

Health Standards Section

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>BO0004642</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>12/07/2009</b>
NAME OF PROVIDER OR SUPPLIER  <b>DELTA CLINIC OF BATON ROUGE, INC</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>756 COLONIAL DRIVE BATON ROUGE, LA 70806</b>		
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S 000	Explicit Statements-01  An unannounced Licensure and a complaint survey, complaint #9AB28180, were performed from 12/02/09 through 12/7/09. All tags cited were the result of the licensure and complaint survey.	S 000		
S4405	GOVERNING BODY  This Rule is not met as evidenced by: §4405. Governing Body  A. The abortion facility must have a governing body which meets at least annually. The governing body is the ultimate authority of the facility, and as such, it shall approve and adopt all bylaws, rules, policies, and procedures formulated in accordance with these licensing standards. All bylaws, rules, policies, and procedures formulated in accordance with these licensing standards shall be in writing, revised as necessary, and reviewed annually. If, due to type of ownership or other reasons, it is not possible or practical to establish a governing body, as such, then documents shall reveal the person(s) who are legally responsible for the conduct of the facility and are also responsible for carrying out the functions and obligations contained herein pertaining	S4405		

DHH/Health Standards Section

TITLE

(X6) DATE

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

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S4405	Continued From page 1 to the governing body.  B. The responsibilities of the governing body shall include, but not be limited to: 7. establishing a system for periodic evaluation of its operation (quality assurance).  C. The governing body shall establish formal lines of communication with the medical staff through a liaison committee or other acceptable methods. This committee will address problems and programs of mutual concern regarding topics including, but not limited to, patient care, cost containment and improved practice.  D. Minutes of meetings of the governing body shall be maintained to adequately reflect the discharging of its duties and responsibilities.  Based on record review and interview the governing body failed to ensure the facility had an effective quality assurance program as evidence by: 1) failing to ensure the governing body reviewed data collected by the Quality Assurance Department. 2) failing to ensure problem prone areas were identified by the Quality Assurance Department and reported to the governing body for the implementation of corrective action. Findings:  1. Failing to ensure the governing body reviewed data collected by the Quality Assurance	S4405			

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S4405	<p>Continued From page 2</p> <p>Department.</p> <p>Review of the Annual Meeting of the Board of Directors (identified by Facility Manager S1 as the Governing Body) dated 4/13/09 revealed a discussion was held regarding building repairs, insurance policies, funding for building repairs, and a search for new physicians due to increased work loads. Further review revealed no documented evidence that the governing body reviewed any quality improvement data to include infection control.</p> <p>During a face to face interview on 12/04/09 at 10:30 a.m., Facility Manager S1 indicated she was the responsible party for collecting, tracking, and trending Quality Assurance Data to include Infection Control. S1 further indicated the 2009 Quality Indicators being monitored at the facility included Employee Occurrences, Patient Occurrences, Infections, Grievances, Ectopic Pregnancies, Medical Re-Aspiration, Surgical re-aspiration, Follow Ups, Chart Completion, Daily cleaning, Quality Controls, and Confidentiality. S1 indicated the 1/2009 annual report with summary of data collected revealed 3 retained tissues, 3 yeast infections, and 2 urinary tract infections (all surgical patients). Patients were given antibiotics and Methergine (confirmed with record review). Facility Manager S1 further indicated the Governing Board had never reviewed Quality Assurance Data and had never been forwarded any Quality Assurance information for their review.</p> <p>Review of the facility's Quality Assurance Plan presented by the facility as their current Plan revealed in part, "Monitoring and evaluation information is communicated to the necessary individuals and departments through the</p>	S4405		

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S4405	Continued From page 3  established channels. Relevant findings from all monitoring activities are included in staff profiles for consideration at the time of evaluation. The Quality Assurance Plan and the Quality Assurance manual are reviewed and approved annually by the clinic Administrator, Medical Director, Quality Assurance Director and other appropriate clinic staff." Further review revealed no documented evidence of how information would be provided to the governing body for periodic evaluation of the quality of it's operation.  2. Failing to ensure problem prone areas were identified by the Quality Assurance Department for the implementation of corrective action.  Review of the Quality Assurance Plan presented by the facility as their current plan revealed in part, "The primary purpose of this clinics Quality Assurance (QA) Plan is the ongoing monitoring and evaluation of the appropriateness of patient care. The QA Plan's goal is to consistently strive to improve the clinics provision of care in accordance with patients' needs, and professional and regulatory standards. The QA Plan insures that the monitoring and evaluation of care is performed by the clinic staff who are directly involved with the care of the patient, and as close to the time the care is provided as possible. The QA plan allows the identified problems to be solved in an orderly and constructive manner and provides for measures to address identified opportunities for improvement. The QA plan also incorporates certain QA activities that focus on areas with significant impact on the quality care for the clinic. These may include the Infection Control Log, the Employee and Patient Incident Report Logs and the Grievance Log. Reports from these areas will	S4405			

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S4405	Continued From page 4  be evaluated to determine trends, patterns and/or problems. The clinic QA committee will then make recommendations to resolve identified problems.  During a face to face interview on 12/04/09 at 10:30 a.m., Facility Manger S1 confirmed the facility had failed to identify the following problem prone areas and as a result had implemented no corrective actions: 1) Failure to ensure aseptic technique was maintained by prefilling syringes with Nubain and Phenergan with no cover on the hub of the syringes with placement in a non-sterile zip log bag (see findings sited at 4409). 2) Failure to document in the medical records of patients receiving Conscious Sedation the medication name, time, route, dose, and/or rate of administration (see findings cited at 4409). 3) Failure to document monitoring of patients receiving conscious sedation regarding their cardiac status, respiratory status, and level of consciousness during the medical procedure (see findings cited at 4409). 4) Failure to document the start and end time of the surgical procedure to terminate pregnancy (See findings cited at 4409). 5) Failure to ensure practices in the facility complied with R.S. 40:1299.35.6 which requires the woman seeking an abortion to be counseled individually and in a private room to protect her privacy and maintain the confidentiality of her decision (see findings cited at 4411). 6) Failure to ensure safeguards were established to maintain confidentiality allowing 17 documents with patient information to reach the public (see findings cited at 4415). 7) Failing to ensure Office of Public Health Vital Records registry contained accurate and complete information (See findings cited at 4415).	S4405		

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S4405	Continued From page 5  8) Failure to ensure aseptic technique was maintained when preparing injections for Intravenous administration (see findings cited at 4419 and 4421). 9) Failure to follow the manufacturers suggested guideline for decontamination of equipment (vaginal probes) between patient use (see findings cited at 4419). 10) Failure to ensure single use Intravenous fluid was only used for one patient for one administration (see findings cited at 4419 and 4421).	S4405		
S4409	<b>PERSONNEL</b>  This Rule is not met as evidenced by: §4409. Personnel B. Nursing Personnel 1. The nursing services shall be provided under the direction of a qualified registered nurse or medical director.  5. Nursing care policies and procedures shall be in writing and be consistent with accepted nursing standards. Policies shall be developed for all nursing service procedures provided at the facility. The procedures shall be periodically reviewed and revised as necessary.  An Immediate Jeopardy situation was identified and the facility's Office Manager S1 and Medical Director S2 were notified on 12/03/09 at 3:35 p.m. The Immediate Jeopardy situation was a result of the facility's failure to ensure standards of practice were followed for the administration of	S4409		

