Health Standards Section

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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| | BO0004601 | A. BUILDING: _____ B. WING _____ | 02/01/2017 |

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| BOSSIER CITY MEDICAL SUITE | 1505 DOCTORS DRIVE BOSSIER CITY, LA 71111 |

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|---|---|---|---|---|
| S 000 | Initial Comments<br><br>Re-licensing Survey<br><br>Abbreviations<br><br>ADM Administrator<br>CDC Centers for Disease Control<br>CSR Central Sterile Room<br>DON Director of Nursing<br>GB Governing Body<br>IC Infection Control<br>ITOP Induced termination of pregnancy (report)<br>LDH Louisiana Department of Health<br>HSS Health Standards Section<br>LEERS Louisiana Electronic Event Registration System<br>LPN Licensed Practical Nurse<br>Med.Dir. Medical Director<br>PI Performance Improvement<br>QA Quality Assurance<br>QAPI Quality Assurance Performance Improvement<br>RN Registered Nurse<br>ST Surgical Technologist | S 000 | Received 3/20/2017 [illegible], RN<br><br>RECEIVED<br>MAR 17 2017<br>HEALTH STANDARDS | |
| S 043 | 4407 E Survey Activities<br><br>E. Statement of Deficiencies. Following any survey, the department surveyors shall complete the statement of deficiencies documenting relevant findings including the deficiency, the applicable governing rule, and the evidence supporting why the rule was not met including, but not limited to, observations, interviews, and record review of information obtained during the survey. The outpatient abortion facility shall receive a copy of the statement of deficiencies.<br>1. Display. The following statements of | S 043 | S 043<br><br>The Clinic Director monitored by the Medical Director will ensure that the most recent statement of deficiencies from the last survey (licensing, follow up, and/or complaints) resulting in a statement of deficiencies will be displayed in a conspicuous place on the licensed premises. The Clinic Director will monitor on a monthly basis to ensure compliance.<br><br>March 15, 2017 | |

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| S 043 | Continued From page 1<br>deficiencies issued by the department to the outpatient abortion facility must be posted in a conspicuous place on the licensed premises:<br>a. the most recent annual licensing survey statement of deficiencies; and<br>b. any follow-up and/or complaint survey statement of deficiencies issued after the most recent annual licensing survey.<br>2. Public Disclosure. Any statement of deficiencies issued by the department to an outpatient abortion facility shall be available for disclosure to the public within 30 calendar days after the outpatient abortion facility submits an acceptable plan of correction to the deficiencies or within 90 days of receipt of the statement of deficiencies, whichever occurs first.<br><br>This Rule is not met as evidenced by:<br>Based on observation and interview, the facility failed to display the statement of deficiencies from the most recent surveys (licensing, follow up, and/or complaint) in a conspicuous place on the licensed premises as evidenced by no displayed survey results from the last survey.<br>Findings:<br><br>Observations of the facility on 01/31/17 at 10:10 a.m., escorted by S1ADM revealed no evidence to indicate the facility had posted a copy of the statement of deficiencies from the most recent surveys (licensing, follow up, and/or complaint) in a conspicuous location on the licensed premises.<br><br>In an interview on 01/31/17 at 10:10 a.m., S1ADM confirmed that the facility had no posted copy of the statement of deficiencies from the most recent surveys (licensing, follow up, and/or complaint) in a conspicuous location on the | S 043 | | |

