STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	C5103	A. BUILDING: _____ B. WING _____	02/28/2013

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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 Administration (1)(a) Governing Authority. 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 interview, review of medical records and review of policy and procedures it was determined the governing body failed to ensure: 1. The clinic staff was properly trained to provide safe quality patient care in the use of Nitrous Oxide. Refer to 420-5-1-.03 Patient Care. 2. The clinic had policies and procedures related to administering Nitrous Oxide. Refer to 420-5-1-.03(2)Patient Care Policies and Procedures. 3. Patient Care Infection Control. All equipment was cleaned after use. Refer to 420-5-1-.03(8) 4. All patient used equipment had a record of routine inspection and maintenance. Refer to	L 100		

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L 100	Continued From page 1 420-5-1-.04 (5)(b)Physical Environment Preventive Maintenance. **** 420-5-1-.02 Administration (8) Records and Reports. (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 and all forms required by law. (b) Authentication of Records. All records shall be legibly written, dated, and signed in an indelible manner with the identity of the writer indicated. The requirements of this rule were not met as evidenced by: Based on record review and interview with the staff, it was determined the abortion center failed to ensure the staff signed all entries with name and title. 1. Medical record # 1359 was first seen in the center for counseling on 1/11/13 and a surgical abortion was performed on 1/17/13. Review of the Patient Notes dated 2/6/13 at 8:00 AM revealed documentation the patient came to the center for a follow up after the surgical abortion 1/17/13 and had a positive pregnancy test and ultrasound for retained tissue or blood clots. The writer instructed the patient to "take Methergine 0.2 mg (milligrams) 4 tablets every 12 hours until gone." The patient was advised if she began to pass clots or tissue to, call ASAP	L 100		

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L 100	Continued From page 2 (as soon as possible). There were only initials at the end of this entry. Review of the Patient Notes dated 2/6/13 at 2:40 PM revealed after the writer spoke to the Administrator the writer called the patient and instructed her not to take the Methergine. There were only initials at the end of this entry. Review of the Patient Notes dated 2/13/13 at 8:00 AM revealed documentation that the patient returned to the center as instructed with a "very positive" (no further documentation was on the note). There was no documentation of who made this entry in the medical record. An interview was conducted with Employee Identifier # 1, the Administrator on 2/28/13 at 8:00 AM who verified there was no documentation of the persons signature or title. ********** 420-5-1-.03 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 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	L 100		

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L 100	Continued From page 3 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. (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. The requirements of this rule were not met as evidenced by: Based on observation, review of medical records and interview it was determined the abortion center was using Nitrous Oxide (NO2) for anesthesia and failed to: 1. Have a policy and procedure available for the staff to utilize the NO2 2. Include the use of the NO2 equipment in orientation for staff competency 3. Have material safety data information for NO2 4. Have documentation of the patient during the use of the NO2, the length of time it was used and any vital sign assessment during the use of	L 100		

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L 100	Continued From page 4 the NO2 5. Have a physician's order for the use of NO2. Findings include: Nitronox Material Safety Data Sheet from Air Liquid issued August 2009 Chemical name: 50% Nitrous Oxide(N20)/ 50% Oxygen (O2) Precautionary Statements: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. Do not breath gas, unless under medical supervision. In case of fire: Stop leak if safe to do so. Move away from cylinder and cool with water from a protected position. Personal Protection: Personnel engaged in the movement of cylinders shall be provided with safety footwear, safety glasses and leather or PVC gloves. Full cover overalls are recommended. All personal protective equipment must be free from oil and grease. General: Only experienced and properly instructed personnel should handle compressed gases. Consumer Medicine Information from Air Liquide Healthcare/ Treatment Guidelines 1020/Pharm/Nitrous. html Last updated September 2011	L 100		

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Nitronox is a nominal gas mixture of 50% medical nitrous oxide and 50% medical oxygen used for pain relief during moderately painful procedures and surgery and as an adjunct in anesthesia. It is usually given by a doctor, anaesthetic, dentist, ambulance officer or nurse via a mask or mouthpiece in which you breathe the gas.

Using Nitronox: The amount of Nitronox given to you will be decided by your doctor, depending on the amount of pain relief required.

Facility findings:

During the tour of the abortion center 2/27/13 at 12:30 PM, the surveyors observed a crate with dividers separating cylinders of Oxygen and Nitrous Oxide. The surveyors then observed equipment sitting outside procedure room number 2 at the end of the hallway. The equipment was on a dual stand with one cylinder of nitrous oxide and one cylinder of oxygen attached to a dispenser with a plastic mouthpiece.