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S4409	<p>Continued From page 6</p> <p>Conscious Sedation by:</p> <ol style="list-style-type: none"> <li>1) Failing to ensure aseptic technique was maintained by prefilling syringes with Nubain and Phenergan with no cover on the hub of the syringes and with placement in a non-sterile zip lock bag.</li> <li>2) Failing to document in the medical records of patients receiving Conscious Sedation the medication name, time, route, dose, and/or rate of administration for 5 of 5 patients reviewed for conscious sedation (#11, #12, #13, #17, #18)..</li> <li>3) Failing to document monitoring of patients receiving conscious sedation regarding their cardiac status, respiratory status, and level of consciousness during the medical procedure for 5 of 5 patients reviewed for conscious sedation (#11, #12, #13, #17, #18)..</li> <li>4) Failing to document the start and end time of the procedure for 5 of 5 patients reviewed for surgical procedures (#11, #12, #13, #17, #18)..</li> </ol> <p>The Immediate Jeopardy was lifted on 12/07/09 at 11:25 a.m. as a result of a plan put in place at the facility which included the following: "Effective immediately, the Clinic will discontinue the practice of pre-filling Nubain and Promethazine syringes. Medication used for Conscious Sedation will be drawn up by the physician and administered to the patient immediately. No procedures will be done at the facility until after December 8, 2009. A meeting is scheduled to be held on Tuesday, December 8, 2009 with the Medical Director, Office Manager, and all medical personnel. They will discuss the clinic citation issued by DHH (Department of Health and Hospitals) regarding the prefilling of and non-labeling and storage of conscious sedation medication - - Nubain and Phenergan. Discussion will include the risks and possible infections due to the un-sterile conditions. Upon</p>	S4409			

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S4409	Continued From page 7  arrival at the Clinic on Wednesday, December 9, 2009, the Office Manager will also inform (Physician S10) of the citations issued by DHH regarding all deficiencies stressing conscious sedation. The office manager will be responsible for daily monitoring of this task for one year. By checking the refrigerator, monitoring staff, and monitoring the physician.  Effective immediately, the patient medical record will reflect the name of the medication, the dosage, route, time, and the rate that it was administered. The record will also reflect the signature of the physician administering the medication. A meeting is scheduled to be held on Tuesday, December 8, 2009 with the Medical Director, Office Manager, and all medical personnel. We will introduce the new operative record to (Physician S10). No procedures will be done at facility until after December 8, 2009. The Office Manager will be responsible for assuring the proper notations in the patient's medical record on a daily basis.  Effective immediately, when Conscious Sedation is used, the patient's level of consciousness and vital signs will be monitored and documented in the patient's medical record. The patient's blood pressure, pulse, respiration and oxygen level will be monitored every 5 minutes by a third person in the room for who this will be their sole task. All sedation patients will be done in procedure room where emergency equipment will be kept. A vital sign monitor with pulse ox has been ordered and received. No patient will receive Conscious Sedation until . . . properly trained on the use of this equipment. . . .  The patient medical records has been changed to reflect the start and completion time of the procedure. . . The Office Manager will be responsible for assuring the proper notations in	S4409		



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S4409	<p>Continued From page 8</p> <p>the patient's medical record on a daily basis."</p> <p>Based on observation, record review, and interview the facility failed to ensure standards of practice and hospital policies were followed for the administration of Conscious Sedation and failed to have policies in place to ensure the clinic followed the law regarding mandatory reporting of carnal knowledge with minors for 1 of 3 minors reviewed (Patient #3):</p> <p>1) Failing to ensure aseptic technique was maintained by prefilling syringes with Nubain and Phenergan with no cover on the hub of the syringes with placement in a non-sterile zip log bag.</p> <p>Observations on 12/02/09 at 10:05 a.m. revealed a refrigerator located in the recovery room that contained two zip lock bags. Further observations revealed syringes located in the two bags (4 syringes in a bag labeled Nalbuphine 20 mg (milligrams)/ ml. (milliliter) and Promethazine 25 mg./ml.) (2 syringes in a bag labeled Nalbuphine 20 mg./ ml. and Promethazine 50 mg./ml.) to contain 2 ccs of clear fluid with fluid droplets inside the bags. Observations revealed no label on any of the syringes, no cap on the hubs of the syringes, no identifying label on the syringes, and no documented evidence of who drew up the liquid located in the syringes.</p> <p>During a face to face interview on 12/02/09 at 10:05 a.m., the facility's Office Manager S1 confirmed the presence of unlabeled clear fluid filled un-capped leaking syringes located in non-sterile zip lock bags to be located in the recovery room refrigerator. S1 indicated the fluid located in the syringes was the medication that was listed on the outside of the bag: 4 syringes</p>	S4409			

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S4409	<p>Continued From page 9</p> <p>with Nalbuphine 20 mg/ml mixed with Promethazine 25 mg/ml. and 2 syringes with Nalbuphine 20 mg/ml mixed with Promethazine 50 mg/ml. S1 confirmed there was no documented evidence of how many cc's of each medication was drawn into the syringes. S1 further indicated the zip lock bags were not sterile bags. S1 confirmed there was no label on the syringes to indicate how much Nalbuphine and how much Promethazine had been drawn up in the syringes. S1 indicated it had been the practice of the facility for the Licensed Practical Nurse to draw up medication the night before procedures were to be done in the facility and to place these syringes in a zip lock bag in the refrigerator. S1 indicated she had never identified the practice as being an infection control risk. S1 confirmed the storage of open medication filled syringes (no cap on the hub) in non-sterile containers presented a risk for cross contamination.</p> <p>Review of the facility policy titled, "Drawing Medication from a Vial" presented by the facility as their current policy revealed in part, "Check that you now have the correct amount of medication in the syringe and replace the needle cap until ready to use. Make sure your fingers do not touch the needle."</p> <p>Review of the facility policy titled, "Medication Administration" presented by the facility as their current policy revealed in part, "Medications will be administered by the Physician or the LPN (Licensed Practical Nurse). All medication orders are to contain the following: a) name of the drug, b) dosage, c) frequency, d) method of administration. Medications and injections of narcotics will be administered by the physician. . . Medications will be administered using strict</p>	S4409			

