The Center failed to have a procedure for aseptic care of the patient, cleaning equipment, follow hand washing guidelines and infection control for safety of the patients and staff. **** 420-5-1-.03 Patient Care. (6) Post Operative Procedures. (d) Post-Operative Policies and Procedures: A facility must develop and follow written policies and procedures detailing the sequence of post-operative care. The facility	L 100		

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L 100	Continued From page 50 must have a 24 hour answering service that immediately refers all calls related to post abortion problems to a qualified registered nurse, nurse practitioner, physician assistant, or physician. If a registered nurse, nurse practitioner, or physician assistant will be the initial medical contact, clear protocols must be developed and approved by the medical director, all facility physicians, and any outside covering physicians to establish when a physician will be contacted, which physician will be initially contacted, how the outside covering physician will be contacted if immediate care is needed, and how the patient will be contacted and receive the physician's instructions. (e) Call Records: In addition to the infection control record required by these rules, a facility must keep a record of all calls taken by the registered nurse, nurse practitioner, physician assistant, or physician. The call record should include the patient ' s name, time and date of call, a brief description of the reason for the call, and any action taken in response. A full description of any adverse conditions and the instructions or treatment given in response must be noted in the patient ' s medical record. The requirements of this rule were not met as evidenced by: Based on review of medical records, review of answering service call logs and interview it was determined that the Center failed to return calls to patients in a timely manner and document instructions and responses to patients. This had the potential to affect all patients served by the Center. Findings include:	L 100		

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L 100	Continued From page 51 During an interview on 1/27/10 at 1:35 PM, EI# 2, the Registered Nurse, verified she did not write down calls from patients received during business hours. There was no program to consistently track the patients with concerns following their procedures. 1. Patient Identifier (PI) # 22 had a surgical abortion procedure on 12/12/09. The Consent to Outpatient Surgery dated 12/9/09 documented, "Emergency: If I develop a fever, heavy bleeding, severe cramping or pain or any other symptom, I agree to notify BEACON at once. I have been given an emergency telephone number that I can call 24 hours a day for assistance." A telephone log dated 12/12/09 at 7:31 PM, documented the Center's answering service received a call from PI # 22, "I have just passed a hugh blood clot. Please call." The answering service documented a call to EI# 2, the Registered Nurse, at 7:35 PM. The answering service record documented the voice mail was full and no message could be left for EI # 2. At 7:50 PM the answering service record again documented the voice mail for the EI # 2 was full. The next call was placed at 7:51 PM. EI # 2 was not at home per documentation. The answering service placed a call at 8:06 PM, the answering service documented the call went to a full mail box. The "Post TAB (Therapeutic Abortion) Problem Sheet" dated 12/12/09 at 8:24 PM (53 minutes after initial call), documented EI # 2, "Spoke (with) Pt (patient) and she stated that her clot was	L 100		

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L 100	Continued From page 52	L 100		

fairly large but it was only one. Instructed the pt to massage her uterus and refill her Methergine. I also reminded the pt that passage of clots were normal."

There was no documentation of teaching the patient how to massage her uterus on the Post TAB Problem sheet or medical record. The agency also was not able to produce a policy and procedure for phone triage during business hours.

During an interview 2/1/10 at 10:00 AM, EI # 2 stated that a reasonable amount of time to return a call to a patient would be 5 to 15 minutes.

2. PI # 2 had a surgical abortion procedure on 12/10/09.

An answering call log dated 12/16/09 at 8:12 AM, documented the Center's answering service received a call from PI # 2... "I had an abortion Thursday and I have been passing huge golf ball size blood clots ever since. I called about this yesterday and no one called me back."

There was a "Post TAB Problem Sheet" completed by EI # 2 explaining, "That the clots would stop but call back if the problem persists." There was no documentation regarding a previous call the patient stated she made 12/15/09.