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|---|---|---|---|---|
| S 043 | Continued From page 2<br>licensed premises. | S 043 | | |
| S 115 | 4421-C - 12 - 15 Governing Body<br><br>12. ensuring services that are provided through a contract with an outside source are provided in a safe and effective manner;<br>13. ensuring that the outpatient abortion facility develops, implements, monitors, enforces, and reviews at a minimum, quarterly, a quality assurance and performance improvement (QAPI) program;<br>14. developing, implementing, monitoring, enforcing, and reviewing annually written policies and procedures relating to communication with the administrator, medical director, and medical staff to address problems, including, but not limited to, patient care, cost containment, and improved practices;<br>15. ensuring that disaster plans for both internal and external occurrences are developed, implemented, monitored, enforced, and annually reviewed and that annual emergency preparedness drills are held in accordance with the disaster plan. The outpatient abortion facility shall maintain documentation on the licensed premises indicating the date, type of drill, participants, and materials;<br><br>This Rule is not met as evidenced by:<br>Based on record review and interview, the facility's Governing Body failed to ensure that all contracted services that were provided were evaluated through the QAPI program to ensure they were provided in a safe and effective way.<br>Finding: | S 115 | **S 115**<br><br>The Governing Body will amend the Quality Assurance and Performance Improvement Program (QAPI) policy to include quarterly review of contracted services to ensure they are provided in a safe and effective manner.<br><br>April 1, 2017 | |

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Health Standards Section

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|---|---|---|---|---|
| S 115 | Continued From page 3<br><br>Review of the facility's contracted services revealed there was no documented evidence that contracted services for bio-hazard waste disposal, pathology laboratory examinations, or pest control were being evaluated through the QAPI program.<br><br>Further review of QA documents provided revealed no evaluation(s) of contracted services provided in the facility.<br><br>In an interview on 02/01/17 at 11:40 a.m., S1ADM indicated the facility had not evaluated their contracted services to ensure they were provided in a safe and effective manner. | S 115 | | |
| S 159 | 4425 -A Patient Med. Records/Reporting Requirements<br><br>A. General Provisions<br>1. The outpatient abortion facility shall establish and maintain a patient medical record on each patient.<br>2. The patient medical record shall be:<br>a. completely and accurately documented; and<br>b. readily available and systematically organized to facilitate the gathering of information.<br>3. The outpatient abortion facility shall ensure compliance with privacy and confidentiality of patient medical records, including information in a computerized medical record system, in accordance with the Health Insurance Portability and Accountability Act (HIPAA) regulations, and/or all applicable state laws, rules, and regulations.<br>4. Safeguards shall be established to protect | S 159 | **S 159**<br><br>The Governing Body will begin on April 1, 2017 to cause all medical records both current and those previously stored to be scanned to a digital file format. The Clinic Director will ensure that digital hardware containing the digital files will be placed in a locking, fireproof/waterproof storage unit at the end of each clinic day. | |



Robert Dross 3-22-17

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|---|---|---|---|---|
| S 159 | Continued From page 4<br>the patient medical records from loss or damage and/or breach of confidentiality in accordance with all applicable state laws, rules, and regulations.<br><br>This Rule is not met as evidenced by:<br>Based on observation, record review, and interview the facility failed to ensure safeguards were established and implemented to protect the patient medical records against loss and/or damage.<br>Findings<br><br>Review of the Facility's Policy titled "Medical Records"(no number or date), presented by S1ADM as current, read in part: Medical records are stored and safeguarded within the facility.<br><br>An observation 1/31/17 at 5:05 p.m., of the business office in the reception area, revealed 9 cardboard "Banker's" boxes, labeled "2016", with patient medical records inside, stacked on the floor. Further observation revealed a metal vertical file cabinet with drawers. S1ADM, present for the observation, reported the vertical file cabinet contained current 2017 patient medical records, and the Banker's boxes contained medical records from 2016. The administrator indicated the 2016 boxes were stored in this location so they were readily assessable if they were needed. S1ADM confirmed there were no safeguards from loss or damage for the medical records such as fire or water. S1ADM reported the facility did not have a sprinkler system installed, and did not have a fire extinguisher located in the location of the files.<br><br>An observation 1/31/17 at 5:10 p.m. revealed a | S 159 | | |