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S4409	Continued From page 10  aseptic technique. For proper medication administration, all supplies will be examined for defects and expiration dates."  2) Failing to document in the medical records of patients receiving Conscious Sedation the medication name, time, route, dose, and/or rate of administration for 5 of 5 patients reviewed for conscious sedation out of a total sample of 21 patients.  Patient #11: Review of Patient #11's medical record revealed the patient was administered "Twilight" on 6/06/08 by Physician S11 as preoperative preparation for the surgical termination of her pregnancy. Further review of the entire medical record revealed no documented evidence of the medication name, the route, the dose, the time, or the rate of the "twilight" medication administered to Patient #11.  Patient #12: Review of Patient #12's medical record revealed the patient was administered "Sedation" on 1/09/09 by Physician S11 as preoperative preparation for the surgical termination of her pregnancy. Further review of the entire medical record revealed no documented evidence of the medication name, the route, the dose, the time, or the rate of the "Sedation" medication administered to Patient #12.  Patient #13: Review of Patient #13's medical record revealed the patient was administered Phenergan 25 milligrams IV (Intravenous) and Nubain 20 milligrams on 1/03/06 at 12:15 p.m. by Physician S10 as preoperative preparation for the surgical termination of her pregnancy. Further review of	S4409		

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S4409	<p>Continued From page 11</p> <p>the entire medical record revealed no documented evidence of the rate of administration of Phenergan Intravenously or the route the Nubain was administered.</p> <p>Patient #17: Review of Patient #17's medical record revealed the patient was administered "Sedation" Intravenously on 9/30/09 by Physician S11 as preoperative preparation for the surgical termination of her pregnancy. Further review of the entire medical record revealed no documented evidence of the medication name, the dose, the time, or the rate of the intravenous "Sedation" administered to Patient #17.</p> <p>Patient #18 Review of Patient #18's medical record revealed the patient was administered "Twilight" on 6/19/09 by Physician S11 as preoperative preparation for the surgical termination of her pregnancy. Further review of the entire medical record revealed no documented evidence of the medication name, the dose, the time, or the rate of the "Twilight" medication administered to Patient #18.</p> <p>These findings were confirmed by Medical Director S2 on 12/03/09 at 1:00 p.m. who further indicated documentation in patient's medical records should contain the name of medications administered, the route, the date, the time, the rate, and the patient's response to the medications.</p> <p>Review of the facility's "National Abortion Federation 2009 Clinical Policy Guidelines" presented by the facility as their current "Standards of Practice" revealed in part, "Conscious Sedation - a minimally depressed</p>	S4409			

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S4409	Continued From page 12  level of consciousness that retains the patient's ability to maintain a patent airway independently and continuously, to be easily aroused, and to respond appropriately to physical stimuli and verbal commands. . . Standard 1: When conscious sedation, deep sedation, or general anesthesia are used, monitoring of the patient's level of consciousness must be documented. Standard 2: When conscious sedation or local anesthesia is used, the practitioner responsible for the treatment of the patient and/or the administration of drugs for sedation must be appropriately trained. Standard 3: When conscious sedation is used, a person other than the clinician, trained to monitor appropriate physiological parameters, must be present. Recommendations 3.1: During conscious sedation the patient should be checked frequently for verbal responses. Standard 4: The personnel administering conscious sedation must recognize that conscious sedation may lead to deep sedation with hypoventilation and be prepared to provide respiratory support. Standard 5: The supervising practitioner must be immediately available when conscious sedation is administered. Standard 6: When conscious sedation is used, monitoring must be of a degree which can be expected to detect the respiratory, cardiovascular, and neurological effects of the drugs being used. Option 6.01: Pulse oximetry may be used to enhance this monitoring. Recommendation 0.1: During conscious sedation or local anesthesia, IV access should be maintained for patients in ASA P-3, P-4, and P-5. . . Standard 12: When conscious sedation, deep sedation, or general anesthesia is used, there must be documentation that the patient has been warned of possible transient mental impairment. . . Classification of Physical Status: P1 - A normal health patient. P2- A patient with mild systemic	S4409			

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S4409	<p>Continued From page 13</p> <p>disease. P3- A patient with severe systemic disease. P4- A patient with sever systemic disease that is a constant threat to life. P5 - A moribund patient who is not expected to survive without the operation. P6- A declared brain-dead patient whose organs are being removed for donor purposes."</p> <p>3) Failing to document monitoring of patients receiving conscious sedation regarding their cardiac status, respiratory status, and level of consciousness during the medical procedure.</p> <p>Patient #11: Review of Patient #11's medical record revealed the patient was administered "Twilight" on 6/06/08 by Physician S12 as preoperative preparation for the surgical termination of her pregnancy. Review of the entire medical record revealed no documented evidence that Patient #11 was monitored during the surgical procedure for the effects of conscious sedation to include monitoring of the patient's cardiac, respiratory, and neurological responses (Level of Consciousness and Verbal Response).</p> <p>Patient #12: Review of Patient #12's medical record revealed the patient was administered "Sedation" on 1/09/09 by Physician S11 as preoperative preparation for the surgical termination of her pregnancy. Review of the entire medical record revealed no documented evidence that Patient #12 was monitored during the surgical procedure for the effects of conscious sedation to include monitoring of the patient's cardiac, respiratory, and neurological responses (Level of Consciousness and Verbal Response).</p>	S4409		

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S4409	Continued From page 14  Patient #13: Review of Patient #13's medical record revealed the patient was administered Phenergan 25 milligrams IV (Intravenous) and Nubain 20 milligrams on 1/03/06 at 12:15 p.m. by Physician S11 as preoperative preparation for the surgical termination of her pregnancy. Review of the entire medical record revealed no documented evidence that Patient #13 was monitored during the surgical procedure for the effects of conscious sedation to include monitoring of the patient's cardiac, respiratory, and neurological responses (Level of Consciousness and Verbal Response).  Patient #17: Review of Patient #17's medical record revealed the patient was administered "Sedation" Intravenously on 9/30/09 by Physician S12 as preoperative preparation for the surgical termination of her pregnancy. Review of the entire medical record revealed no documented evidence that Patient #17 was monitored during the surgical procedure for the effects of conscious sedation to include monitoring of the patient's cardiac, respiratory, and neurological responses (Level of Consciousness and Verbal Response).  Patient #18: Review of Patient #18's medical record revealed the patient was administered "Twilight" on 6/19/09 by Physician S11 as preoperative preparation for the surgical termination of her pregnancy. Review of the entire medical record revealed no documented evidence that Patient #18 was monitored during the surgical procedure for the effects of conscious sedation to include monitoring of the patient's cardiac, respiratory, and neurological responses (Level of	S4409			