An answering call log dated 12/26/09 at 9:50 AM, documented the Center's answering service received a call from PI # 2... "I have a yellow vaginal discharge that smells bad. I had an abortion almost 2 weeks ago." There was a "Post TAB Problem Sheet" completed by EI # 2 explaining, "Spoke with pt (patient) and advised

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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
L 100	Continued From page 53 her that the yellow vaginal discharge isn't normal and neither is the foul odor. The pt. states that she had a bad bacterial infection prior to her procedure with the same symptoms. The pt. stated she would get Flagyl from her private MD (medical doctor)." A second call was recorded 12/26/09 at 9:49 PM... "I have a bad bacterial infection." A third call was recorded 12/26/09 at 9:52 PM..."This is the 4th time that I have called, I really need to speak with the OC(on call). I had an abortion about 2 weeks ago, and I am having a lot of problems with infection. Patched to OC. The OC said it's not her 4th call, she has talked to her numerous times today." There was a "Post TAB Problem Sheet" completed by EI # 2 explaining, "Spoke with pt 4 times. The patient stated that she had a bacterial infection prior to having the procedure. She states that she needs some more antibiotics." There was no documentation of 4 calls back to the patient. On 2/4/10 at 11:55 AM, a follow-up telephone interview was conducted with EI #2 concerning the documentation of after hour calls received from PI # 2. Employee Identifier # 2 was asked if she phoned in a prescription for PI # 2 for the reported bacterial infection. EI # 2 stated PI # 2 came to the clinic to pick up antibiotics. EI # 2 stated PI # 2 had an infection prior to her procedure and the infection was on-going prior to her coming to the abortion clinic. EI # 2 verified she did not document this in the medical record for PI # 2. ****	L 100		

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L 100	Continued From page 54 420-5-1.03(8) Infection Control (c) Abortion or reproductive health centers shall adhere to regulations of the United States Occupational Safety and Health Administration for handling medical waste, and regulations of the Alabama Department of Environmental Management and other applicable federal regulations for disposal of medical waste (medical waste includes, but is not limited to disposable gowns, soiled dressings, sponges, surgical gloves, bacteriological cultures, blood and blood products, excretions, secretions, other bodily fluids, catheters, needles, IV tubing with needles attached, scalpel blades, glassware, and syringes that have been removed from their original sterile containers). The requirements of this rule were not met as evidenced by: Based on interviews and review of the Center's contract, it was determined that the Center failed to have a medical waste contract in place for the pick up of medical waste on a regular basis from May 2009 to January 2010. Findings include: On 1/28/10 at 1:20 PM, EI # 7, the Medical Director, was interviewed and asked how the Center disposed of its medical waste. EI # 7 stated the Center had a company that came to pick up the containers when they were full. On 1/28/10 at 3:23 PM, EI # 8, the Executive Director, was interviewed and asked if the Center had a contract for the disposal of medical waste. EI # 8 stated Stericycle came once a week for pick up.	L 100		

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L 100	Continued From page 55 Employee Identifier #8 gave the surveyors a copy of the last receipt of where Stericycle came to pick up five 28 gallon containers of medical waste on 1/26/10. On 2/3/10 at 9:40 AM, a telephone interview was conducted with EI # 3, one of the Center's medical assistants. EI # 3 was asked how the clinic disposed of biomedical waste and she responded the Center owed a lot of money to Stericycle. EI # 3 stated Stericycle had stopped coming to pick up medical waste from the Center and EI # 3 was not sure how the Center was disposing of medical waste. A telephone interview was conducted with Stericycle on 2/3/10. Stericycle confirmed the last pick up from the abortion clinic was on 2/2/10. The company is scheduled to pick up once a week on Tuesdays. Prior to the 1/26/10 pick up the company had not picked up from the abortion clinic since 5/12/09. For a total of 8 months there was no pick up from Stericycle at the Center. A copy of the Center's Stericycle service agreement was received via fax on 2/3/10. The contract was only signed by EI # 8, the Executive Director of the Center, and not a company representative from Stericycle. The Executive Director had signed the contract on 1/14/10. A telephone interview was conducted with EI # 8 on 2/4/10 at 1:55 PM. During the telephone interview EI # 8 verified she was aware the abortion clinic had no biomedical waste pick up since August 2009. EI # 8 stated the previous administrator had not paid the bill and the owner of the abortion clinic was to be responsible for	L 100		