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|---|---|---|---|---|
| S 159 | Continued From page 5<br>storage room, inside the facility, that contained, in part, numerous cardboard boxes (Banker's) boxes with medical records in them. S1ADM, present for the observation reported she could not say how many boxes or records were stored in the room. S1ADM confirmed there were no safeguards in place to protect the patient medical records stored in the storage room from loss or damage, such as fire or water, either. | S 159 | | |
| S 169 | 4425 - E-F Patient Med Records/Reporting Requirements<br><br>E. Other Reports. The outpatient abortion facility shall maintain a daily patient roster of all patients receiving a surgical or chemically induced abortion. Patients may be identified corresponding to the patient's medical record. This daily patient roster shall be retained for a period of three years<br>F. Reporting Requirements<br>1. The outpatient abortion facility shall maintain documentation to support that the outpatient abortion facility is compliant with all reporting requirements, including, but not limited to, the induced termination of pregnancy (ITOP) form and other documentation as required by federal, state, and local statutes, laws, ordinances, and department rules and regulations.<br>2. The outpatient abortion facility shall report in accordance with all applicable state laws for the reporting of crimes against a child that include but are not limited to:<br>a. rape;<br>b. sexual battery;<br>c. incest; and<br>d. carnal knowledge of a juvenile | S 169 | **S 169**<br>(1)<br><br>The Governing Body will ensure there is a written policy & procedure for the reporting of ITOP reports.<br><br>The Clinic Director monitored by the Medical Director will ensure that the certification and registration date of each ITOP report is recorded within each patient medical record. The Nursing Director will audit medical records on a monthly basis to ensure continued compliance.<br><br>April 1, 2017 | |

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|---|---|---|---|---|
| S 169 | Continued From page 6 | S 169 | | |

This Rule is not met as evidenced by:
Based on record review and interview the facility failed to maintain documentation to show they were in compliance with all reporting requirements. This deficient practice was evidenced by:
1) failure to maintain documentation to support the facility was compliant with state statues and licensing regulations to have ITOP reports completed/certified within 30 days after the date of the abortion. This deficient practice was evidenced by no documentation maintained to evidence the ITOP reports had been certified and registered within 30 day of the abortion procedure for 12(#1, #2, #3, #4, #5, #6, #7, #8, #9, #10, #14, #15) of 15(#s 1-15) medical records reviewed for requirements related to ITOP reporting, and
2) Failure to provide evidence of a report, to appropriate authorities, of rape for 1 (#1) of 5 (#1, #2, #3, #4, #7) minors' record reviewed for reporting of crimes against a child.
A total sample of 15 medical records were reviewed.
Findings:

1) failure to maintain documentation to support the facility was compliant with state statues and licensing regulations to have ITOP reports completed/certified within 30 days after the date of the abortion.

Review of LA RS 40:1299.35.10 Reports, revealed, in part "A. An individual abortion report for each abortion performed or induced shall be completed by the attending physician ...The

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|---|---|---|---|---|
| S 169 | Continued From page 7<br>report shall include:(25) Signature of the attending physician... C. All abortion reports shall be signed by the attending physician and submitted to the Department of Health and Hospitals within thirty days after the date of the abortion.<br><br>Review of the facility's Policy & Procedure Manual revealed the facility had no Policy & Procedure on the reporting of ITOP reports.<br><br>Patient #1<br>Review of the medical record for patient #1 revealed she had an abortion 9/9/16. Further review of the medical record revealed no certification or registration date on the ITOP form, which had a printed date of 9/14/16.<br>Review of an ITOP report for Patient #1, provided by the LDH State Registrar and Vital Records office, revealed a certification date of 9/14/16 and registration date of 9/16/16.<br><br>Patient #2<br>Review of the medical record for patient #2 revealed she had an abortion 7/21/16. Further review of the medical record revealed no certification or registration date on the ITOP form, which had a printed date of 8/9/16.<br>Review of an ITOP report for Patient #2, provided by the LDH State Registrar and Vital Records office, revealed a certification date of 8/9/16 and registration date of 8/10/16.<br><br>Patient #3<br>Review of the medical record for patient #3 revealed she had an abortion 8/24/16. Further review of the medical record revealed no certification or registration date on the ITOP form, which had a printed date of 9/9/16.<br>Review of an ITOP report for Patient #3, provided | S 169 | | |