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S4409	<p>Continued From page 15</p> <p>Consciousness and Verbal Response).</p> <p>These findings were confirmed by Medical Director S2 on 12/03/09 at 1:00 p.m.</p> <p>During a face to face interview on 12/04/09 at 10:30 a.m., Facility Manager S1 confirmed the facility had failed to follow the Standards of Practice outlined in the 2009 National Abortion Federation Clinical Policy Guidelines, that the facility had adopted as their current policy, regarding Conscious Sedation by failing to monitor patients' cardiac, respiratory, and neurological status during their surgical procedures.</p> <p>During a face to face interview on 12/03/09 at 12:15 P.M., Medical Assistant S3 indicated she was the employee assigned to assist physicians during their surgical abortion procedure. S3 indicated she obtained vital signs on patients prior to their procedure. S3 indicated during the procedure her primary function was to assist the physician. S3 indicated she had no knowledge of the side effects of Nubain and/or Phenergan. S3 confirmed that she did not take any vital signs on patients during their surgical procedure.</p> <p>During a face to face interview on 12/03/09 at 12:20 p.m., Medical Assistant S5 indicated she assisted physicians during the surgical termination of pregnancies. S5 indicated her duties included pre-operative vital signs (upon admission), assisting the physician with the procedure, and emotionally comforting patients. S5 indicated Nubain and Phenergan were given to patients prior to the procedure by the physician to help them relax. S5 indicated the medication would sometimes make patients cough; therefore she would monitor their respirations. S5</p>	S4409			



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S4409	Continued From page 16  confirmed she did not document any monitoring of patient's respirations during the surgical procedure and that she did not take any other vital signs (Blood Pressure/Heart Rate/Oxygen Saturation) during the procedure. S5 indicated Nubain and Phenergan would sometimes make patients feel drunk, droopy, drowsy, and/or dizzy.  4) Failing to document the start and end time of the procedure.  Patient #11: Review of Patient #11's medical record revealed the patient had a surgical procedure for the termination of her pregnancy on 6/06/09. Further review of the entire medical record revealed no documented evidence of the start and end time of Patient #11's surgical procedure.  Patient #12: Review of Patient #12's medical record revealed the patient had a surgical procedure for the termination of her pregnancy on 1/09/09. Further review of the entire medical record revealed no documented evidence of the start and end time of Patient #12's surgical procedure.  Patient #13: Review of Patient #13's medical record revealed the patient had a surgical procedure for the termination of her pregnancy on 1/03/06. Documentation revealed the procedure was completed at 12:35 p.m. Further review of the entire medical record revealed no documented evidence of the start time of Patient #13's surgical procedure.  Patient #17: Review of Patient #17's medical record revealed	S4409		

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S4409	<p>Continued From page 17</p> <p>the patient had a surgical procedure for the termination of her pregnancy on 9/30/09. Further review of the entire medical record revealed no documented evidence of the start and end time of Patient #17's surgical procedure.</p> <p>Patient #18: Review of Patient #18's medical record revealed the patient had a surgical procedure for the termination of her pregnancy on 6/19/09. Further review of the entire medical record revealed no documented evidence of the start and end time of Patient #18's surgical procedure.</p> <p>These findings were confirmed by Medical Director S2 on 12/03/09 at 1:00 p.m. who further indicated there should be clear documentation as to when a surgical procedure is begun and when it is completed in the medical record of all patients having surgery.</p> <p>5) Failing to ensure polices were in place to ensure the clinic followed the law regarding mandatory reporting of carnal knowledge:</p> <p>Review of the Louisiana Revised Statute 14:80 revealed in part, " Part V. Offenses affecting the Public Morals Subpart A. Offenses affecting sexual immorality. 1. " Sexual Offenses affecting minors. " presented by the facility as information relayed to them by the State Police Department for reporting consensual sex with minors revealed in part, " Felony carnal knowledge of a juvenile is committed when: 1) A person who is seventeen years of age or older has sexually intercourse, with consent, with a person who is thirteen years of age or older but less than seventeen years of age. When the victim is not the spouse of the offender and when the difference between the age of the victim and the age of the offender is</p>	S4409			

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S4409	Continued From page 18  four years or greater; or 2) A person commits a second or subsequent offense of misdemeanor carnal knowledge of a juvenile, or a person who has been convicted one or more times of violating one or more crimes for which the offender is required to register as a sex offender under R.S. 15:542 commits a first offense of misdemeanor carnal knowledge of a juvenile. . "	S4409		
	Review of the Louisiana Revised Statute 14:80.1 revealed in part, " Misdemeanor carnal knowledge of a juvenile. A Misdemeanor carnal knowledge of a juvenile is committed when a person who is seventeen years of age or older has sexual intercourse, with consent, with a person who is thirteen years of age or older but less than seventeen years of age, when the victim is not the spouse of the offender, and when the difference between the age of the victim and age of the offender is greater than two years, but less than four years. "			
	Patient #2: Review of the "Minor Pregnancy Investigation" form in the record of Patient #2 (age 15) revealed the patient had consensual sex with an 18 year old male. Further review revealed no documented evidence the incident was reported to the police.			
	During a face to face interview on 12/02/09 at 2:30 p.m., Facility Manager S1 indicated she was informed by the police department that the clinic did not need to report cases that involved consensual sex unless the age difference between the patient and the partner were 4 years or greater. S1 indicated in the case of Patient #2 the age difference was three years and did not need to be reported. S1 indicated the police department provided her with the law that			

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S4409	Continued From page 19  supported this practice and presented surveyors with Revised Statute 14:80 for review. S1 indicated consensual sex with minors with an age difference of less than 4 years had not been reported to the police by the facility.	S4409		
S4411	<b>PRE-OPERATIVE PROCEDURES</b>  This Rule is not met as evidenced by: §4411. Pre-Operative Procedures D. Information and Informed Consent. Prior to an Abortion:1. A written informed consent shall be obtained in accordance with R.S. 40:1299.35.6(B);2. The clinical record shall reflect informed consent for general anesthesia, if it is to be administered, as well as an indication of the patients history of negative or positive response (for example, allergic reactions) to medications or any anesthesia to be given;  Based on record review and interview the facility 1.Failed to ensure practices in the facility complied with R.S. 40:1299.35.6 which requires the woman seeking an abortion to be counseled individually and in a private room to protect her privacy and maintain the confidentiality of her decision and 2. Failed to ensure that a pre-operative assessment was performed on a patient and documented by the physician before a procedure was performed on 1 out of total sample of 21. (#1) Findings:  1. Review of Louisiana Revised Statute 1299.35.6 "Woman's Right to Know" revealed in part, "It is the purpose of this act to ensure that every woman considering an abortion receive complete information on her alternatives and that every woman submitting to an abortion do so only after	S4411		

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S4411	<p>Continued From page 20</p> <p>giving her voluntary and informed consent to the abortion procedure. . . Reduce the risk that a woman may elect an abortion only to discover later, with devastating psychological consequences, that her decision was not fully informed. . . The information required by this Section is provided to the woman individually and in a private room to protect her privacy and maintain the confidentiality of her decision, to ensure that the information focuses on her individual circumstances, and that she has an adequate opportunity to ask questions."</p> <p>Review of medical records for all sampled patients (21 patients) revealed a consent form present in the medical record that indicated the physician had explained the procedure (non-surgical or surgical) and that all their questions had been answered. All consents were signed by the patient.</p> <p>During a face to face interview on 12/03/09 at 1:00 p.m., Medical Director S2 indicated she was the person responsible for counseling patients 24 hours before their elective abortion procedure. Medical Director S2 further indicated her practice was to provide counseling in a group format. Medical Director S2 indicated she would offer patients the opportunity to speak with her privately after the group session if they wished to do so. Medical Director S2 further indicated there were certain patients that were always seen individually which included patients with a Hematocrit less than 35, patients with positive medical histories, all minors, all patients with ultrasound results showing no visible signs of pregnancy in their uterus (ectopic precautions), all patients receiving medical terminations, and any patient that wished to speak to her privately. Medical Director S2 indicated she did not speak</p>	S4411			

