

Alabama Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>C5103</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>08/02/2006</b>
NAME OF PROVIDER OR SUPPLIER  <b>REPRODUCTIVE HEALTH SERVICES</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>811 SOUTH PERRY STREET MONTGOMERY, AL 36104</b>		
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L 000	INITIAL COMMENTS  Complaint # AL00008552 and complaint # AL00008516 were investigated during this survey. Deficiencies were cited as a result of the complaint investigation.	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-.03 Patient Care  (5) Post Operative Procedures.  (b) The medical director or another physician associated with each abortion or reproductive health center shall have admitting privileges at an acute care hospital within the same standard metropolitan statistical area, or alternatively, the abortion or reproductive health center shall have a contractual arrangement with a physician who has admitting privileges at an acute care hospital within the same standard metropolitan statistical area. The physician shall provide or make appropriate arrangements for continuing medical care for patients who develop complications medically related to an abortion performed at the center.  This regulation is not met as evidenced by:  Based on interviews, answering service logs and record reviews, it was determined the facility did not have a physician to provide continuing care for patients who develop complications.  When interviewed regarding the back up physician on August 1, 2006 at 8:00 A.M., the	L 100		

Health Care Facilities

TITLE

(X6) DATE

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

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L 100	<p>Continued From page 1</p> <p>Administrator stated Dr. # 1 covers and has admission privileges. At 9:15 A.M., the Administrator stated that they did not have a written agreement with Dr. # 1, only a verbal agreement.</p> <p>Dr. # 1 was the same physician who was named on a document which stated that he would provide care from October 30, 2003 to October 30, 2004.</p> <p>In a later interview with the facility Administrator on August 2, 2006, at 10:00 A.M., the Administrator stated "We do not have a contract. The back-up physician we had was a verbal contract with Dr. # 1." The Administrator was asked " If we called Dr. # 1, will he verify this?" The Administrator responded, "He won't remember."</p> <p>On August 7, 2006, a telephone interview was conducted with Dr. # 1 with whom the facility stated they "had a verbal contract with." The physician reported "No, I do not provide care for those patients. She called me about a year ago, I think, and I told her I would not do it [anymore]."</p> <p>The following policy does not meet the requirement at 420-5-1-.03(5)(b) for a physician to make arrangements for continuing medical care for patients who develop complications medically related to an abortion performed at the center, because it explicitly anticipates that there will be occasions when a physician will not be available to provide care.</p> <p>The Facility Protocol Standing Orders for Post Abortion Problems state:</p> <p>"Although these are standing orders, the</p>	L 100		

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L 100	Continued From page 2  physician should be notified and/or review the records of all post abortion patient problems not resolved in a reasonable time frame. If for any reason the physician is unavailable, the patient may be advised to go to the nearest emergency room, if her complications warrant emergency attention.  c. Cramps: (Lower abdominal or lower back pain)  1. Fill the Naproxen 500 mg. prescription and take 1 every 6 hours or substitute Aleve, 2 tablets, every 4 hours. Acetaminophen, 1000 mgs. may be taken in addition to the Naproxen for added cramp relief. Patient is to be reminded not to take any aspirin or aspirin products.  2. Patient should be advised to be resting in bed and may apply heat to the lower abdomen or lower back. (Heat should not be advised if bleeding is excessive.) In addition, patient may be advised to lie on her side with her knees drawn up towards her chest to relieve pressure from her abdomen.  3. Patient is to be recalled in 1 to 2 hours after taking medications. If the patient's condition has not improved, the physician should be notified for further instructions or additional medication orders. If the patient's condition is improved then the patient may be seen at the next procedure day or as a routine follow-up.  Even this defective facility protocol was not followed by the facility in the care of Patient # 18. The facility's nurse failed to notify the doctor in accordance with the protocol.  1. Patient # 18 made her first visit to the facility June 12, 2006. An ultrasound performed June 12,	L 100		

