Health Standards Section

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	BO0004641	A. BUILDING: _____ B. WING _____	C 06/17/2020

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WOMENS HEALTH CARE CENTER INC	2701 GENERAL PERSHING STREET NEW ORLEANS, LA 70115

(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
S 000	Initial Comments Licensing Survey in conjunction with Complaint #s: LA00054458, LA00055261, LA00055283. Survey aborted after 1st day onsite (3/12/2020), due to suspension of survey activities related to COVID19 pandemic. Survey reconvened 06/04/2020. Deficiencies written related to complaints are as follows: LA00054458: 0107, 0111, 0115, 0117, 0177 Abbreviations: Adm - Administrator AORN - Association of periOperative Registered Nurses CBG - Capillary Blood Glucose CDC - Centers for Disease Control and Prevention DSW - Direct Service Worker EPA- Environmental Protection Agency FDA - (US) Food and Drug Administration GB - Governing Body MD - Medical Doctor Med Dir - Medical Director N/A - Not Applicable NAF - National Abortion Federation OAF - Outpatient Abortion Facility OSHA - Occupational Safety and Health Administration POR - Plan of Removal P & P - Policy and Procedure Recpt - receptionist US or U/S - Ultrasound QA- Quality Assurance S/S - Signs and Symptoms Tech - technician	S 000		
S 107	4421 A-B Governing Body	S 107		

DHH/Health Standards Section

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

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S 107	Continued From page 1 A. The outpatient abortion facility shall be in compliance with all applicable federal, state, and local statutes, laws, rules, regulations, and ordinances. B. The outpatient abortion facility shall have a governing body that assumes full responsibility for the total operation of the outpatient abortion facility. 1. The governing body shall consist of at least one individual who will assume full responsibility. 2. The outpatient abortion facility shall maintain documentation on the licensed premises identifying the following information for each member of the governing body: a. Name; b. contact information; c. address; and d. terms of membership. 3. The governing body shall develop and adopt bylaws which address its duties and responsibilities. 4. The governing body shall, at minimum, meet annually and maintain minutes of such meetings documenting the discharge of its duties and responsibilities. This Rule is not met as evidenced by: Based on record reviews and interview, the outpatient abortion facility failed to: 1. ensure it was in compliance with all applicable	S 107		

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S 107	Continued From page 2 federal, state, and local statutes, laws, rules, regulations, and ordinances. This deficient practice is evidenced by facility's failure to ensure each direct care staff person was in good standing and without restrictions with the Direct Service Worker (DSW) Registry and/or Adverse Action Site before hire and every 6 months thereafter, as evidenced by failure to have documentation of these requirements for 3 of 3 (S6Tech, S7US, S11Tech) personnel files of unlicensed staff that provided direct care to patients reviewed, out of a total of 8 personnel files reviewed, and failure to have a policy and procedure in place to check the Louisiana State Adverse Actions List Search website on hire and every 6 months for any unlicensed staff member that provided direct care to patients; and 2. maintain documentation on the licensed premises identifying information for each member of the governing body that included name, contact information, address, and terms of membership. Findings: 1). Failure to ensure the outpatient abortion facility was in compliance with all applicable federal, state, and local statutes, laws, rules, regulations, and ordinances. This deficient practice is evidenced by facility's failure to ensure each direct care staff person was in good standing and without restrictions with the Direct Service Worker (DSW) Registry and/or Adverse Action Site before hire and every 6 months thereafter, and failure to have a policy and procedure in place to check the Louisiana State Adverse Actions List Search website on hire and every 6 months for any unlicensed staff member that provided direct care to patients. The outpatient abortion facility failed to have documentation of these requirements for 3 of 3	S 107		

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S 107	Continued From page 3 (S6Tech, S7US, S11Tech) personnel files of unlicensed staff that provided direct care to patients. Review of LAC: Title 48, Chapter 92, Direct Service Worker Registry, revealed in part, the following: 9202. C. Licensed and/or certified health care providers shall access the registry to determine if there is a finding that a prospective hire, or currently employed or contracted DSW, has been determined to have committed exploitation, extortion, abuse or neglect of an individual being supported, or misappropriated the individual's property or funds. If there is such a finding on the registry, the prospective employee shall not be hired as a DSW nor shall a current employee have continued employment as a DSW with the licensed and/or certified health care provider. Further review revealed, 9231. Health Care Provider Responsibilities, A. Prior to hiring any DSW or trainee, the licensed and/or certified health care provider shall:...3. access the registry in accordance with the provisions of §9202.C-C.1. B. The health care provider shall: have a written policy/process to check the DSW registry on the department's designated database at least every six months to determine if any currently employed or contracted DSW or trainee has been placed on the registry with a finding that he/she has been determined to have committed abuse or neglect of an individual being supported or misappropriated the individual's property or funds or committed exploitation or extortion of an individual being supported. 1. The provider shall follow the agency's process in demonstration of compliance with this procedure ... Review of the Louisiana State Adverse Actions	S 107		