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S4411	Continued From page 21  with all patients privately. Medical Director S2 indicated she had not made it a practice to document which patients did not receive private counseling.  2. Patient #1  Review of the medical record for #1 revealed that she had an abortion on 10/7/09. There was no documentation of a pre-operative assessment in the medical record.  An interview was held with #7, Medical Assistant on 12/03/09 at 2:05 pm. She indicated that the physician was the person responsible for completing this information before the start of the procedure. She added that this was not the responsibility of the nurse.  An interview was held with Medical Director 2 on 12/03/09 at 1:00 p.m. After review of the medical record for #1, she indicated that the pre-operative assement should have been completed and documented by the physician before the procedure.	S4411		
S4415	PATIENT RECORDS AND REPORTS  This Rule is not met as evidenced by: §4415. Patient Records and Reports A. Retention of Patient Records 1. An abortion facility shall establish and maintain a medical record on each patient. The facility shall maintain the record to assure that the care and services provided to each patient is completely and accurately documented, and that records are readily available and systematically organized to facilitate the compilation and retrieval of information. Safeguards shall be	S4415		

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S4415	Continued From page 22  established to maintain confidentiality and protection from fire, water, or other sources of damage. B. Content of Medical Record 1. The following minimum data shall be kept on all patients: a. identification data; b. date of procedure; c. medical and social history; d. physical examination; e. chief complaint or diagnosis; f. clinical laboratory reports (when appropriate); g. pathology report (when appropriate); h. physicians orders; i. radiological report (when appropriate); j. consultation reports (when appropriate); k. medical and surgical treatment; l. progress notes, discharge notes, and summary; m. nurses' records of care given, including medication administration records; n. authorizations, consents or releases; o. operative report; p. anesthesia report, including post-anesthesia report; and q. special procedures reports. 2. Signatures. Clinical entries shall be signed by the physician as appropriate, i.e., attending physician, consulting physician, anesthesiologist, pathologist, etc. Nursing notes and observations shall be signed by the nurse. 3. Nurses' Notes. All pertinent observations, treatments and medications given shall be entered in the nurses' notes. All other notes relative to specific instructions from the physician shall be recorded. 4. Completion of the medical record shall be the responsibility of the attending physician. C. Nothing in this §4415 is intended to preclude the use of automated or centralized computer systems or any other techniques for the storing of	S4415		

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S4415	Continued From page 23  medical records, provided the regulations stated herein are met. E. Confidentiality 1. If the department, in the course of carrying out licensing responsibilities under this Chapter 44, obtains any patient identifiable health information regarding a patient from an abortion facility, it shall keep such information strictly confidential and shall not disclose it to any outside person or agency, except as follows: a. to the patient who is the subject of the patient identifiable health information;b. pursuant to and in compliance with a valid written authorization executed by the patient who is the subject of the patient identifiable health information; or c. when required by the secretary of the U.S. of Health and Human Services to investigate or determine DHH's compliance with the requirements of the Code of Federal Regulations, Title 45, Part 164, Subpart E. 2. Any person who knowingly discloses such patient identifiable information in violation of Subsection A shall be subject to punishment pursuant to 42 U.S.C. §1320d-6 as follows: a. a fine of not more than \$50,000, or imprisonment for not more than one year, or both;b. if the violation is committed under false pretenses, a fine of not more than \$100,000, or imprisonment for not more than five years, or both; an c. if the violation is committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, a fine of not more than \$250,000, or imprisonment for not more than 10 years, or both.  Based on record review and interview the facility failed to ensure patient medical records and reports were handled appropriately by: 1) Failing to ensure safeguards were established	S4415			



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S4415	Continued From page 24  to maintain confidentiality allowing 17 documents with patient information to reach the public. 2) Failing to ensure Office of Public Health Vital Records registry contained accurate and complete information. Findings:  1.Failing to ensure safeguards were established to maintain confidentiality allowing 17 documents with patient information to reach the public:  Review of the documents presented by a public citizen (complainant) to the Department of Health and Hospitals on 11/24/09 (reportedly found in the dumpster outside the facility) revealed the following Documents containing patient names with medical information and/or billing information:  Sampled Patients Patient #2: Consent to Non-Surgical Abortion Patient #5: Telephone Message dated 1/12/07 with questions regarding post op symptoms Patient #7: Non Surgical Follow Up Document dated 6/16/09 Patient #7: Telephone Message dated 1/12/07 with questions regarding post op symptoms Patient #13: Telephone Message dated 1/12/07 with questions regarding post op symptoms Patient #15: Non Surgical Follow Up Document dated 4/15/09 Patient #16: Recovery Room Note dated 2/29/08 Patient #20: Consent for Surgical Abortion dated 4/10/09  Random Patients Patient #R1: Lab Order form with patient's name and name of clinic dated 10/31/08 Patient #R2: Lab Order form with patient's name and name of clinic dated 6/05/09 Patient #R3: Lab Order form with patient's name and name of clinic dated (unreadable)/16/09	S4415			

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NAME OF PROVIDER OR SUPPLIER  <b>DELTA CLINIC OF BATON ROUGE, INC</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>756 COLONIAL DRIVE BATON ROUGE, LA 70806</b>		
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S4415	<p>Continued From page 25</p> <p>Patient #R4: Lab Order form with patient's name and name of clinic dated 10/31/09 Patient #R5: Telephone Message dated 3/06/05 with questions regarding post op symptoms Sales by Customer Summary Date 4/25/08 Summary with 19 patient names listed Date 4/29/08 Summary with 32 patient names listed Date 6/06/08 Summary with 22 patient names listed Date 11/28/08 Summary with 40 patient names listed Date 4/09/09 Summary with 33 patient names listed</p> <p>During face to face interviews the following staff confirmed (after viewing the documents listed above) the documents originated from the facility, the information was confidential, and the confidential information never should have been available for public viewing. Further all interviewed indicated they had never discarded confidential information outside the facility and had no knowledge of confidential information leaving the building. Facility Manager S1 on 12/02/09 at 1:10 p.m. Medical Assistant S5 on 12/03/09 at 12:20 p.m. Medical Assistant S7 on 12/02/09 at 1:10 p.m. Accounting Staff S6 on 12/02/09 at 10:55 a.m.</p> <p>During a face to face interview on 12/03/09 at 1:00 p.m., Medical Director S2 indicated she had no knowledge that confidential information had not been protected by the facility. S2 further indicated it was strictly prohibited for patient information to be disclosed to the public. S2 confirmed that the information presented to the Department of Health and Hospitals by a public figure revealed a violation of patient</p>	S4415		

