

Please be advised that the Department's Bureau of Health Facilities Licensing is requiring the facility to submit corrective action plans in response to the Licensing reports of visit. Information on the resolution of the corrective action is expected to be available upon written request within fifteen days of the date the corrective action plans are due.



Location Information		Audit Information	
License Number:	AB-0005	Audit Form:	Abortion Clinic ROV 20150827
Mail Stop:	HL- Abortion Clinic	Audit Type:	L01 Routine
Location Name:	CHARLESTON WOMEN'S MEDICAL CENTER	Start Date:	Thursday, September 03, 2015
Address 1:	1312 ASHLEY RIVER RD	Stop Date:	Friday, September 04, 2015
City/State/Postal Code:	CHARLESTON , SC , 29407- 5365 , Charleston	Auditor:	Michell Hatcher
Phone 1:	843-571-5161	Contact Name:	
Email:	JANICECWMC@AOL.COM		

<p>Bureau of Health Facilities Licensing 2600 Bull St Columbia SC 29201-1708</p> <p>REPORT NOTICE: If applicable, this Report of Visit includes a detailed description of the conditions, conduct or practices that were found to be in violation of requirements. This inspection or investigation is not to be construed as a check of every condition that may exist, nor does it relieve the licensee (owner) from the need to meet all applicable standards, regulations and laws. The South Carolina Code of Laws requires this Department to establish and enforce basic standards for the licensure (permitting), maintenance, and operation of health facilities and services to ensure the safe and adequate treatment of persons served in this State. It also empowers the Department to require reports and make inspections and investigations as considered necessary. Furthermore, the Code authorizes the Department to deny, suspend, or revoke licenses (permits) or to assess a monetary penalty against a person or facility for (among other reasons), violating a provision of law or departmental regulations or conduct or practices detrimental to the health or safety of patients, residents, clients, or employees of a facility or service. If applicable to the type of report being made, the signature of the activity representative indicates that all of the items cited were reviewed during the exit discussion. If this Report of Visit is required by regulation to be made available in a conspicuous place in a public area within the facility, redaction of the names of those individuals in the report is required as provided by Sections 44-7-310 and 44-7-315 of the S.C. Code of Laws, 1976, as amended.</p>	<p>Report Notice</p>
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ADMINISTRATOR'S SIGNATURE - PLAN OF CORRECTION	
<p>PLAN OF CORRECTION - Administrators Certification: I certify that the attached plan of correction describes:</p> <p>(1) the actions taken to correct each cited deficiency, (2) the actions taken to prevent similar recurrences, and (3) the actual or expected completion dates of those actions.</p> <p>PRINT NAME: _____</p> <p>TITLE: _____</p> <p>SIGNATURE: _____</p> <p>DATE: _____</p> <p>Any violations cited in this report of visit were observed at the time of the inspection.</p> <p>Administrator returns a copy of this report (original signature required) with description of corrective actions to: SCDHEC, Bureau of Health Facilities Licensing, 2600 Bull St, Columbia, SC, 29201</p>	<p>POC REQUIRED</p>

Your response to this report must be received in our office by close of business (5:00 p.m.) no later than the date listed below:

Plan of correction required within 15 days of receipt of this report.

INSPECTION INFORMATION

Inspection Includes Licensing:	YES
Inspection Includes Fire & Life Safety:	NO
Is this an On-Site Visit?	YES
Select the Type of Inspection to be Performed:	Abortion Clinic Inspection (Licensing and/or FLS)
What Date Did the Auditor Arrive at the Facility?	3 Sep 2015
What Time Did the Auditor Arrive at the Facility?	8:30:45 AM
Facility Administrator:	Leisa Boyle
Enter the name and title of the Facility/Activity Representative for this Report of Visit.	Sabrina Draytron and Janice Nichols
Is the Current Facility/Activity Administrator the same as the Administrator of Record?	YES
Are there any other individuals accompanying the auditor for this visit? <i>Janice Mcfaddin, RN (DHEC) and Charlene Bell, Field Manager (DHEC), Crispulo Isiminger, Leslie Yasinsac</i>	YES

AC REGULATION PARTS I-VII 61-12

302.B. Clinics performing abortions beyond 14 weeks from the first day of the last menstrual period must meet the requirements of Section 309. (Class I Violation) <i>White blood counts were not available in the medical records for 3 of 3 medical records reviewed for patients 14 weeks gestation or higher. Staff members A and B report the facility does not obtain a white blood count or determine the blood type for patients 14 weeks gestation or higher. (See 309. D .1.)</i>	OUT
303.F. Records. Records shall be kept of all stock supplies of controlled substances giving an accounting of all items received and/or administered. (Class II Violation) <i>A record of the accounting of all medications administered from the facility's stock supply of controlled substances was not available for review. The controlled medicines were locked in the physician's office and staff members did not have access to the office.</i>	OUT
304.B.3. Prior to the procedure, laboratory tests shall include a recognized urine pregnancy test unless the physician identifies fetal heart beats or fetal movements on physical examination. If positive, the following additional tests are required: Determination of Rh factor (including the Du variant when the patient is Rh negative); Rh (D) immune globulin (human) shall be administered, prior to discharge, to patients who are determined to be Rh negative. (Class II Violation) <i>Determination of Rh factor was not documented in the record or otherwise available for review 21 of 25 medical records reviewed.</i>	OUT
309.D. Clinics which perform abortions beyond 14 weeks from the first day of the last menstrual cycle shall, in addition to those requirements in all other sections of	OUT

this regulation, have the following in place: Laboratory tests/procedures shall include: 1. White blood count and determination of blood type; 2. Sickle cell, when indicated; 3. Ultrasonogram. (Class I Violation)

Staff members A and B stated to the inspectors that the facility does not obtain a white blood count for patients who are beyond 14 weeks since from the first day of the last menstrual cycle. White blood counts were not documented in the record or otherwise available for 3 of 3 medical records reviewed for patients beyond 14 weeks since the last menstrual cycle.