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L 100	Continued From page 56 paying the bills once this was discovered. EI # 8 was asked how the clinic was disposing of medical waste during this time period. EI # 8 stated she asked the previous administrator and the previous administrator, EI # 1, verified the medical waste was placed in black trash bags and placed in the abortion clinic dumpster. EI # 8 was asked when she became aware the abortion clinic had not disposed of medical waste according to state rules and she stated probably a few days before she signed the contract with Stericycle. Employee Identifier # 8 was asked why this information was not shared with the surveyors while on-site and she stated she did not want to, "open that can of worms. I guess I should have told you. I thought after we got the contract all was okay." EI # 8 was asked if there was any other information she wanted to come forth with about the clinic and she stated, "Nothing that I know of. That's the truth. You can hold me to that." The surveyors attempted to contact the previous administrator, EI # 1, on three different occasions but was unable to interview her about the above information.	L 100		
L 200	ALABAMA LICENSURE DEFICIENCIES This Rule is not met as evidenced by: 420-5-1-.03(1) Patient Care (1) Patient Care. All patient care must be rendered in accordance with all applicable federal, state, and local laws, these rules, and current standards of care, including all professional standards of practice. As with any surgical procedure, the physician performing the procedure is responsible for the procedure and	L 200		

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L 200	Continued From page 57 for ensuring that adequate follow-up care is provided. In order to facilitate continuity of patient care, the facility physician shall contact and communicate with any physician rendering care for complications arising from the abortion as soon as he [or she] is informed of the existence of such complications... The requirements of this rule were not met as evidenced by: Based on observation, interview, and review of Center for Disease Control and Prevention injection safety practice it was determined that the physician, EI # 7, failed to follow current standards of care related to infection control and patient safety. Findings include: Center for Disease Control and Prevention Injection Safety Safe Injection Practices to Prevent Transmission of Infections to Patients Excerpted from Guidelines for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007. Recommendations IV. H. Safe Injection Practices IV. H. 1 Use aseptic technique to avoid contamination of sterile injection equipment. Category IA IV. H. 2 Do not administer medications from a syringe to multiple patients, even if the needle or	L 200		

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L 200	Continued From page 58 cannula on the syringe is changed. Needles, cannulae and syringes are sterile, single use items; they should not be reused for another patient nor to access a medication or solution that might be used for a subsequent patient. IV. H. 6. If multidose vials must be used, both the needle or cannula and syringe used to access the multidose vial must be sterile. IV. H. 7. Do not keep multidose vials in the immediate patient treatment area and store in accordance with the manufacturer's recommendations; discard if sterility is compromised or questionable. The surveyor observed a procedure on 12/10/09 at approximately 3:00 P.M. EI # 7 drew up 10 cc's (cubic centimeters) of Lidocaine from a bottle held by the medical assistant with a needle in the stopper. The syringe was removed from the needle and attached to a spinal needle for injection into the cervix. Upon use of the 10 cc's, EI # 7 asked for more Lidocaine. The medical assistant held up the bottle of Lidocaine with the used needle still in the stopper. EI # 7 withdrew 3-5 cc's of Lidocaine from the bottle using the original syringe used to draw up the first 10 cc's of Lidocaine. The syringe was detached from the bottle, a spinal needle attached and EI # 7 proceeded with the cervical injection. The vial was empty after the second withdrawal and discarded. Observation of the surgical procedures on 1/28/10 starting at 3:15 PM, revealed EI # 7 had the medical assistant, in the room during the procedure, hold the Lidocaine bottle upside down. EI # 7 entered the new bottle of Lidocaine with a 10 cc syringe and a needle attached to the	L 200		