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S4415	<p>Continued From page 26</p> <p>confidentiality.</p> <p>Review of the facility policy titled, "Clinical Record Documentation" presented by the facility as their current policy revealed in part, "All clinical record information is confidential."</p> <p>2. Failing to ensure Office of Public Health Vital Records registry contained accurate and complete information:</p> <p>Review of Louisiana Revised Statute 40:64 revealed in part, "The state registrar shall prescribe forms for the collection of information and statistics with respect to abortions. Such forms shall require, but not limited to, the following information: 4) The age, marital status, and state and parish of residence of the father, if known. . . . 9) Other significant conditions of the fetus and mother. . ."</p> <p>Review of a facility's pre-printed "Report of Induced Termination of Pregnancy Performed in Louisiana" form revealed the section titled, "Information on Father (of fetus)" to contain typed data indicating the father's age was unk (unknown), father's residence/state was unk (unknown), and the father's parish was unk (unknown). Further review revealed the section titled "Termination Procedure, Complications, reason for termination, post abortion procedure" to contain typed data indicating there were no complications of pregnancy termination.</p> <p>These findings were confirmed by the Facility Manager S1 on 12/02/09 at 1:10 p.m. who further indicated the forms were pre-printed with the above data already completed prior to seeing patients. Facility Manager S1 further indicated it had not been the practice of the facility to ask any</p>	S4415			

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S4415	Continued From page 27  questions about the patient's father therefore any information regarding the father of the fetus would be unknown to the staff at the facility. Facility Manager S1 indicated she had never questioned the accuracy of the report by placing unknown in the area regarding the father when they had never asked patients for the information.  During a face to face interview on 12/03/09 at 1:00 p.m., Medical Director S2 confirmed that the "Report of Induced Termination of Pregnancy performed in Louisiana" had pre-printed question responses prior to ever seeing the patients. Medical Director S2 further indicated that the reports were due within 15 days of the procedure; therefore, it would be unlikely that a patient would have complications prior to that time. When questioned if complications could ever occur at the time of the procedure or prior to the 15 days, S2 replied that it was possible. Medical Director S2 also confirmed that it had not been the practice at the facility to question any patient about the father of the fetus.  Review of Medical By Laws presented by the facility as their current By Laws revealed in part, "The physician will provide complete and accurate information to the clinic concerning the patient. The physician will assume the responsibility for completion of all medical records."	S4415		
S4417	PHYSICAL ENVIRONMENT  This Rule is not met as evidenced by: §4417. Physical Environment  A. The facility shall have a safe and sanitary environment that is properly constructed,	S4417		

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S4417	<p>Continued From page 28</p> <p>equipped and maintained to protect the health and safety of patients and staff at all times.</p> <ol style="list-style-type: none"> <li>1. Abortions shall be performed in a segregated procedure room, removed from general traffic lines with a minimum of 120 square feet, exclusive of vestibule, toilets or closets.</li> <li>2. There shall be a hand washing fixture within each procedure room.</li> <li>3. The facility shall have a separate recovery room or area with a minimum clear area of 2 feet, 6 inches around the three sides of each stretcher or lounge chair for work and circulation.</li> <li>4. The following equipment and supplies shall be maintained to provide emergency medical care for problems that may arise and be immediately available to the procedure and recovery room(s):               <ol style="list-style-type: none"> <li>a. surgical or gynecologic table;</li> <li>b. surgical instruments for the performance of abortion;</li> <li>c. emergency drugs (designated as such by the medical director);</li> <li>d. oxygen;</li> <li>e. intravenous fluids;</li> <li>f. sterile dressing supplies.</li> </ol> </li> <li>5. All openings to the outside shall be maintained to protect against the entrance of insects and animals.</li> <li>6. A nurse's station with a countertop, space for supplies, provisions for charting and a communication system shall be provided.</li> </ol> <p>Based on observations and interview the facility failed to ensure outdated supplies were not available for patient use. Findings:</p> <p>Observations on 12/02/09 at 10:20 a.m. revealed the following:</p> <p>1000 cc bag of Lactated Ringers that expired on 10/09 in Exam A.</p> <p>1000 cc bag of Lactated Ringers that expired on 10/09 in Exam B.</p> <p>This finding was confirmed by Facility Manager S1</p>	S4417		

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S4417	Continued From page 29  at the time of observations who further indicated that all supplies in the facility should be checked for quality which included expiration dates and the expired Lactated Ringers should have been removed and replaced.  Review of the facility policy titled, "Medication Administration" presented by the facility as their current policy revealed in part, "For proper medication administration, all supplies will be examined for defects and expiration dates."	S4417			
S4419	<b>INFECTION CONTROL</b>  This Rule is not met as evidenced by: <b>§4419. Infection Control</b>  A. The facility shall have policies and procedures that address:1. decontamination;2. disinfection; 3. sterilization; and 4. storage of sterile supplies. B. The facility shall make adequate provisions for furnishing properly sterilized supplies, equipment, utensils and solutions. 1. It is expected that some disposable goods shall be utilized; but when sterilizers and autoclaves are used, they shall be of the proper type and necessary capacity to adequately meet the needs of the facility. 2. Procedures for the proper use of equipment and standard procedures for the processing of various materials and supplies shall be in writing and readily available to personnel responsible for sterilizing procedures. 3. Acceptable techniques for handling sterilized and contaminated supplies and equipment shall be established to avoid contamination. 4. Medically necessary surgical instruments used to enter the uterine cavity shall be sterilized for each abortion procedure.	S4419			

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S4419	<p>Continued From page 30</p> <p>C. There shall be a separate sink for cleaning instruments and disposal of liquid waste.</p> <p>D. Each facility shall develop, implement, and enforce written policies and procedures for the handling, processing, storing and transporting of clean and dirty laundry.</p> <p>E. The facility shall provide housekeeping services that shall assure a safe and clean environment.</p> <p>1. Housekeeping procedures shall be in writing and followed.</p> <p>2. Housekeeping supplies shall be provided to adequately maintain the facility.</p> <p>F. All garbage and waste materials shall be collected, stored and disposed of in a manner designed to prevent the transmission of contagious diseases, and to control flies, insects, and animals.</p> <p>Based on observation and interview the facility failed to ensure Infection Control Measures were in place by:</p> <p>1) failing to ensure aseptic technique was maintained when preparing injections for Intravenous administration of pre-operative medications.</p> <p>2) failing to follow the manufacturers suggested guideline for decontamination of equipment (vaginal probes) between patient use.</p> <p>3) failing to ensure single use Intravenous fluid was only used for one patient for one administration. Findings:</p> <p>1. Failing to ensure that the facility maintained aseptic technique when predrawing and storing intravenous medications to be administered to patients as evidence by having prefilled syringes placed in moisture/droplet filled zip lock bags that had handwritten documentation on the outside of the zip lock bags that contained 4 uncapped</p>	S4419			

