

Alabama Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>C4911</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  <b>11/21/2014</b>
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NAME OF PROVIDER OR SUPPLIER  <b>PLANNED PARENTHOOD OF ALABAMA, INC</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>717 W DOWNTOWER LOOP MOBILE, AL 36609</b>
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L 000	<p>INITIAL COMMENTS</p> <p>Survey Introduction</p> <p>On November 21, 2014, Department surveyors visited the licensed abortion or reproductive health center operated by Planned Parenthood of Alabama (" the Center "), located at 717 West Downtowner Loop, Mobile, Alabama to conduct an on-site annual survey. During the visit the following deficiencies were cited and require a plan of correction.</p>	L 000		
L 100	<p>ALABAMA LICENSURE DEFICIENCIES</p> <p>THE FOLLOWING ARE LICENSURE DEFICIENCIES AND REQUIRE A PLAN OF CORRECTION.</p> <p>This Rule is not met as evidenced by: 420-5-1-.02 Administration.</p> <p>(2) Policies &amp; Procedures. Policies and procedures for operation of the facility shall be formulated and reviewed annually by the governing authority. They shall include at least the following: (a) Purpose of the facility, to include scope and quality of services; (b) Method to ensure compliance with all relevant federal, state, and local laws that govern operations of the facility;</p> <p>Based on the review of the Alabama Code 1975, Title 26, Chapter 14, Reporting of Child Abuse or Neglect, facility's policies and procedures, medical record (MR), and interview, it was determined the facility failed to report reasonable suspected abuse or neglect for a minor. This affected MR # 16 and had the potential to affect</p>	L 100		

Health Care Facilities  
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE \_\_\_\_\_ TITLE \_\_\_\_\_ (X6) DATE \_\_\_\_\_

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L 100	<p>Continued From page 1</p> <p>all patients served by this facility.</p> <p>Findings include:</p> <p>Ala. Code 1975: TITLE 26 Infants and Incompetents CHAPTER 14 Reporting of Child Abuse or Neglect</p> <p>§ 26-14-1. Definitions.</p> <p>For the purposes of this chapter, the following terms shall have the meanings respectively ascribed to them by this section:</p> <p>(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.</p> <p>(2) Neglect. Negligent treatment or maltreatment of a child, including the failure to provide adequate food, medical treatment, supervision, clothing, or shelter.</p>	L 100		

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L 100	<p>Continued From page 2</p> <p>(3) Child. A person under the age of 18 years.</p> <p>(4) Duly constituted authority. The chief of police of a municipality or municipality and county; or the sheriff, if the observation of child abuse or neglect is made in an unincorporated territory; or the Department of Human Resources; or any person, organization, corporation, group, or agency authorized and designated by the Department of Human Resources to receive reports of child abuse and neglect; provided, that a "duly constituted authority" shall not include an agency involved in the acts or omissions of the reported child abuse or neglect.</p> <p>§ 26-14-3. Mandatory reporting.</p> <p>(a) All hospitals, clinics, sanitariums, doctors, physicians, surgeons, medical examiners, coroners, dentists, osteopaths, optometrists, chiropractors, podiatrists, physical therapists, nurses, public and private K-12 employees, school teachers and officials, peace officers, law enforcement officials, pharmacists, social workers, day care workers or employees, mental health professionals, employees of public and private institutions of postsecondary and higher education, 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 orally, either by telephone or direct communication immediately, followed by a written report, to a duly constituted authority.</p> <p>Facility's Policy: Evaluation and Mandatory Reporting of Abuse or Neglect of Minors</p>	L 100		

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L 100	<p>Continued From page 3</p> <p>Policy:</p> <p>PPSE (Planned Parenthood Southeast) protects the safety of our minor clients and complies with state-mandated reporting laws in Georgia, Alabama, and Mississippi. Our work in reproductive and sexual health means all staff must understand how to identify and respond to sexual abuse, neglect and victimization of teens. Teens, particularly young teens, who are in a sexual relationships may be in unsafe relationships and are at risk of being abused. Our priority is to protect the safety of our clients and comply with the law.</p> <p>State: Alabama</p> <p>What to report: Rape</p> <p>Definition of minor Report sexual intercourse: Minor is between 12 and 16 with any person 2 or more years older than the minor.</p> <p>How to report: If abuse or neglect is identified or suspected, initiate the following reporting process: 1. Clinic Manager or designee will contact by telephone the local police, if indicated, and other duly constituted authority to make a report. ( see where to report below.) 2. The Clinician shall make a note of the telephone notification in the minor's medical record. 3. Clinic Manager will submit a written report, if indicated, to the DHR(Department of Human Services)/DFACS (Division of Family and Children Services) (required for Alabama clinics). A copy of the report will be placed in the minors</p>	L 100		