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L 200	Continued From page 59 syringe. After withdrawal of 10 cc's of the medication EI # 7 removed the needle from the syringe. The needle continued to stick out of the bottle of Lidocaine with only the hub showing on the outside and the metal needle clearly visible in the Lidocaine fluid left in the bottle. EI # 7 proceeded to inject the patient with the Lidocaine. Following the procedure, during the clean up of the room, the Lidocaine with the used needle in the Lidocaine bottle continued to be available for patient use. The next patient was brought into the room and prepped for the procedure. EI # 7 accessed the same Lidocaine bottle by placing a new 10 cc syringe onto the used needle hub sticking out of the bottle of Lidocaine. He then injected the patient with the 10 cc of Lidocaine withdrawn from the previously used Lidocaine bottle. EI # 7 was questioned after the two procedures concerning the Lidocaine. He verified the Lidocaine had a needle without a syringe in the bottle and he would use the Lidocaine until gone. He stated the Lidocaine was sterile and he was the only one to touch the Lidocaine after it was opened. **** 420-5-1-.03(7)(e) Pharmaceutical Services (e) Records. Records shall be kept of all stock controlled substances giving an account of all items received and administered. Records shall be kept in a manner which allows accurate reconciliation. The requirements of this rule were not met as evidenced by: Based on review of the Center drug log, interview	L 200		

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L 200	Continued From page 60 and observation it was determined that the Center failed to record and document an accurate count of its narcotics. Findings include: On 12/10/09, the surveyor observed EI # 2, the Registered Nurse, drop a 10 mg (milligram) Valium tablet. The nurse turned to the surveyor and asked," Are you going to witness that?" Surveyors are not allowed to witness the wasting of a controlled drug. A review of the Drug Log dated 12/10/09 was completed 12/16/09 at 11:00 AM. There was no documentation of the dropped Valium. EI # 2 was interviewed 12/16/09 at 11:21 AM and asked where they normally recorded wasted pills. Employee Identifier # 2 stated that she normally writes it at the top of the count page. EI # 2 went on to say that she told EI # 7, the Medical Director, and EI # 1, the Administrator, she dropped the pill. EI # 7 witnessed her put the pill in the sharps container. EI # 2 stated that there was no other place to document it. The Center has a narcotic discrepancy sheet to be completed when the count is wrong. A discrepancy sheet was not completed for the dropped Valium. A closer review of the narcotic log indicated PI # 3 received Valium 10 mg at 3:18 PM. This patient did not receive this drug as she did not have a driver and the drug was marked off on the procedure form. EI # 2, the RN, was interviewed again on 12/16/09 at 12:10 PM and asked if PI # 3	L 200		

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L 200	Continued From page 61 received the Valium. She stated, " She didn't get none its scratched off. I didn't give her nothing you were standing right here." The surveyor asked EI # 2 why the narcotic log had been re-written. EI # 2 stated,"I wrote it over because the names didn't look right, I did it last week. I re-did it last week. She didn't get any Valium I promise. You were right here. She didn't get any." Refer to 420-5-1-.02(8)(a) Records and Reports Alabama Board of Nursing, Standards of Practice Chapter 610-X-6-.06 Documentation Standards (d)(iii) (d) Timely. (i) Charted at the time or after the care, including medications, is provided... (ii) Should the registered nurse or licensed practical nurse add documentation that was omitted, the documentation shall reflect " late entry" including a date and time the late entry was made as well as the date and time the care was provided. (iii) A mistaken entry in the record by a licensed nurse shall be corrected by a method that does not obliterate, white-out, or destroy the entry. EI # 2 was asked by the surveyor how the narcotic count came out right on 12/10/09 at the end of the day and again on 12/12/09. EI # 2 stated, " I don't know how the count is right. I threw it away and that's the count I came up with." EI # 1 was asked during an interview 12/16/09 at 11:48 AM if she was aware EI # 2 dropped a Valium and the count is wrong. EI # 1 stated that she was back there and counted with EI # 7 and EI # 2 as well. She looked at the count form and	L 200		

