

Alabama Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: C4911	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED 01/14/2021
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NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD SOUTHEAST - MOBILE CLII	STREET ADDRESS, CITY, STATE, ZIP CODE 717 W DOWNTOWER LOOP MOBILE, AL 36609
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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 000	INITIAL COMMENTS An on-site licensure survey conducted on 1/14/21 Planned Parenthood Southeast Mobile. Licensure deficiencies were cited and require a Plan of Correction.	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: Chapter 420-5-1-.02 -Administration (1) Governing Authority. (a) Responsibility. The governing authority is the person or persons responsible for the management, control, and operation of the facility, including 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. (2) Policies and 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;	L 100		

Health Care Facilities LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	Signed by: <i>Janet Lepowitz</i>	TITLE DO	(X6) DATE 2/8/2021
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NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD SOUTHEAST - MOBILE CLII	STREET ADDRESS, CITY, STATE, ZIP CODE 717 W DOWNTOWER LOOP MOBILE, AL 36609
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L 100	<p>Continued From page 1</p> <p>(5) Personnel.</p> <p>(c) Medical Director. Each abortion facility shall have a medical director who shall be responsible for supervising all clinical functions and ensuring that the facility meets the requirements of these rules and all professional standards of care... The medical director shall ensure that all clinical staff, including both facility and outside covering physicians associated with the facility, are competent as required by these rules and professional standards of care.</p> <p>(d) Physician Qualifications.</p> <p>1. Only a physician may perform an abortion... All physicians performing abortions at the facility shall be qualified through training and experience in performing abortions and recognizing and managing complications.</p> <p>2. Before a physician performs any procedure at the facility, the Medical Director shall credential each physician on the basis of his or her qualifications, and a file shall be kept at the facility detailing the qualifications and experience of each physician...</p> <p>This file shall be kept current. The medical director shall review the physician's qualifications at the time the physician is hired and at least yearly thereafter. This review shall include direct observation of the physician's clinical skills, and the results of this review shall be placed in the physician's file...</p> <p>The Rule is not met as evidenced by:</p>	L 100		