DHEC 0282 (05/2010) AUDIT - [Records Retention Schedule #SBH-F&S-17]

Retention

PROTECTED INFORMATION

Is this information CONFIDENTIAL? This section names or identifies certain individuals related to cited violations. If you identify by name any patient, client, resident, participant, or staff you must check 'YES' by CONFIDENTIAL. Otherwise, check 'NO.'



YES

Auditor Signature: Michell Hatcher

No Signature Available

Representative Signature:

No Signature Available



Location Information		Audit Information	
License Number:	AB-0005	Audit Form:	Abortion Clinic ROV 20150827
Mail Stop:	HL- Abortion Clinic	Audit Type:	L07 Investigation
Location Name:	CHARLESTON WOMEN'S MEDICAL CENTER	Start Date:	Thursday, September 03, 2015
Address 1:	1312 ASHLEY RIVER RD	Stop Date:	Friday, September 04, 2015
City/State/Postal Code:	CHARLESTON , SC , 29407-5365 , Charleston	Auditor:	Michell Hatcher
Phone 1:	843-571-5161	Contact Name:	
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<p>Bureau of Health Facilities Licensing 2600 Bull St Columbia SC 29201-1708</p> <p>REPORT NOTICE: If applicable, this Report of Visit includes a detailed description of the conditions, conduct or practices that were found to be in violation of requirements. This inspection or investigation is not to be construed as a check of every condition that may exist, nor does it relieve the licensee (owner) from the need to meet all applicable standards, regulations and laws. The South Carolina Code of Laws requires this Department to establish and enforce basic standards for the licensure (permitting), maintenance, and operation of health facilities and services to ensure the safe and adequate treatment of persons served in this State. It also empowers the Department to require reports and make inspections and investigations as considered necessary. Furthermore, the Code authorizes the Department to deny, suspend, or revoke licenses (permits) or to assess a monetary penalty against a person or facility for (among other reasons), violating a provision of law or departmental regulations or conduct or practices detrimental to the health or safety of patients, residents, clients, or employees of a facility or service. If applicable to the type of report being made, the signature of the activity representative indicates that all of the items cited were reviewed during the exit discussion. If this Report of Visit is required by regulation to be made available in a conspicuous place in a public area within the facility, redaction of the names of those individuals in the report is required as provided by Sections 44-7-310 and 44-7-315 of the S.C. Code of Laws, 1976, as amended.</p>	Report Notice
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INSPECTION INFORMATION	
Inspection Includes Licensing:	YES
Inspection Includes Fire & Life Safety:	NO
Is this an On-Site Visit?	YES
Select the Type of Inspection to be Performed:	Abortion Clinic Investigation
Section Team Log Number: <i>M08052-15</i>	Section Team Log Number
Reason for Investigation: <i>The South Carolina Department of Health and Environmental Control conducted this investigation in accordance with the August 18, 2015 request by Governor Nikki Haley.</i>	
What is the Source:	Other

Date Agency (DHEC) Notified: <i>August 18, 2015</i>	Date Agency (DHEC) Notified:
Detailed Results of this Investigation: <i>The South Carolina Department of Health and Environmental Control's Bureau of Health Facilities Licensing and Bureau of Land and Waste Management conducted a joint investigation in accordance with August 18, 2015 request by Governor Nikki Haley. The Department made an unannounced visit to Charleston Women's Medical Center for Investigation M08052-15 to determine compliance with state laws and regulations. Department personnel interviewed facility staff regarding, but not limited to, facility operational and patient care policies and procedures, memoranda of agreement, agreement with a board certified OB-GYN physician with admitting privileges at a local hospital, and consultation agreements. Department personnel also reviewed staff personnel files relating to professional licensure, orientation, in-service training, infection control, patient confidentiality, job descriptions, and 25 patient medical records. A walk through of the facility was also conducted pertinent to the collection, processing, storage, and disposal of tissue. During the walk through a red biohazard container was observed in the sterilization room, however, there were no contents in the container. The container was labeled with biohazard markings on the outside of the container. Facility staff reports the products of conception are collected in this red biohazard container in the individual bags and held until placed in storage for pick up. There were no violations cited during this investigation.</i>	Detailed Results
Is this an Unlicensed Facility/Activity?	NO
Has the Initial QI Review Been Completed?	NO
What Date Did the Auditor Arrive at the Facility?	3 Sep 2015
What Time Did the Auditor Arrive at the Facility?	8:30:28 AM
Facility Administrator:	Lisa Boyle
Enter the name and title of the Facility/Activity Representative for this Report of Visit.	Sabrina Drayton, Patient Care Tech
Is the Current Facility/Activity Administrator the same as the Administrator of Record?	YES
Are there any other individuals accompanying the auditor for this visit? <i>Janice McFaddin, Charlene Bell, Leslie Yasinsac, Crispulo Isminger</i>	YES
DHEC 0282 (05/2010) AUDIT - [Records Retention Schedule #SBH-F&S-17]	Retention
PROTECTED INFORMATION	
Is this information CONFIDENTIAL? This section names or identifies certain individuals related to cited violations. If you identify by name any patient, client, resident, participant, or staff you must check 'YES' by CONFIDENTIAL. Otherwise, check 'NO.'	

Auditor Signature: Michell Hatcher
No Signature Available

Representative Signature:
No Signature Available