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L 100	<p>Continued From page 3</p> <p>2006 confirmed the pregnancy. A second ultrasound was performed June 26, 2006 with a gestational age of 6 weeks 6 days. A Suction Curettage was performed July 12, 2006.</p> <p>The patient returned to the facility July 14, 2006 at 10:00 A.M., with a complaint of severe lower abdominal cramping. An ultrasound was performed at the facility by a registered nurse. The patient was advised by the nurse that her condition appeared to be okay and was sent home.</p> <p>The patient called the facility again about 5:45 P.M., stating that she had intolerable pain, and she was going to the emergency room. The patient was admitted to the hospital July 14, 2006 and an emergency suction dilatation and curettage was performed 2 days after the abortion procedure.</p> <p>An interview on August 1, 2006 with an LPN employed by the facility acknowledged she was taking call July 14, 2006 when Patient # 18 called. The LPN stated after the patient left the clinic she called back at 5:45 P.M. and told the LPN she was going to the emergency room. The LPN told her, "You don't need to go to the emergency room, "and stated that the patient told her she wanted to see her own doctor.</p> <p>The LPN stated that the next call she received was from Dr. # 2 at 10:30 P.M. who stated that a patient of the facility was in the emergency room and what do you want me to do with her? The LPN told the doctor that the patient was in the emergency room to be treated. The physician told her, " I didn't do the abortion." The LPN told Dr. # 2 she would have her doctor call him. Doctor # 2 asked for the name of the doctor who would be</p>	L 100		

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L 100	<p>Continued From page 4</p> <p>calling and was told by the LPN," I can't tell you her name." The response from Dr. # 2 was," I guess I'm suppose to take a call from an anonymous doctor. The LPN did state that after the third call from Dr. # 2, she refused to talk with him again.</p> <p>A letter received from Dr. # 2 stated "Later, I was told that a doctor (Dr. # 3) did call back, but refused to call me personally on my cell or beeper." Dr. # 3 did not leave a phone number for Dr. # 2 to return the call.</p> <p>Dr. # 3, who performed the procedure at the facility, does not live in the same area as the facility, and does not have admitting privileges to any local hospital.</p> <p>An interview with Patient # 18 on August 8, 2006 , confirmed that she did call the facility on July 14, 2006, and returned to the facility and had an ultrasound and was sent home saying everything looked fine.</p> <p>When asked if they offered to call in a prescription for her severe pain she stated: "No, they told me to take Aleve or Advil or if I had any pain med at home I could take it." When asked if she told the on call nurse she wanted to see her own doctor, she responded: "No, I didn't tell her I wanted to see my doctor. I told her I was in so much pain I couldn't stand it and asked her if I should tell them [emergency room staff] about the abortion. The LPN said it was up to me."</p> <p>When asked, Patient # 18 said: The doctor that saw me [Dr. # 2]; I gave him all the information they had given me and he called them. The doctor came back to the room and said the on call nurse wanted to know if I wanted to talk to</p>	L 100			

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L 100	<p>Continued From page 5</p> <p>her and I told him, "No, if they couldn't help me before what could they do now."</p> <p>A letter dated July 15, 2006, received from Dr. # 2, who treated the patient at the emergency room included this statement, "I personally called .... and spoke to the "nurse in charge". She informed me that there were no physicians from their practice available to care for post-operative complications. She went on to say that "everyone was out of town" and since the patient was in the ER," I guess it's your problem."</p> <p>*****</p> <p>420-5-1-.03 Patient Care</p> <p>(4) Operative Procedures</p> <p>(c) Before a physician performs an abortion, the physician shall examine the fetus by use of ultrasound and by such other techniques as to produce a reasonably accurate method of determining the gestational age and viability of the fetus. After such examination, the physician shall enter into the patient's medical record the test or examinations performed, and his findings regarding viability.</p> <p>This regulation is not met as evidenced by:</p> <p>Based on a review of medical records, it was determined that although the facility was performing ultrasounds and determining gestational age, the physician failed to enter into the patient's medical record his findings regarding viability in 32 of 32 charts reviewed.</p> <p>*****</p> <p>420-5-1-.03 Patient Care</p>	L 100		

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L 100	Continued From page 6  (1) Patient Care Policies and Procedures.  Patient Care Policies and Procedures shall be developed, reviewed yearly, and revised as necessary. Patient Care Policies and Procedures shall be consistent with professionally recognized standards of practice and shall be in accordance with the Alabama Nurse Practice Act.  This regulation is not met as evidenced by:  The facility failed to follow standards of practice by leaving pre-filled and unlabeled syringes of a clear liquid substance out in the open and unsecured.  The Alabama Board of Nursing adopted the Council Recommendations, "Recommendations to Enhance Accuracy of Administration of Medications" Revised June 02, 2005, from the National Coordinating Council for Medication Error Reporting and Prevention.  Recommendations:  8. .... health care professional administer only medications that are properly labeled .....	L 100		