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L 100	<p>Continued From page 2</p> <p>Based on review of the facility policy and procedure, physician personnel files, and interview it was determined the facility failed to ensure</p> <p>A. The policy for physician qualifications to include the Medical Director observation of clinical skills, as required in the Alabama Board of Health Alabama Department of Public Health Chapter 420-5-02, was developed and implemented which affected 4 out of 4 physicians personnel files reviewed.</p> <p>B. The Medical Director observed each physician's clinical skills and documented the result in the physician's file upon hire and prior to the physician performing any procedure at the facility which affected 1 out of 4 physicians personnel files reviewed.</p> <p>This had the potential to affect all patients served at this facility.</p> <p>Findings include:</p> <p>Policy: Clinician Skills Assessment, Proctoring and Performance Monitoring Reviewed: 2017</p> <p>Policy All newly employed and contracted clinicians will have a skills assessment and be proctored by the Medical Director, Lead Clinician, manufacturer representative, or designee. The Medical Director will review the skills assessment/proctoring documents and grant privileges before the clinician can work independently...</p> <p>Procedure</p>	L 100	<p>Planned Parenthood Southeast's (PPSE) Clinic Policies and Procedures are reviewed on an annual basis; the last review was completed in September of 2020. The structure of PPSE requires that we have policies and procedures in place that are applicable to all three states that we serve. Included in these policies are credentialing, proctoring, and privileging of all licensed staff. Based on feedback from ADPH regarding the clarity of these policies and how they apply to ADPH regulations, the applicable policies and documents have been updated.</p> <p>Clinician Assessments for our Alabama physicians providing abortion will now be conducted separately from other assessment documents applying to non-Alabama health centers. The PPSE: ADPH Abortion Clinical Review: Initial and PPSE: ADPH Abortion Clinical Review: Annual documents went into effect on January 21, 2021. All physicians providing abortion care at PPSE's Alabama health centers either have had an initial or annual evaluation using this new review document or will be evaluated on their next scheduled clinic day. In accordance with the Alabama Department of Public Health Chapter 420-5-02, all physicians will be directly observed by the PPSE Medical Director of Alabama Reproductive Services prior to independent work and annually; direct observation has been explicitly named in the policy and the skills assessment document. The PPSE: Physician Skills Assessment, Proctoring, & Performance Monitoring: Alabama Abortion Services policy was created to solely reflect the ADPH regulations. These edits include explicitly stating that only the Medical Director of Alabama Reproductive Services will proctor/privilege and perform annual reviews on the physicians.</p>	1/21/21
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L 100	<p>Continued From page 3</p> <p>Initial Appointment</p> <p>2. The Medical Director, Lead Clinician, or designee will observe and proctor the clinician and complete the Clinician Proctoring form.</p> <p>Annual Performance Review</p> <p>1. The Medical Director, Lead Clinician, or designee reviews each clinician and evaluates them using the Clinician Performance Evaluation form.</p> <p>2. Review findings are to be discussed with the clinician. Any problems must be presented to the Medical Director for review.</p> <p>Time Frame</p> <p>1. Credentialing verification is completed every three years,</p> <p>2. Annual Physician reviews are completed by the end of May.</p> <p>3. Annual NP (Nurse Practitioner), PA (Physician's Assistant), CNM (Certified Nurse Midwife), CRNA (Certified Registered Nurse Anesthetist) reviews are completed by the end of May.</p> <p>1. Review of the facility policy, Clinician Skills Assessment, Proctoring and Performance Monitoring, revealed the policy did not adhere to the Rules of Alabama for Abortion or Reproductive Health Centers, which requires the facility Medical Director to observe each physician's clinical skills upon hire prior to the physician performing any procedure at the facility and yearly thereafter.</p> <p>2. Review of Employee Identifier (EI) # 3,</p>	L 100	<p>Upon the hire of a new physician, the applicable PPSE Health Center Manager and the PPSE Medical Director of Alabama Reproductive Services will schedule time with the new provider for direct observation prior to independent services being provided.</p> <p>The PPSE Medical Director of Alabama Reproductive Services is responsible for completing annual evaluations, including chart review by June 30th each year. The Director of Human Resources as part of the Human Resources Audit will review all of the assessment documentation for the Alabama physicians semiannually.</p> <p>The Vice President of Clinical Operations is responsible for implementing the Plan of Correction.</p> <p>The following documents are attached with the Plan of Correction: ADPH Abortion Clinical Review: Initial, ADPH Abortion Clinical Review: Annual, and revised Physician Skills Assessment, Proctoring, & Performance Monitoring: Alabama Abortion Services.</p>	<p>2/23/21</p> <p>6/30/21</p>

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L 100	<p>Continued From page 4</p> <p>physician, personnel file revealed no documentation EI # 4, Medical Director, performed a clinical skills observation of EI # 3 upon hire and prior to performing an abortion procedure.</p> <p>On 1/14/2021, two medical abortion procedures were observed. In both procedures EI # 3, administered the abortion medication, Mifepristone, to the patients and provided them with additional medications for home use to complete the abortion.</p> <p>On 1/14/2021 at 9:45 AM, an interview was conducted with EI # 3, who stated 1/14/2021 was his/her first day in the Mobile facility. EI # 3 verbalized EI # 4, Medical Director, had not observed his/her clinical skills in performing abortion procedures.</p> <p>On 1/14/2021 at 10:18 AM, an interview was conducted with EI # 4 via telephone, who verbalized she/he had not performed an observation of EI # 3 prior to EI # 3 performing abortion procedures at the facility on 1/14/2021.</p> <p>On 1/14/2021 at 4:13 PM, an interview was conducted with EI # 1, Health Center Manager, who stated EI # 4 was the Medical Director over abortions for the facility and responsible for the direct observations of the physicians when performing abortions for the facility.</p>	L 100		