A review of eight personnel files on 2/28/13 failed to include any education to the staff regarding the use of the Nitrous Oxide or equipment to administer the Nitrous Oxide.

A review of the policy and procedure book on 2/27/13 failed to reveal a policy for the use of Nitrous Oxide.

A review of the material safety data notebook failed to reveal a safety data sheet on Nitrous Oxide.

A review of medical records revealed a stamped red NO2 on the outside of the folder and on the

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L 100	Continued From page 6	L 100		

form for Operative Report. The medical record had no documented order for the use of the Nitrous Oxide, no documented time frame of the use of the Nitrous Oxide, no vital signs assessed during the use and no documentation of who attended the patient. The physician and technician were the only persons documented as having been in the room.

1. Medical record(MR) # 12893 first visited the clinic 10/30/12 and received counseling. The client was notified of a failed abortion identified through the pathology report on 11/7/12. The client returned to the clinic for a resuction procedure 11/27/12. The resuction paperworkrecovery room notes documented : " If NO2 used pre-op SAT(prior to procedure oxygen saturation)/ Pulse 97%/ 75. Post-op SAT (after procedure)/Pulse 100%/ 83."

The procedure paperwork documented the physician entered the room at 8:45 AM and the patient was assisted to the recovery room at 8:53 AM. There was no documentation of the actual time the NO2 was used or who administered the NO2.

An interview with Employee Identifier (EI) # 1, the Administrator, on 2/28/13 at 1:30 PM, confirmed the above information.

2. MR # 12797 first visited the clinic was on 10/02/12 for counseling. The client returned to the clinic for a surgical abortion on 10/05/12. The Procedure paperwork documented the physician entered the room at 8:38 AM and the patient was assisted to the recovery room at 8:38 AM (which was the same time the physician entered the procedure room).

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L 100	Continued From page 7	L 100		

The Recovery Room Notes documented, " If NO2 used pre-op SAT/ Pulse 98%/100. Post-op SAT/Pulse 101%/100." There was no documentation of the actual time the NO2 was used or who administered the NO2.

An interview conducted with EI # 1 on 2/28/13 at 11:15 AM, confirmed the above information.

3. MR # 12193 first visited the clinic on 2/18/13 for counseling. The client returned to the clinic for a surgical abortion on 2/22/13. The Procedure paperwork documented the physician entered the room at 2:21 PM and the patient was assisted to the recovery room at 2:32 PM.

The Recovery Room Notes documented, " If NO2 used pre-op SAT/ Pulse 100%/76. Post-op SAT/Pulse 99%/84." There was no documentation of the actual time the NO2 was used or who administered the NO2.

In an interview conducted with EI # 1 on 2/28/13 at 11:25 AM, confirmed the above information.

4. MR # 1259's first visited the clinic was on 1/11/13 for counseling. The client returned to the clinic due to a failed abortion on 1/17/13 for a resuction on 2/16/13. The Procedure paperwork documented the physician entered the room at 8:25 AM and the patient was assisted to the recovery room at 8:35 AM.

The Recovery Room Notes documented, " If NO2 used pre-op SAT/ Pulse 97%/88. Post-op SAT/Pulse 100%/110." There was no documentation of the actual time the NO2 was used or who administered the NO2.

In an interview conducted with EI # 1 on 2/28/13

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L 100	Continued From page 8 at 11:35 AM, confirmed the above information. ********** (5) Operative Procedures. 420-5-1-.03 Patient Care. (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 tests or examinations performed, and his findings regarding viability. If the physician determines that the fetus is viable, the pregnancy shall not be terminated at the abortion or reproductive health center except when an immediate abortion is necessary to preserve the life or physical health of the mother. The requirements of this rule were not met as evidenced by: Based on record review and interview with the staff, it was determined the physician failed to document if the patient had a viable or not viable pregnancy. This affect 1 of 20 records reviewed. Findings include: 1. Medical record # 13208 was seen in the clinic on 2/20/13 for counseling. The patient returned on 2/22/13 for a surgical abortion. Review of the medical record revealed no documentation if the pregnancy was viable or not viable as instructed per Alabama State Rules.	L 100		

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L 100	Continued From page 9 An interview was conducted on 2/28/13 at 11:10 AM with Employee Identifier # 1, the Administrator who verified the above. **** 420-5-1-.03 Patient Care (8) 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 the abortion center failed to: 1. Clean electric heating pads used on multiple patients in the recovery room. 2. Replace a mouthpiece on the Nitronox machine after each patient use. Findings include: During observations in the recovery room on 2/28/13 at 10:20 AM, the surveyor observed the technician cleaning the chairs in the recovery room and placing the heating pads on the back of the chairs. The patients were brought from the procedure room into the recovery room wearing a hospital gown and a heating pad was placed across the abdomen while they recovered in the chair. Once a patient was discharged the chair was wiped down and the next patient that came into the room would be placed in the chair and the uncovered and uncleaned heating pad would be placed on her abdomen.	L 100		