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L 100	Continued From page 7  *****  420-5-1-.03(7)(d) Investigation of Infections  1. Reports of infections observed during any follow-up or return visits of the patient shall be made and kept as part of the patient's medical record. Each facility shall maintain a surveillance logbook recording all follow-up visits and telephone inquiries in which infections or other complaints are reported or observed. This logbook shall be reviewed at least quarterly by the facility's medical director. The facility's medical director may specify certain patient complaints, such as mild cramps, which, in his professional opinion and judgement, do not warrant being recorded in the logbook. The logbook shall in all events contain documentation of the following:  (i) Any report by a patient of severe cramps;  (ii) Any report by a patient of passage of a blood clot as large or larger than three centimeters, or one and one fourth inches, in diameter (the approximate size of a fifty cent piece);  (iii) Any report by a patient that she has passed tissue;  (iv) Any report by a patient of foul smelling discharge;  (v) Any report by a patient that she has soaked two or more sanitary pads in one hour;  (vi) Any report by a patient of a body temperature of 100 degrees Fahrenheit or more;  (vii) Any diagnosis of perforation of the uterus;	L 100		



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L 100	Continued From page 8  and  (viii) Any hospitalization of a patient for adverse conditions resulting from a procedure performed at the facility.  This regulation is not met as evidenced by:  Based on a review of medical records, answering service call logs, and interview it was determined the facility failed to maintain a surveillance log book recording complaints of pain, infection, patients requiring hospital admission related to a complication from an abortion, and patients who required a repeat procedure.  Findings include:  An interview with the facility Administrator on August 1, 2006 at 10:10 A.M. was held and the following information was requested: the infection control committee minutes, a list of members, the infection control logbook of infections, and ways to prevent/follow-up on infections. The Administrator replied, "We don't have any."  The examples listed below should have been included in a facility surveillance logbook, which shall include items (i) through (viii) as listed above, and reviewed at least quarterly by the medical director.  1. The answering service log record for the month of July 2006 was 3 pages long, had 35 calls, 11 of which were for directions, to schedule an appointment, or non-medical from information recorded by the call service. The following calls are broken down into the above complications as follows:	L 100			

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L 100	Continued From page 9  (i) Severe cramps; 2 patients called with this complaint. One of these patients, # 18 was hospitalized.  (ii) Passing large clots; 1 patient called with this complaint One of these patients, # 18 was hospitalized.  (vi) Report of a body temperature of 100 degrees Fahrenheit or more; 1 patient called with this complaint.  (viii) Any hospitalization for adverse conditions resulting from a procedure performed at the facility. There were 8 calls regarding Patient # 18 recorded on the log, some from the patient, the Physician at the hospital, the Physician who performed the procedure, and between the facility nurse and Administrator.  The examples listed below should have been included in a facility surveillance logbook, which shall include items (i) through (viii) as listed above, and reviewed at least quarterly by the medical director.  2. The answering service log record for the months of May and June 2006 was 5 pages long, had 66 calls, 36 of which were for directions, to schedule an appointment, or non-medical from information recorded by the call service. The following calls are broken down into the above complications as follows:  (i) Severe cramps; 5 patients called with this complaint.  (ii) Passing large clots; 15 patients called with this complaint.	L 100		

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L 100	<p>Continued From page 10</p> <p>(v) Any report by a patient that she has soaked two or more sanitary pads in one hour; 1 patient called with this complaint.</p> <p>The following patients required repeat procedures and these should have been included in the surveillance log and were not.</p> <p>1. Patient # 14 returned to the facility for a routine follow up visit on June 20, 2006. An ultrasound performed on that day revealed debris in the uterus, and lab reported a positive pregnancy test.</p> <p>The repeat procedure was performed on June 23, 2006.</p> <p>2. Patient #15 called the facility on July 5, 2006 with complaints of vomiting. An ultrasound done at the facility revealed debris in the uterus.</p> <p>The repeat procedure was performed on July 7, 2006.</p> <p>3. Patient # 16 called the facility on June 13, 2006 with complaints of large clots and stomach cramps.</p> <p>The repeat procedure was performed on June 14, 2006, after an ultrasound revealed clots and debris in the uterus.</p> <p>4. Patient # 18 called the facility on July 14, 2006 with complaints of cramping. An ultrasound was performed by the facility on July 14, 2006, and the patient was advised to return home.</p> <p>The patient was admitted to an area hospital later on July 14, 2006 with ultrasound results of clots</p>	L 100		