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|---|---|---|---|---|
| S 169 | Continued From page 8<br>by the LDH State Registrar and Vital Records office, revealed a certification date of 9/14/16 and registration date of 9/16/16.<br><br>Patient # 4<br>Review of the medical record for patient #4 revealed she had an abortion 8/20/16. Further review of the medical record revealed no certification or registration date on the ITOP form, which had a printed date of 8/22/16.<br>Review of an ITOP report for Patient #4, provided by the LDH State Registrar and Vital Records office, revealed a certification date of 8/22/16 and registration date of 8/24/16.<br><br>Patient #5<br>Review of the medical record for patient #5 revealed she had an abortion 8/26/16. Further review of the medical record revealed no certification or registration date on the ITOP form, which had a printed date of 9/9/16.<br>Review of an ITOP report for Patient #5, provided by the LDH State Registrar and Vital Records office, revealed a certification date of 9/14/16 and registration date of 9/16/16.<br><br>Patient #6<br>Review of the medical record for patient #6 revealed she had an abortion 11/5/16. Further review of the medical record revealed no certification or registration date on the ITOP form, which had a printed date of 11/8/16.<br>Review of an ITOP report for Patient #6, provided by the LDH State Registrar and Vital Records office, revealed a certification date of 11/8/16 and registration date of 11/22/16.<br><br>Patient #7<br>Review of the medical record for patient #7 revealed she had an abortion 8/13/16. Further | S 169 | | |

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|---|---|---|---|---|
| S 169 | Continued From page 9<br>review of the medical record revealed no certification or registration date on the ITOP form, which had a printed date of 8/27/16. Review of an ITOP report for Patient #7, provided by the LDH State Registrar and Vital Records office, revealed a certification date of 8/30/16 and registration date of 8/30/16.<br><br>Patient #8<br>Review of the medical record for patient #8 revealed she had an abortion 12/2016. Further review of the medical record revealed no certification or registration date on the ITOP form, which had a printed date of 1/11/16.<br><br>Patient #9<br>Review of the medical record for patient # revealed she had an abortion 12/27/16. Further review of the medical record revealed no certification or registration date on the ITOP form, which had a printed date of 12/27/16.<br><br>Patient #10<br>Review of the medical record for patient #10 revealed she had an abortion 11/5/16. Further review of the medical record revealed no certification or registration date on the ITOP form, which had a printed date of 12/6/16.<br><br>Patient #14<br>Review of the medical record for patient #14 revealed she had an abortion 10/08/16. Further review of the medical record revealed no certification or registration date on the ITOP form, which had a printed date of 11/6/16.<br><br>Patient #15<br>Review of the medical record for patient #15 revealed she had an abortion 9/2/16. Further review of the medical record revealed no | S 169 | | |

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|---|---|---|---|---|
| S 169 | Continued From page 10<br>certification or registration date on the ITOP form, which had a printed date of 9/14/16.<br><br>In an interview 2/1/17 at 9:35 a.m. S1ADM reported she electronically entered information into the LEERs system after a patient had been discharged after an abortion procedure. S1ADM, after the review of ITOP reports for Patient # 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 14, 15, confirmed there was no certification or registration date on the ITOP report copies in the medical record. S1ADM reported she could provide no documented evidence ITOP reports were certified and registered in the LEERS system within 30 days of each abortion procedure. S1ADM confirmed that the facility had no written policy & procedure on ITOP reporting. S1ADM indicated she knew from memory that ITOP reports were required to be entered into the LEERS system within 30 days (of an abortion procedure).<br><br>2) Failure to provide evidence of a report, to appropriate authorities, of rape for 1 (#1) of 5 (#1, #2, #3, #4, #7) minors' record reviewed for reporting of crimes against a child.<br><br>Review of the facility's Policy & Procedure titled " Reporting of Suspected Child Abuse and Neglect", presented by S1ADM as being current, read in part: "It is the policy of this facility that all staff persons required by Louisiana law to report suspected child abuse and neglect will make such reports as required by law. Specifically, each staff person will ensure that a report of suspected child abuse is filed with the appropriate authorities whenever a staff person examines, treats, or diagnoses a minor patient and has cause to believe that the minor's physical or mental health or welfare has been endangered by | S 169 | **S 169**<br>(2)<br><br>The Clinic Director monitored by the Medical Director will ensure, in accordance with the Clinic's existing policies and procedures, that when a case of suspected child abuse or neglect is reported to the appropriate authorities in accordance with law, documentation of that report will be kept in the minor's medical record, to include any notes or correspondence (oral or written) between the Clinic and law enforcement. The Nursing Director will audit medical records on a monthly basis to ensure continued compliance.<br><br>April 1, 2017 | |