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S4419	<p>Continued From page 31</p> <p>syringes with 2 ml of a clear liquid and another zip lock bag that contained 2 uncapped syringes with 2ml of clear liquid. The syringes were not labeled with the name of the contents, not dated when the contents were drawn or the name of the person who drew up the contents in the syringes.</p> <p>An observation was made in the refrigerator located in the recovery room on 12/02/09 at 10:05 am. A moisture/droplet filled zip lock bag that had handwritten documentation on the outside of the zip lock bag, Nalbuphine 20mg(milligrams)/ml(milliliter) and Promethazine 25 mg/ml contained 4 uncapped syringes with 2 ml of a clear liquid. The syringes were not labeled with the name of the contents, not dated when the contents were drawn or the name of the person who drew up the contents in the syringe. Further observation revealed moisture/droplet filled zip lock bag that had handwritten documentation on the outside of the zip lock bag, Nalbuphine 20mg/ml (milligrams)/ml(milliliter) and Promethazine 50 mg/ml containing 2 uncapped syringes with 2 ml of a clear liquid. The syringes were not labeled with the name of the contents, not dated when the contents were drawn or the name of the person who drew up contents in the syringe.</p> <p>During a face to face interview on 12/02/09 at 10:05 a.m., the facility's Office Manager S1 confirmed the presence of unlabeled clear fluid filled un-capped leaking syringes located in non-sterile zip lock bags to be located in the recovery room refrigerator. S1 indicated the fluid was located in the syringes was the medication that was listed on the outside of the bag: 4 syringes with Nalbuphine 20 mg/ml mixed with Promethazine 25 mg/ml. and 2 syringes with Nalbuphine 20 mg/ml mixed with Promethazine</p>	S4419			



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S4419	<p>Continued From page 32</p> <p>50 mg/ml. S1 confirmed there was no documented evidence of how many cc's of each medication was drawn into the syringes. S1 further indicated the zip lock bags were not sterile bags. S1 confirmed there was no label on the syringes to indicate how much Nalbuphine and how much Promethazine had been drawn up in the syringes. S1 indicated it had been the practice of the facility for the Licensed Practical Nurse to draw up medication the night before procedures were to be done in the facility and to place these syringes in a zip lock bag in the refrigerator. S1 indicated she had never identified the practice as being an infection control risk. S1 confirmed the storage of open medication filled syringes (no cap on the hub) in non-sterile containers presented a risk for cross contamination. S1 added that the physician was the person that administered the medications in the unlabeled pre-filled syringe that was located in the moisture filled zip lock bag.</p> <p>Review of the facility policy titled, "Drawing Medication from a Vial" presented by the facility as their current policy revealed in part, "Check that you now have the correct amount of medication in the syringe and replace the needle cap until ready to use. Make sure your fingers do not touch the needle."</p> <p>Review of the facility policy titled, "Medication Administration" presented by the facility as their current policy revealed in part, "Medications will be administered by the Physician or the LPN (Licensed Practical Nurse). All medication orders are to contain the following: a) name of the drug, b) dosage, c) frequency, d) method of administration. Medications and injections of narcotics will be administered by the physician. . . Medications will be administered using strict</p>	S4419			

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S4419	Continued From page 33  aseptic technique. For proper medication administration, all supplies will be examined for defects and expiration dates."  2. Failing to ensure that an ultrasound vaginal probe was decontaminated between patient use according to the manufacturers guidelines.  Observation made during the initial tour revealed a vaginal ultrasound probe that was placed in an empty stainless steel container on the counter of the ultrasound room. An interview was held with S2, Office Manager on 12/2/09 at 10:20 am. She indicated that the vaginal probe was soaked for 1 minute between each patient use in a solution of ½ Cavicide and ½ water solution, then the solution was wiped off with a paper towel before the vaginal probe was sheathed with a condom for patient use. S2 further indicated that the solution was not measured between each use and added that the sonographer would " eyeball " the ½ and ½ mixture of Cavicide and water. A review of the manufacturer's suggested guidelines on the back of the Cavicide solution revealed that the appropriate mixture for the soaking solution should be 2 milliliters of Cavicide to 1 gallon of water and allowing the instrument to set for 5 minutes before patient use.  3) Failing to ensure single use Intravenous fluid was only used for one patient for one administration (Single Use):  Observations on 12/02/09 at 9:50 a.m. revealed a 50 cc bag of Normal Saline with fluid missing located in the supply room of the facility. Further observations revealed the bag to contain the following statement: "Single Dose Container". This finding was confirmed by Facility Manager S1 at the time of the observation. S1 indicated	S4419		

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S4419	Continued From page 34  physicians had been using the single dose bag of Intravenous Fluids for multiple patients by mixing the fluid with Lidocaine for cervical blocks (local anesthesia). S1 indicated she had never realized the bags were for single use only.  During a face to face interview on 12/03/09 at 1:00 p.m., Medical Director S1 indicated she had instructed the staff to draw up Lidocaine mixed with Normal Saline for cervical blocks that she administered. S1 further indicated she had not been aware that the Normal Saline being used was for single use only.	S4419		
S4421	<b>PHARMACEUTICAL SERVICES</b>  This Rule is not met as evidenced by: §4421. Pharmaceutical Services A. The facility shall provide pharmacy services and these services shall be commensurate with the needs of the patients and in conformity with state and federal laws. B. There shall be policies and procedures for the storage, distribution, and handling and administration of drugs and biologicals in the facility. C. The facility shall provide facilities for proper storage, safeguarding and distribution of drugs. 1. Drug cabinets must be constructed and organized to assure proper handling and safeguard against access by unauthorized personnel. 2. Storage areas shall have proper controls for ventilation, lighting and temperature. 3. Locked areas shall be designed to conform with state and federal laws. D. In accordance with all applicable laws, records shall be kept on: 1. all ordering, purchasing, dispensing, and	S4421		

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S4421	<p>Continued From page 35</p> <p>distribution of drugs; and</p> <p>2. the disposal of unused drugs.</p> <p>E. Records for prescription drugs dispensed to each patient shall contain the:</p> <ol style="list-style-type: none"> <li>1. full name of the patient;</li> <li>2. name of the prescribing physician;</li> <li>3. name and strength of the drug;</li> <li>4. quantity dispensed; and</li> <li>5. date of issue.</li> </ol> <p>F. Provision shall be made for emergency pharmaceutical service.</p> <p>G. All outpatient abortion facilities shall have a site-specific Louisiana controlled dangerous substance license and United States Drug Enforcement Administration controlled substance registration for the facility in accordance with the Louisiana Uniform Controlled Dangerous Substance Act and Title 21 of the United States Code.</p> <p>H. Drugs and biologicals shall be administered in compliance with an order from an individual who has prescriptive authority under the laws of Louisiana. Such orders shall be in writing and signed by the individual with prescriptive authority under the laws of Louisiana.</p> <p>I. There shall be a supply of drugs for stabilizing and/or treating medical and surgical complications.</p> <p>Based on observation and interview the facility failed to ensure the proper storage, safeguarded, handling and distribution of intravenous medications administered in the facility as evidence of::</p> <ol style="list-style-type: none"> <li>1. Failing to ensure that the facility maintained aseptic technique when predrawing and storing intravenous medications to be administered to patients as evidence by having prefilled syringes</li> </ol>	S4421			