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L 100	<p>Continued From page 11</p> <p>versus retained products of conception requiring an emergency dilation and curettage.</p> <p>*****</p> <p>420-5-1-.03(7)(a) Infection Control</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>2. There shall be procedures to govern the use of sterile and aseptic techniques in all areas of the facility.</p> <p>3. There shall be continuing education provided to all staff on causes, effects, transmission, prevention, and elimination of infection at least annually.</p> <p>This regulation is not met as evidenced by:</p> <p>Based on interview, it was determined that the facility failed to have an infection control committee and procedures to govern the use of sterile and aseptic techniques.</p> <p>Findings include:</p> <p>An interview conducted with the Administrator August 01, 2006 at 2:05 P.M., confirmed that she did not have an infection control committee. She stated, " I guess I don't have those policies for infection control committee, decontamination, and that other you asked for."</p>	L 100		

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L 100	<p>Continued From page 12</p> <p>*****</p> <p>420-5-1-.03(6)(b)Pharmaceutical Services</p> <p>Administering, Dispensing, and Prescribing Drugs and Medicines. All oral or telephone orders for medications shall be received by a physician, a registered professional nurse, licensed practical nurse, or a registered pharmacist and shall be reduced to writing on the physician's order reflecting the prescribing physician and the name and title of the person who wrote the order. Telephone or oral orders shall be signed by the prescribing physician within 48 hours. Standing orders shall be used only in accordance with a policy of the facility reduced to writing. Drugs and medications shall not be dispensed, except by or under the supervision of a physician or pharmacist. Any patient requiring medications outside the facility shall be given a written prescription permitting her to obtain the medications from a licensed pharmacy.</p> <p>This regulation is not met as evidenced by:</p> <p>Based on observation, review of medical records, and interview, it was determined that the physician failed to follow standards of practice for prescription requirements.</p> <p>Findings include:</p> <p>Rules of the Alabama Board of Medical Examiners Chapter 540x4-.05(1)(e)," It is improper for a physician to pre-sign blank prescription pads or forms and make them available to non-physician employees or support personnel under any circumstances."</p> <p>On a tour of the facility on August 2, 2006, multiple prescription pads were found presigned,</p>	L 100			

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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	<p>Continued From page 13</p> <p>none had any patient name, some by the medical director, and some by the other physician. The medication on the prescription was stamped in to say "Naproxen 500 mg, SIG: 1 TID, Disp # 12."</p> <p>Also found was one presigned prescription signed by the medical director. It had no patient name, nor any medication listed.</p> <p>*****</p> <p>420-5-1-.03(6)(f)2 Emergency Kit or Emergency Drugs</p> <p>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.</p> <p>This regulation is not met as evidenced by:</p> <p>Based on observation, the facility failed to assure the emergency drug box was inaccessible to any unauthorized person.</p> <p>Findings:</p> <p>On a tour of the facility by the surveyors, unescorted by facility personnel on August 1, 2006 at 9:00 A.M. it was noted the emergency box was located in the back hallway, on the opposite end of the facility from the office area. The box was unlocked and contained the following medications for injection: Adrenalin, Aminophylline, Atropine, Benadryl, Dilantin, Vistaril, Lasix, Methergine, Phenergan, Pitocin and Sodium Bicarbonate. It also contained Albuterol for inhalation and intravenous fluids to include Dextrose, Lactated Ringers and Normal Saline.</p>	L 100		

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L 100	<p>Continued From page 14</p> <p>The back hallway is used by the patients to go from the waiting area to the procedure rooms and the recovery room. The emergency box was also noted to be unlocked on procedure day, Wednesday, August 2, 2006.</p> <p>*****</p> <p>420-5-1-.03(6)(f)5 Emergency Kit or Emergency Drugs</p> <p>5. Emergency kits and the stock supply of drugs shall be inspected with sufficient frequency to permit the removal of all outdated drugs. Each kit shall contain a log documenting such inspections.</p> <p>This regulation is not met as evidenced by:</p> <p>Based on observation, the facility failed to assure all outdated drugs were removed from potential use.</p> <p>Findings include:</p> <p>On a tour of the facility on August 1, 2006 at 9:00 A.M., the following items were found to be outdated: Cytology fixative spray 1 bottle which expired November 26, 1998, Ammonia inhalent 1 box which expired in June 2005, Peroxide 1 bottle which expired November 2005, Pitocin 4 ampules which expired May 2005, and the Emergency eye wash which expired July 2004.</p> <p>420-5-1-.02(5)(b) Personnel</p> <p>Personnel Files. There shall be a personnel file for each employee which shall include:</p> <p>1. Job Description. A written job description that describes the duties and responsibilities, position</p>	L 100		