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L 200	Continued From page 62 stated," I don't know." **** 420-5-1-.03(7)(b) Pharmaceutical Services. Administering, Dispensing, and Prescribing Drugs and Medicines. Only physicians and properly credentialed nurse practitioners and physician assistants may prescribe or order medications. Nurse practitioners and physician assistants may prescribe only those medications described in their individual collaborative agreements. Except for standing orders as permitted below, medications shall be prescribed for patients of the facility after an appropriate medical evaluation. Oral and telephone orders shall be received only by a physician, nurse practitioner, physician assistant, registered nurse, licensed practical nurse, or a pharmacist. Oral and telephone orders shall be immediately documented in writing by the individual receiving the order. Prescribing, dispensing, and administration of medications shall meet all standards required by law and by regulations of the State Board of Medical Examiners and the State Board of Pharmacy. The requirements of this rule were not met as evidenced by: Based on review of the patient records, interview and review of medication administration documentation it was determined: 1. In 5 of 19 patient records reviewed that had surgical abortion procedures on 12/10/09 the nurse, EI # 2, failed to document the route the drugs were administered. 2. In 3 of 3 RH negative patientsEI # 2 failed to	L 200		

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L 200	Continued From page 63 document the dose of Rhogam administered. 3. In 3 of 3 patient records reviewed that were greater than 14w5d(14 weeks 5 days) gestation by ultrasound, intravenous (IV) Pitocin was administered by EI # 7, the physician, IV push with no dilution. This had the potential to affect all patients served. Findings include: According to Potter and Perry, Fundamentals of Nursing, 6th Edition Copyright 2005, Mosby, Inc. "A medication order is required for any medication to be administered by a nurse...If the medication order is incomplete, the nurse should inform the prescriber and ensure completeness before carrying out any medication order." "A medication order is incomplete unless it has the following parts: client's full name, date that the order is written, medication name, dose, route of administration, time and frequency of administration, and signature of physician, nurse practitioner, or physician assistant." The medications that were given at the Center included Aleve and Valium. The medication Valium may be administered orally, intramuscularly, rectally or intravenously according to the Mosby's Nursing Drug Reference book 21st Edition 2008. The medication Aleve may be administered orally or rectally according to the Mosby's Nursing Drug Reference book 21st Edition 2008.	L 200		

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L 200	Continued From page 64 Rhogam standard dose for pregnancy termination less than 13 weeks is 50 mcg (micrograms) a mini-dose or pregnancy termination greater than 13 weeks is 300 mcg or standard dose according to the Mosby's Nursing Drug Reference book 21st Edition 2008. Drug Insert: Pitocin-oxytocin injection King Pharmaceuticals, Inc. RX Only. Prescribing information as of March 2007. C. Treatment of Incomplete, Inevitable, or Elective Abortion Intravenous infusion of 10 units of Pitocin added to 500ml(militers) of a physiologic saline solution or 5% dextrose-in water solution may help the uterus contract after a suction or sharp curettage for an incomplete, inevitable, or elective abortion. http://medical-dictionary.thefreedictionary.com/Oxytocics documents: # 1.Do not give by I.V. bolus injection. Infuse I.V. using controlled-infusion device. Be aware that drug is not routinely given I.M. (intramuscular). Know that drug should be given only to inpatients at critical care facilities when prescriber is immediately available. 1. Patient Identifier (PI) # 2 had a surgical abortion procedure on 12/10/09. The patient received a Rhogam injection, but no dose was documented as to a Full or Mini dose. 2. Patient Identifier (PI) # 8 had a surgical abortion procedure on 12/10/09. The patient received a Rhogam injection, but no dose was documented as to a Full or Mini dose. The pre-op medication Valium 10 mg and Aleve 220 mg was	L 200		