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S4421	<p>Continued From page 36</p> <p>placed in moisture/droplet filled zip lock bags that had handwritten documentation on the outside of the zip lock bags that contained 4 uncapped syringes with 2 ml of a clear liquid and another bag that contained 2 uncapped syringes with 2ml of clear liquid. The syringes were not labeled with the name of the contents, not dated when the contents were drawn or the name of the person who drew up the contents in the syringes.</p> <p>An observation was made in the refrigerator located in the recovery room on 12/02/09 at 10:05 am. A moisture/droplet filled zip lock bag that had handwritten documentation on the outside of the zip lock bag, Nalbuphine 20mg(milligrams)/ml(milliliter) and Promethazine 25 mg/ml contained 4 uncapped syringes with 2 ml of a clear liquid. The syringes were not labeled with the name of the contents, not dated when the contents were drawn or the name of the person who drew up the contents in the syringe. Further observation revealed moisture/droplet filled zip lock bag that had handwritten documentation on the outside of the zip lock bag, Nalbuphine 20mg/ml (milligrams)/ml(milliliter) and Promethazine 50 mg/ml containing 2 uncapped syringes with 2 ml of a clear liquid. The syringes were not labeled with the name of the contents, not dated when the contents were drawn or the name of the person who drew up contents in the syringe.</p> <p>During a face to face interview on 12/02/09 at 10:05 a.m., the facility's Office Manager S1 confirmed the presence of unlabeled clear fluid filled un-capped leaking syringes located in non-sterile zip lock bags to be located in the recovery room refrigerator. S1 indicated the fluid was located in the syringes was the medication that was listed on the outside of the bag: 4</p>	S4421			

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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	
S4421	<p>Continued From page 37</p> <p>syringes with Nalbuphine 20 mg/ml mixed with Promethazine 25 mg/ml. and 2 syringes with Nalbuphine 20 mg/ml mixed with Promethazine 50 mg/ml. S1 confirmed there was no documented evidence of how many cc's of each medication was drawn into the syringes. S1 further indicated the zip lock bags were not sterile bags. S1 confirmed there was no label on the syringes to indicate how much Nalbuphine and how much Promethazine had been drawn up in the syringes. S1 indicated it had been the practice of the facility for the Licensed Practical Nurse to draw up medication the night before procedures were to be done in the facility and to place these syringes in a zip lock bag in the refrigerator. S1 indicated she had never identified the practice as being an infection control risk. S1 confirmed the storage of open medication filled syringes (no cap on the hub) in non-sterile containers presented a risk for cross contamination. S1 added that the physician was the person that administered the medications in the unlabeled pre-filled syringe that was located in the moisture filled zip lock bag.</p> <p>Review of the facility policy titled, "Drawing Medication from a Vial" presented by the facility as their current policy revealed in part, "Check that you now have the correct amount of medication in the syringe and replace the needle cap until ready to use. Make sure your fingers do not touch the needle."</p> <p>Review of the facility policy titled, "Medication Administration" presented by the facility as their current policy revealed in part, "Medications will be administered by the Physician or the LPN (Licensed Practical Nurse). All medication orders are to contain the following: a) name of the drug, b) dosage, c) frequency, d) method of</p>	S4421			

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S4421	<p>Continued From page 38</p> <p>administration. Medications and injections of narcotics will be administered by the physician. . . Medications will be administered using strict aseptic technique. For proper medication administration, all supplies will be examined for defects and expiration dates."</p> <p>2. Failing to ensure single use Intravenous fluid was only used for one patient for one administration (Single Use):</p> <p>Observations on 12/02/09 at 9:50 a.m. revealed a 50 cc bag of Normal Saline with fluid missing located in the supply room of the facility. Further observations revealed the bag to contain the following statement: "Single Dose Container". This finding was confirmed by Facility Manager S1 at the time of the observation. S1 indicated physicians had been using the single dose bag of Intravenous Fluids for multiple patients by mixing the fluid with Lidocaine for cervical blocks (local anesthesia). S1 indicated she had never realized the bags were for single use only.</p> <p>During a face to face interview on 12/03/09 at 1:00 p.m., Medical Director S1 indicated she had instructed the staff to draw up Lidocaine mixed with Normal Saline for cervical blocks that she administered. S1 further indicated she had not been aware that the Normal Saline being used was for single use only.</p> <p>3. Failing to ensure physician's standing orders were timed, dated, and signed by the physician for 2 of 2 physician's standing orders used in the facility (Physician S2 and S10).</p> <p>Review of Credentialing file folders for Physicians S2 and S10 revealed "Standing Orders" for each physician. Further review revealed no</p>	S4421			

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S4421	<p>Continued From page 39</p> <p>documented evidence of the date, time, or signature of the ordering physician. This finding was confirmed by Facility Manger S1 on 12/07/09 at 9:50 a.m. During this interview S1 further indicated the Standing Orders in the Credentialing files of both physicians were being used in the facility at the time of the survey.</p> <p>4) Failing to ensure written prescriptions signed by the physician contained the name of the patient to whom the medication was prescribed.</p> <p>A tour of the facility was conducted on 12/02/09 from 9:25 am to 10:50 am and in presence of S1, Office Manager. An observation was made of a tablet of prescriptions lying on the desk in the front office that did not contain the name of a patient(s) and with the signature of S2, Medical Director on all prescriptions in the complete pad. The pre-printed medication on the prescription pad (all prescriptions in the pad) was for Promethazine (Phenergan) 25 milligrams tablets, qty 10, ½ -1 tablet 4 times daily, PRN (as needed) for nausea. An interview was held with S1, Office Manager at this time. She indicated that S2, Medical Director pre-signed the prescriptions on the pad and the LPN (Licensed Practical Nurse) would write the patient ' s name on the pre-signed Promethazine prescription and this prescription was given to the patient in the recovery room.</p> <p>During a face to face interview on 12/07/09 at 9:30 a.m., Facility Administrator S13 and Facility Manager S1 indicated pre-written prescription pads for Promethazine were intended to be kept in the Medical Director ' s office (Physician S2); however, she confirmed that the pre-signed Promethazine prescriptions had been located on the front desk in the main lobby of the clinic on</p>	S4421			



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S4421	Continued From page 40  12/02/09. Facility Administrator S13 confirmed that anyone could take one of the pre-signed pre-written prescriptions and have them filled simply by filling in their name at the top of the prescription. S2 and S13 indicated physicians should not sign prescriptions until they were complete and ready to be given to the prescribed patient with the patient ' s name filled in.	S4421			