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|---|---|---|---|---|
| S 169 | Continued From page 11 | S 169 | | |

abuse or neglect, as those terms are defined by Louisiana law ...Whenever a staff member of this facility files such a report of suspected child abuse or neglect regarding a patient of this facility, a copy of the report will be retained in the patient's chart."

Patient #1
Review of the medical record for patient #1 revealed she was a 14-year-old who had an abortion 9/9/16. Further review of the Minor Patient Questionnaire revealed an answer to the following question: "Did he force you to have sex? "Yes". She indicated on the questionnaire that the age of the father was "16." Continued review of the record revealed no documented evidence that the facility had reported the patient response of "forced sex."

In an interview on 01/31/17 at 5:10 p.m., after a review of the record for Patient #1, S1ADM confirmed Patient #1 answered the question (on Minor Patient Questionnaire) "Did he force you to have sex?" with a "yes" response. S1ADM reported, in a conference with Patient #1 and her mother, she was informed they (the patient and her mother) had notified the (out of state) law enforcement authorities in the state and county in which the rape was reported to have occurred. S1ADM indicated the Abortion facility was contacted by detectives from that law enforcement agency requesting tissue from the abortion for DNA testing, but she informed them that there would be none to collect, as the patient was scheduled for a non-surgical abortion . S1ADM confirmed the facility had no documented evidence that a report was filed with the appropriate authorities or of communication between the Law Enforcement Agency and the facility. S1ADM indicated a completed form

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| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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| BOSSIER CITY MEDICAL SUITE | 1505 DOCTORS DRIVE BOSSIER CITY, LA 71111 |

| (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 |
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| S 169 | Continued From page 12<br>documenting a report to authorities, with information related to the report, should have been placed in patient #1's record. | S 169 | | |
| S 243 | 4447 B Infection Control<br><br>A. The outpatient abortion facility shall develop, implement, enforce, monitor, and annually review, with the approval of the medical director, written policies and procedures for preventing, identifying, reporting, investigating, controlling, and immediately implementing corrective actions relative to infections and communicable diseases of patients and personnel. At a minimum, the policies shall address:<br>1. alcohol based hand rub and hand hygiene;<br>2. use of all types of gloves;<br>3. decontamination of equipment between each patient use, including, but not limited to, chairs and procedure room tables;<br>4. linen cleaning, if applicable;<br>5. waste management including, but not limited to, the requirements of Part XXVII of LAC Title 51, Public Health/Sanitary Code;<br>6. environmental cleaning;<br>7. reporting, investigating, and monitoring of surgical infections;<br>8. sterilization procedures and processes, if applicable;<br>9. single use devices;<br>10. disinfecting procedures and processes; and<br>11. breaches of infection control practices.<br><br>This Rule is not met as evidenced by:<br>Based on record review, observation, and | S 243 | **S 243**<br><br>The Governing Body will review and update the Policy & Procedure Manual to ensure inclusion of specific procedures for sterilization and processing instruments that include appropriate wrapping of instruments/supplies and use of chemical indicators inside each package.<br><br>The Clinic Director monitored by the Medical Director will retrain sterilization personnel to ensure that sterilization is accomplished according to clinic policy and procedure, including the usage of "sterile indicator strips" in each pack of autoclaved instruments, proper loading of instrument packs in the autoclave (to prevent pack "browning"), proper handling of instrument packs, as well as the proper inspection of each autoclaved pack for evidence of sterility. Evidence of retraining will be placed in each relevant employee file. The Clinic Director will monitor sterilization personnel on a weekly basis to ensure continued compliance.<br><br>April 1, 2017 | |