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L 100	Continued From page 10 During an initial tour of the facility on 2/27/13 at 11:45 AM the surveyor observed a piece of equipment called Nitronox. There was a white mouthpiece attached to the tubing. An observation was made of the Nitronox which continued to have a mouth piece on 2/28/13 at 7:40 AM. The surveyor asked Employee Identifier (EI) # 2, Patient Care Technician (PCT) why the mouth piece was on the Nitronox. EI # 2 stated, "It must still be on there from the last treatment day." EI # 2 then removed the mouth piece and placed the mouth piece in the regular trash. In an interview with EI # 1, Administrator 2/28/13 at 9:30 AM, she was questioned as to when the last time the Nitronox had been used. EI # 1 stated that the mouthpiece had not been used. EI # 1 stated that no one received the Nitronox on Friday 2/22/13, the last day they did procedures. A review of medical records revealed a stamped red NO2 on the outside of the folder and on the form for Operative Report. Review of the Procedure Day and Discharge Sheet dated 2/22/13 revealed Medical Record # 13193 did have a surgical abortion on 2/22/13 and review of the medical record revealed this patient received nitrous oxide. A Procedure for Nitrous Oxide Gas Sedation was provided to the surveyors 2/28/13 at 7:30 AM when the surveyors asked for manufacturer's recommendations for use of Nitrous Oxide gas. EI # 1 stated she did not have the manufacturer's recommendations, the Preventive Maintenance person had taken it with him when they were trying to order new tubing.	L 100		

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L 100	Continued From page 11 Procedure for Nitrous Oxide Gas sedation: " NO2 in the Nitronox Unit is a patient demand system designed to administer Nitrous and Oxygen mix to treat patient anxiety. " The unit is equipped with settings that cannot be adjusted and will not operate without Oxygen. An automatic shutdown will occur when O2 tank is depleted. Be sure to check gas gauge levels before using to assure tanks have adequate levels. " To check levels on unit the gauges will provide amounts of gases left in tank when the O2 and nitrous is turned on. " You must explain to each patient how the demand works as no gas is dispensed without suction so the patient must draw a deep breath to engage demand valve. " A new mouthpiece will be used for each patient and the demand valve will be disinfected before and after each patient use. Patient oxygen levels and mental status will be monitored during dispensing time and beginning and ending levels will be noted on the recovery notes." The procedure was not included in the policy and procedure book, was not part of the approved policies and not dated or signed off as an approved policy and procedure. In an interview with EI # 1, the Administrator, on 2/28/13 at 1:30 PM, she confirmed the above information.	L 100		

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L 100	Continued From page 12 **** 420-5-1.04 Physical Environment (5) 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: (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 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. The requirements of this rule were not met as evidenced by: Based on observation and interview it was determined the electric heating pads used in the recovery room failed to have a preventive maintenance label to indicate the equipment had been tested and deemed safe for use. The clinic failed to have manufacturer's recommendations for Nitrous Oxide.	L 100		

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L 100	Continued From page 13 Findings include: The preventive maintenance log failed to include the electric heating pads as having been inspected. The surveyor asked EI # 1, the Administrator if this equipment was new. EI # 1 stated that she had bought them in the last year but did not have a receipt. A Procedure for Nitrous Oxide Gas Sedation was provided to the surveyors 2/28/13 at 7:30 AM when the surveyors asked for manufacturer's recommendations for use of Nitrous Oxide gas. EI # 1 stated she did not have the manufacturer's recommendations as the Preventive Maintenance person had taken it with him when they were trying to order new tubing. In an interview with EI # 1, the Administrator, on 2/28/13 at 1:30 PM, she confirmed their was no preventive maintenance on the heating pads. **** 420-5-1.04(5) Physical Environment (d) 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 each month and shall remove from its inventory all deteriorated items and all items for which the expiration date has been reached. The requirements of this rule were not met as evidenced by:	L 100		

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L 100	Continued From page 14 Based on observation and interview it was determined the abortion center failed to remove Hepatitis B vaccine from the refrigerator after the expiration date. Findings include: During a tour of the facility 2/27/13 the surveyor observed in the medication refrigerator 2 Hepatitis B vaccines of 20 mcg(micrograms)/ 1 ml(milliliter) that had an expiration date of 2/22/13. In an interview with EI # 1, the Administrator, on 2/28/13 at 1:30 PM, she confirmed the above information stating, " I had myself a note to remove it."	L 100		