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L 100	<p>Continued From page 4</p> <p>medical record.</p> <p>4. Clinic Manager will notify the respective Director of Clinical Services a report was made and will keep a record of all incidents reported.</p> <p>1. MR # 16 was seen in the facility on 4/9/14 for counseling. Review of the History and Physical dated 4/9/14 revealed MR # 16 was 14 years old and had 2 living children given in separate births.</p> <p>There was no documentation in the medical record of the facility reporting suspected abuse to the proper authorities as required by Ala. Code Reporting of Child Abuse or neglect.</p> <p>An interview was conducted on 11/21/14 at 1:50 PM with Employee Identifier (EI) # 5, Director of Patient Services who verified a report was not made.</p> <p>MR # 16 was seen again in the facility on 8/18/14 for counseling. Review of the History and Physical dated 8/18/14 revealed this was the second abortion in 4 months.</p> <p>There was no documentation in the medical record of the facility reporting suspected abuse to the proper authorities or the reason why a report was not made.</p> <p>An interview was conducted on 11/21/14 at 1:50 PM with EI # 5 who verified a report was not made. During the interview EI # 5 gave no additional information as to why a report was not completed for MR # 16.</p> <p>*****</p> <p>420-5-1-.02 Administration.</p>	L 100		

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L 100	<p>Continued From page 5</p> <p>(8) Records and Reports.</p> <p>(a) 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, a copy of report of abortion made to the Center for Health Statistics, and all forms required by law.</p> <p>Based on record review and interview, it was determined the facility failed to ensure the staff fully completed all medical record information. This affected 7 of 16 records reviewed which included, Medical Record (MR) #s 16, 13, 3, 1, 9, 11, and 5. This had the potential to affect all patients served by this facility.</p> <p>Findings include:</p> <p>1. MR # 16 was first seen in the facility on 4/9/14 for counseling. The patient had a medical abortion on 4/12/14.</p> <p>Review of the medical history dated 4/9/14 revealed MR # 16 was 14 years old with 2 live children.</p> <p>Review of the Request For Medical Services and Acknowledgement Of Receipt Of Notice of Health Information Privacy Practices dated 4/9/14 revealed no documentation of a witness stating the fact the legal guardian received the health information privacy practices.</p> <p>Review of the State of Alabama Consent to Performing Abortion upon Minor (form 723) dated 4/9/14 revealed no documentation the physician or physician's agent witnessed the minor verify</p>	L 100		

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L 100	<p>Continued From page 6</p> <p>the signature of the parent or legal guardian was authentic.</p> <p>An interview was conducted with Employee Indentifer (EI) # 5, Director of Patient Services on 11/21/14 at 1:50 PM who stated the above documentation had been captured on the Quality Improvement audits completed on 10/27/14.</p> <p>Review of the Quality Improvement audits completed on 10/27/14 revealed the form 723 for MR # 16 had been completed correctly. An interview was conducted with EI # 5 on 11/21/14 at 2:00 PM who verified the audit tool did not accurately document the completeness of the form 723 and the form did not document the physician or physician's agent witnessed the minor verify the signature of the parent or legal guardian was authentic.</p> <p>2. MR # 13 was first seen in the facility on 10/21/14 and received a surgical abortion on 10/24/14.</p> <p>Review of the Ultrasound Exam dated 10/24/14 revealed documentation the Gestational age was 14.2 to 14.4 weeks. Further review of the Ultrasound Exam dated 10/24/14 revealed no documentation of the Placental Localization for a gestational age of 14 weeks or greater and not less than 13 weeks.</p> <p>Review of the Request For Surgery or Surgical Procedure dated 10/24/14 was completed for an In-Clinic Suction Abortion - Removal of uterine pregnancy less than 13 weeks... Review of Ultrasound Exam dated 10/24/14 revealed documentation the Gestational age was 14.2 to 14.4 weeks.</p>	L 100		

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L 100	<p>Continued From page 7</p> <p>An interview was conducted with EI # 5 on 11/21/14 at 1:40 PM who verified the above findings.</p> <p>3. MR # 3 was seen in the facility on 5/5/14 for counseling and received a surgical abortion on 5/9/14.</p> <p>Review of the Ultrasound Exam dated 5/9/14 revealed documentation the Gestational age was 14.2 to 14.5 weeks. Further review of the Ultrasound Exam dated 5/9/14 revealed no documentation of the Placental Localization for a gestational age of 14 weeks or greater.</p> <p>An interview was conducted with EI # 1, Registered Nurse, who verified the above findings.</p> <p>4. MR # 1 was first seen on 6/5/14 for counseling and on 6/18/14 MR # 1 had a surgical procedure completed.</p> <p>Review of the MR revealed a Request for Medical Services and Acknowledgement form dated 6/5/14 with the patient's signature and the parent signature but lacked documentation of a witness signature and date.</p> <p>Further review of the MR revealed Surgical Abortion Record Intra-Operative Note dated 6/18/14. Under procedure: Para Cx (cervical) block anesthesia using a total of 15 cc (Cubic Centimeters). Review of the form revealed there was no documentation what type of anesthesia was used.</p> <p>An interview conducted on 11/21/14 at 1:50 PM with EI # 5 who confirmed the above mentioned findings.</p>	L 100		