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| S 243 | Continued From page 13<br>interview the facility failed to ensure infection control policies and procedures were developed, implemented, enforced, and monitored related to sterilization procedures and processes. This deficient practice was evidenced by observation of a) surgical instruments that had been through the sterile processing with no internally placed chemical indicator, and b) processed sterile instrument packages that had brown areas on the package, with some that were not sealed in Procedure Room "A". The facility policy and procedures did not include processes for using chemical indicators inside sterilization packs. A policy and procedure that included inspection of packs for tears or defects that compromised sterility was not enforced. Findings:<br>Review of a facility policy and procedure titled "Decontamination, Disinfection, Sterilization and Storage of Sterile Supplies" (no policy number or date), provided by S1ADM as current, revealed in part instruments were to be packed in self-seal pouches or wrapped in CSR wrap with a strip of "sterile indicator" tape on each pack. Further review revealed no procedure that included the placement of an indicator strip inside the self-seal pouch or wrapped packs. The procedure included, on completion of the autoclave cycle, inspection of the processed packages for tears or defects that could compromise sterility.<br>Review of the CDC Guideline for Disinfection and Sterilization in Healthcare Facilities,2008 revealed, in part, indicate that the item (that underwent sterilization) had been exposed to the sterilization process. Chemical indicators are affixed on the outside of each pack to show that the package has been processed through a sterilization cycle, but these indicators do not prove sterilization has been achieved. Further review revealed a chemical indicator also should be placed on the inside of each pack to verify | S 243 | | |

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| S 243 | Continued From page 14 | S 243 | | |

sterilant penetration.
An observation on 1/31/17 at 9:00 a.m. of instruments in Procedure Room "A" revealed surgical instruments in sealed peel packs, having an outside indicator with a color change indicating the package had been through the sterilization process. Further observation revealed no chemical indicator inside the sealed peel pouch of instruments. Further observation of the instruments stored in the room, revealed some processed peel packs of instruments with brown areas on the white paper side of the package. A processed self-sealing instrument package was observed to have an unsealed area along one side, with brown discoloration of the packaging paper in the same area. This left the package's sterility compromised. S1ADM, present for the observation, verified the findings. S1ADM reported it was not the facility's process to place an indicator inside the peel packs of instruments or in the wrapped instruments. S1ADM opened a sterile pack of instruments wrapped in CSR wrap. It was wrapped in 4 layers of wrapping paper/material, and did not contain a chemical indicator. S1ADM indicated there was no way to demonstrate that the instruments inside the packs had reached the required temperatures for the length of time recommended for sterilization. S1ADM reported the brown areas on the paper of the instruments in the peel packages were probably burn marks from the paper packs touching the sides of the autoclave during processing. S1ADM verified that the packages with the brown markings should have been inspected after removal from the autoclave, should have been reprocessed, and should not have been stored where they could be used before they were reprocessed. S1ADM verified that the sterile package with the open area in the package had the sterility compromised and

Health Standards Section

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| S 243 | Continued From page 15<br>should not have been stored with instruments to be used until it had been repackaged and reprocessed. S1ADM verified the policy and procedure did not include specific procedures for sterilization and processing instruments that included wrapping instruments/supplies and use of indicators in each package and load.<br><br>In an interview 2/1/17 at 9:25 a.m. S5ST reported she was responsible for the sterile processing in the facility. S5ST confirmed that she did not place an indicator inside any of the packages to be sterilized. S5ST indicated the policy and procedure did not include the process of placing an indicator inside of each package of instruments and/or supplies to be sterilized. | S 243 | | |

# ITOP REPORTING

Online ITOP Reporting will be completed and submitted to Vital Statistics within 30 days for each abortion procedure completed.

Data is entered into the LEERS program by the Clinic Director

The records are then certified by the physician and sent to Vital Statistics to be registered.

A copy of each certified record will be maintained in the corresponding patient's file.

03/17/17