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L 100	<p>Continued From page 15</p> <p>title, authority, and qualifications for each employee.</p> <p>2. Application. The licensee shall obtain written applications for employment from all employees. The licensee shall obtain and verify information on the application as to education, training, experience, and appropriate licensure, if applicable.</p> <p>This regulation is not met as evidenced by:</p> <p>Based on a review of 8 personnel files and interview it was determined that 3 of 8 employees did not have an application and 8 of 8 did not have a job description.</p> <p>Findings include:</p> <p>1. The registered nurse/administrator, the licensed practical nurse, and the medical assistant hired December 2005 did not have an application completed and present in their personnel file.</p> <p>2. The registered nurse/administrator, the licensed practical nurse, the medical assistant hired in December 2005, the office manager, the medical assistant hired April 20, 2006, the registered nurse hired January 29, 2004, the medical assistant hired June 2003 and the receptionist hired June 16, 2004 did not have a job description in their personnel file.</p> <p>An interview conducted with the Administrator August 2nd at 10:00 A.M., confirmed no applications or job descriptions were present in the files nor could be provided.</p> <p>*****</p>	L 100		



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L 100	Continued From page 16  420-5-1-.04(4)(h) Preventive Maintenance  There shall be a schedule of preventive maintenance developed for all equipment in the facility to assure satisfactory operation. This equipment shall be checked and tested in accordance with manufacturer's specifications at periodic intervals, not less than annually, to insure proper operation and a state of good repair. After repairs or alterations are made to any equipment, the equipment shall be thoroughly tested for proper operation before returning it to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance.  This regulation is not met as evidenced by:  Based on observation and interview, it was determined the facility failed to assure all equipment in the facility had been tested annually.  Findings include:  1. During a tour of the facility an ultrasound machine was observed in the treatment room. No maintenance sticker was present to determine the last inspection date. An autoclave was observed with no maintenance sticker present to determine the last inspection date.  No maintenance logs were being kept by the facility.  An interview was conducted with the Administrator August 01, 2006 at 10:35 A.M., which confirmed this was the only ultrasound in the facility and she stated," We've never checked	L 100		

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L 100	<p>Continued From page 17</p> <p>it and its been at least 9 years and never had any problems. We've never had the autoclave checked either."</p> <p>*****</p> <p>420-5-1-.03 Patient Care</p> <p>(3) Admission and Examination Procedures.</p> <p>(d) Laboratory Tests.</p> <p>3. If the above tests are performed at the facility, the facility's laboratory personnel shall meet any requirements which are in effect and which apply to the facility under Rules promulgated by the Centers for Medicare and Medicaid Services under the Clinical Laboratory Improvement Act Amendments of 1988.</p> <p>This regulation is not met as evidenced by:</p> <p>Based on observation and interview, it was determined the facility had available for use, outdated tubes to collect blood samples.</p> <p>Findings include:</p> <p>On a tour of the facility on August 1, 2006 at 9:00 A.M., tubes for blood collection were in the laboratory area of the facility, on the counter, next to the chair where the patient sits to get blood drawn from their arm/finger by the laboratory personnel. The tubes were located in a wire mesh basket type container mixed in with other colored top tubes, both larger and smaller than those listed as expired. The purple top tubes contain a liquid substance for anticoagulation purposes. The following items were found to be outdated: twenty one 7 milliliter purple top lab collection tubes which expired May 2006, three 7</p>	L 100		

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L 100	<p>Continued From page 18</p> <p>milliliter purple top lab collection tubes which expired September 2004, and twenty five 7 milliliter purple top lab collection tubes which expired May 2005. These tubes were being used to obtain blood specimens for hematocrit levels.</p> <p>CLIA regulation D5417 requires:</p> <p>42 CFR 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>*****</p> <p>420-5-1-.02 (1)(a)State Board of Health Rule require that the governing authority is the person or persons responsible for the management, control, and operation of the facility, including the appointment of personnel 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.</p> <p>This rule is not met as evidenced by:</p> <p>The deficient practices cited above are of such a nature as to demonstrate that the governing body did not ensure the facility was operated in a manner to provide adequate care.</p> <p>Findings include:</p> <p>The governing body committee members and verification of meetings were requested from the Administrator on August 1, 2006 at 10:00 A.M.</p>	L 100		

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L 100	Continued From page 19  The requested information could not be provided as requested.  An interview with the Administrator on August 1, 2006 at 10:00 A.M. confirmed there had been no meeting.  Refer to Operative Procedures and Investigation of Infections.	L 100		