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L 200	Continued From page 65 administered at 4:13 PM by EI # 2, the RN, but no route of medication administration was recorded. 3. Patient Identifier (PI) # 10 had a surgical abortion procedure on 12/10/09. The pre-op medication Valium 10 mg and Aleve 220 mg was administered at 4:37 PM by EI # 2, but no route of medication administration was recorded. 4. Patient Identifier (PI) # 14 had a surgical abortion procedure on 12/10/09. The pre-op medication Valium 10 mg and Aleve 220 mg was administered at 4:33 PM by EI # 2, but no route of medication administration was recorded. 5. Patient Identifier (PI) # 15 had a surgical abortion procedure on 12/10/09. The pre-op medication Valium 10 mg and Aleve 220 mg was administered at 5:21 PM by EI # 2, but no route of medication administration was recorded. 6. Patient Identifier (PI) # 19 had a surgical abortion procedure on 12/10/09. The patient received a Rhogam injection, but no dose was documented as to a Full or Mini dose. The pre-op medication Valium 10 mg and Aleve 220 mg was administered 5:21 PM by EI # 2, but no route of medication administration was recorded. 7. Patient Identifier (PI) # 6 had a surgical abortion procedure on 12/10/09. The ultrasound dated 12/10/09 has the estimated gestational age of 14.5 weeks and is signed by EI # 7. The procedure section of the procedure record form documented by EI # 7 under, comments has written in Pitocin 1 cubic centimeter (cc). There is no indication if this was given intravenous(IV) by EI # 7 or a time it was administered. EI # 2 was asked about the Pitocin 12/16/09 and she stated	L 200		

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L 200	Continued From page 66 that EI # 7 will sometimes give Pitocin IV after the procedure if patients are 14.5 weeks or greater. The Medical Director, EI # 7, was interviewed on 1/28/10 at 12:55 PM regarding administration of IV Pitocin. He stated,"Yes I give it IV push, we draw back a little blood and give it slowly. It's for the patient's benefit it cuts down on bleeding." EI # 7 was shown the medical record of PI # 6 and asked if he recalled the patient. He stated that he did not write it on this record but it was IV. 8. Patient Identifier (PI) # 22 had a surgical abortion procedure on 12/12/09 to terminate a 16 week pregnancy. The patient was given 1 cc of Pitocin IV following the procedure by EI # 7. 9. Patient Identifier (PI) # 23 was 14 years old. She had a procedure on 12/23/09 to terminate a 16.5 week pregnancy. The patient was given 1 cc of Pitocin IV following the procedure by EI # 7. During an interview on 1/27/10 at 1:35 PM, EI# 2 verified EI # 7 gives the Pitocin IV push after the procedure for pregancies greater than 12 weeks. She also verified there were no IV fluids in the procedure rooms for the Pitocin to be mixed with a physiologic solution and administered in accordance with the drug manufactor's guidelines. Employee Identifier # 2, the Registered Nurse, gave contradictory information to the surveyors on the number of weeks patients are when they receive Pitocin. On 12/16/09 EI # 2 stated patients at 14.5 weeks or greater are given Pitocin and then on 1/27/10 EI # 2 said Pitocin was given for patients 12 weeks or greater. The Center has no policy for the administration of Pitocin.	L 200		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	C5101	A. BUILDING _____ B. WING _____	02/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BEACON WOMEN'S CENTER	1011 MONTICELLO COURT MONTGOMERY, AL 36117

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L 200	Continued From page 67 **** 420-5-1-.02(3) Administration (3) There shall be a facility-wide quality improvement program to evaluate patient care and facility services. The program shall be ongoing, have statistical summaries and a written plan of implementation. The requirements of this rule were not met as evidenced by: Based on review of the quality improvement documentation and interview it was determined that the Center failed to assure there was a written plan in place to correct problem areas for patient care and abortion center services. This had the potential to affect all patients served. Findings include: On 12/1/09 at 2:35 PM, the surveyors requested to review the Quality Improvement (QI) documentation from EI # 1, the Administrator. Upon review of the documentation there were no statistical summaries listed to show monitoring of problems identified. There were no action plans to address any of the problems identified. In an interview with EI # 1 on 12/2/09 at 10:35 AM, it was confirmed the facility did not have QI plans to address concerns found on the QI reviews.	L 200		