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L 100	<p>Continued From page 8</p> <p>5. MR # 9 was first seen on 5/15/14 for counseling and on 5/17/14 a medical procedure was performed.</p> <p>Review of the MR revealed a Request for Surgery and Acknowledge of Receipt dated 5/17/14 was completed with the patient and parent signatures and dates but no documentation of a witness signature or date.</p> <p>An interview conducted on 11/21/14 at 1:25 PM with EI # 5 confirmed the above mentioned findings.</p> <p>6. MR # 11 was first seen on 8/6/14 for counseling and on 8/8/14 a medical procedure was performed.</p> <p>Review of the MR revealed a Certification of Voluntary and Informed Consent for Abortion dated 8/6/14. The signature on page 2 has the mothers signature and a date of 4/6/14 and on page 3 under the Certification of Receipt of Abortion Information the mother signed and dated this area 4/6/14. The procedure was completed on 8/8/14.</p> <p>7. MR # 5 was first seen on 10/29/14 for counseling and on 11/7/14 a surgical procedure was completed.</p> <p>Review of the MR revealed a Surgical Abortion Record- Intra-Operative Note dated 11/7/14. The Para Cx block anesthesia documentation revealed 18 cc was given. Review of the form revealed no documentation as to what type of anesthesia was used.</p> <p>Further review of the Intra-Operative Note dated</p>	L 100		

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L 100	<p>Continued From page 9</p> <p>11/7/14 revealed no documentation of Fetal Viability Outside of the Uterus.</p> <p>An interview conducted on 11/21/14 at 1:40 PM with EI # 5 confirmed the above mentioned findings.</p> <p>*****</p> <p>420-5-1-.03 Patient Care.</p> <p>(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...</p> <p>(4) Admission and Examination Procedures. (d) Laboratory Tests. 1. The following laboratory tests are required prior to an abortion procedure: Hematocrit or hemoglobin, Rh typing, urinalysis as directed by the treating physician, and pregnancy test. Testing for syphilis, gonorrhea, Chlamydia, and HIV shall be performed if such tests are properly consented to by the patient.</p> <p>Based on the review of medical records and the facility's policy and procedure and interview, the facility failed to follow their own standards for Medication Abortion in 2 of 2 records reviewed with a hemoglobin below 10 which affected Medical Record (MR) # 16. This had the potential to affect all patients served by this facility.</p> <p>Findings include:</p> <p>Facility Policy: Mifepristone Medication Abortion Revised October 2012</p>	L 100		

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L 100	<p>Continued From page 10</p> <p>Conditions Requiring Special Evaluation and Management - Conditions that may complicate medication abortion require management by affiliate protocols or consultation with the affiliate medical director before Mifepristone can be administered. These conditions include</p> <ol style="list-style-type: none"> <li>1. severe anemia (hematocrit less than 30 percent, hemoglobin less then 10)</li> </ol> <p>1. MR # 16 was seen in the facility 4/9/14 for counseling for a medication abortion. MR # 16's hemoglobin was 9.3.</p> <p>MR # 16 was seen again in the facility on 4/12/14 and was given Mifepristone. There was no documentation of management by an affiliate or consultation was conducted for the hemoglobin below 10.</p> <p>An interview was conducted on 11/21/14 at 1:50 PM with Employee Identifier (EI) # 5, Director of Patient Services who verified the above findings.</p> <p>MR # 16 was seen again in the facility 8/18/14 for counseling for a medication abortion. MR # 16's hemoglobin was 9.7.</p> <p>MR # 16 was seen again in the facility on 8/29/14 and was given Mifepristone. There was no documentation of management by an affiliate or consultation was conducted for the hemoglobin below 10.</p> <p>An interview was conducted on 11/21/14 at 1:50 PM with EI # 5 who verified the above findings.</p> <p>*****</p> <p>(8) Infection Control.</p>	L 100		

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L 100	<p>Continued From page 11</p> <p>(a) Infection Control Committee.</p> <p>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.</p> <p>Based on the review of the facilities policies and procedures, observation and interviews, it was determined the facility failed to follow the procedure for Instrument Cleaning and Sterilization, gloves and hand hygiene. This had the potential to negatively affect all patients served by this facility.</p> <p>Findings include:</p> <p>Facility Policy: Instrument Cleaning and Sterilization</p> <p>Policy: All instruments used during sterile procedures will be cleaned and sterilized in accordance with produce directions and infection control standards.</p> <p>Procedure:</p> <p>Procedure for sterilizing instruments brought to dirty area of sterilizing room:...</p> <p>3. Make a fresh 1% solution of Liquinox and water (change between patients) Right side of sink in basin (1 gallon of warm water Add 2 1/2 Tbsp (tablespoon) of Liquinox).</p> <p>Observation of the instrument cleaning was conducted on 11/21/14 at 12:25 PM. Employee Identifier (EI) # 2, Health Care Assistant was observed preparing the Liquinox 1% solution. EI # 2 was observed measuring 2 Tbsp and 1/2</p>	L 100		

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L 100	<p>Continued From page 12</p> <p>teaspoons of Liquinox instead of the 2 1/2 Tbsp as directed.</p> <p>An interview was conducted with EI # 5, Director of Patient Services on 11/21/14 at 1:00 PM who verified the amount of Liquinox was not as directed.</p> <p>*****</p> <p>Policy:</p> <p>Infection Control Hand Washing Technique Section G Page 6 Revised April 2010</p> <p>For practical purposes, it is not considered possible to cleanse the skin of all bacteria. Transient flora can become resistant flora and if flora contains pathogenic organisms, the hands may become carriers of disease. To prevent this, it is important that hands are cleansed properly after each contact with contaminated material and before and after each and every client contact.</p> <p>2. Using a bacteriostatic soap, wash hands and wrists for 30 to 60 seconds. 5. Hands and wrists should be washed under running water. 6. During washing, hands are to be held lower than elbows so soiled water will not run up arms. Do not touch sink with hands. 9. Turn off the water with the used paper towel.</p> <p>All employees must wash their hands as soon as possible after removal of gloves or any other personal protective equipment (PPE) such as gowns, protective eyewear, or masks...</p>	L 100		

Alabama Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>C4911</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  <b>11/21/2014</b>
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NAME OF PROVIDER OR SUPPLIER  <b>PLANNED PARENTHOOD OF ALABAMA, INC</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>717 W DOWNTOWER LOOP MOBILE, AL 36609</b>
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L 100	<p>Continued From page 13</p> <p>An observation was conducted on 11/21/14 at 11:45 AM to observe a medical abortion procedure. EI # 4, Medical Doctor, entered room and was observed donning gloves without washing hands properly. An ultra sound was performed on the patient and EI # 4 informed the patient it was to early to complete a medical abortion on this day. EI # 4 removed gloves while talking with patient and then exited the exam room and did not wash hands.</p> <p>On 11/21/14 at 11:10 AM an ultra sound was performed on a surgical abortion patient. After the ultra sound was complete EI # 3, Health Care Aide (HCA), donned gloves and did not wash hands prior to donning gloves. EI # 3 removed the paper from the exam table. EI # 3 then sprayed a spray on the table, obtained paper towels and after approximately 5 minutes wiped the table down. After wiping down the table, EI # 3 removed soiled gloves and donned a new pair without washing hands.</p> <p>On 11/21/14 at 11:20 AM EI # 2, HCA, started the sterile tray set up. EI # 2 placed two pair of sterile gloves on the exam table and opened each package. While opening the packages of sterile gloves EI # 2 touched the inside sterile area of the paper with bare unwashed hands and proceeded to don the first pair of gloves. EI # 2 opened a sterile instrument package and arranged the instruments on a sterile tray. EI # 2 removed the sterile gloves and donned the second pair of sterile gloves without washing hands. EI # 2 opened syringes and needles and placed on the sterile tray. EI # 2 removed the sterile gloves opened the procedure room door and obtained a third pair of sterile gloves. EI # 2 opened the sterile gloves and touched the inside sterile area of the paper with bare hands that</p>	L 100		

Alabama Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>C4911</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  <b>11/21/2014</b>
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L 100	<p>Continued From page 14</p> <p>were not washed. EI # 2 donned gloves and completed the sterile tray set up.</p> <p>At approximately 12:10 PM EI # 4 entered room, washed hands with soap and water for 6 seconds, rinsed hands and shut faucet off with bare hands. EI # 4 then dried hands and disposed of paper towels. After washing hands EI # 4 then arranged the wand and untangled the cords on the ultra sound machine. EI # 4 donned sterile gloves for the procedure and did not wash hands prior to donning the sterile gloves. When the procedure was complete EI # 4 removed blood soiled gloves, washed hands with soap and water for 7 seconds and turned faucet off with bare hand.</p> <p>An interview conducted on 11/21/14 at 1:15 PM with EI # 5, Director of Patient Services, confirmed the above mentioned findings.</p>	L 100		