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S 107	Continued From page 4 List Search website revealed in part, "Employers must use the DSW registry to determine if there is a finding that a prospective hire has abused or neglected an individual being supported, or misappropriated the individual's property or funds. If there is such a finding on the registry, the prospective employee shall not be hired. The provider shall check the registry every six months to determine if any currently employed direct service worker or trainee has been placed on the registry with a finding that he/she has abused or neglected an individual being supported or misappropriated the individual's property or funds." Review of policies and procedures for the provider revealed no policy and procedure for the review of the Louisiana State Adverse Actions List Search website on hire and every six months thereafter for unlicensed personnel that provided any direct patient care. Review of personnel files for S6Tech, S7US, and S11Tech revealed no documented evidence that the Louisiana State Adverse Actions List Search website had been searched for any findings before hire, and every 6 months thereafter to ensure the staff person was in good standing and without restrictions. Further review revealed no documented evidence that S6Tech, S7US, or S11Tech were licensed. In an interview on 06/15/2020 at 12:00 p.m. and on 06/17/2020 at 10:00 a.m. S1Adm confirmed there was no documentation of the review of the state Adverse Action website for S6Tech, S7US, or S11Tech. S1Adm reported she was responsible for the content of staff credentialing and personnel files. S1Adm further reported she did not check the state's Adverse Action website	S 107		

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S 107	Continued From page 5 for unlicensed personnel before hire, and every 6 months thereafter. 2). Failure to maintain documentation on the licensed premises identifying information for each member of the governing body that included name, contact information, address, and terms of membership. Review of a list of Governing Board of Directors dated January 03, 2020, provided by S1Adm as current, revealed the members included S12GB. Review of current documentation on the licensed premises with the identifying information for each member of the governing body that included name, contact information, address, and terms of membership revealed there was no information for S12GB. In an interview on 06/16/2020 at 12:50 p.m., S1Adm stated S12GB was currently a governing body board member and the facility did not ensure her name, contact information, address, and terms of membership were added to the facility's governing body contact information form and the required information was not available at this time. S1Adm confirmed S12GB became a board member effective 01/03/2020.	S 107		
S 111	4421 - C5 - d Governing Body 5. ensuring that upon hire and prior to providing care to patients and, at a minimum, annually, each employee is provided with orientation, training, and evaluation for competency according to their respective job descriptions; 6. developing, implementing, enforcing,	S 111		

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S 111	Continued From page 6 monitoring, and annually reviewing in collaboration with the administrator, medical director, and registered nurse, written policies and procedures governing the following: a. the scope of medical services offered; b. personnel practices, including, but not limited to: i. developing job descriptions for licensed and non-licensed personnel consistent with the applicable scope of practice as defined by federal and state law; ii. developing a program for orientation, training, and evaluation for competency; and iii. developing a program for health screening; c. the management of medical emergencies and the immediate transfer to a hospital of patients and born alive infants regardless of gestational age requiring emergency medical care beyond the capabilities of the outpatient abortion facility and such policies and procedures shall identify emergency medical equipment and medications that will be used to provide for basic life support until emergency medical services arrive and assume care; and d. disaster plans for both internal and external occurrences; This Rule is not met as evidenced by: Based on policy review and interview, the governing body failed to, in collaboration with the administrator, medical director, and registered nurse, annually review written policies and	S 111		

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S 111	Continued From page 7 procedures governing the following: the scope of medical services offered; personnel practices, including, but not limited to: developing job descriptions for licensed and non-licensed personnel consistent with the applicable scope of practice as defined by federal and state law; developing a program for orientation, training, and evaluation for competency; and developing a program for health screening; the management of medical emergencies and the immediate transfer to a hospital of patients and born alive infants regardless of gestational age requiring emergency medical care beyond the capabilities of the outpatient abortion facility and such policies and procedures shall identify emergency medical equipment and medications that will be used to provide for basic life support until emergency medical services arrive and assume care; and disaster plans for both internal and external occurrences. Findings: Review of all facility policies and procedures revealed no signature for a registered nurse, the signature of S2MedDir dated 01/10/2019, and the signature of S1Adm dated 05/17/2019. On 06/16/2020 at 12:50 p.m., S1Adm reviewed the facility's operational manuals and stated these manuals contained all current policies and procedures. She confirmed signatures as above and no signature by a registered nurse. She stated the required annual review of policies and procedures was not done. On 06/16/2020 at 2:30 p.m., a phone interview with S2MedDir revealed she did not perform the annual review of policies and procedures as required. She confirmed her last documented signature in 2019 was the most current review of	S 111		

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S 111	Continued From page 8 policies and procedures.	S 111		
S 115	4421-C - 12 - 15 Governing Body 12. ensuring services that are provided through a contract with an outside source are provided in a safe and effective manner; 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; 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; 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; This Rule is not met as evidenced by: Based on policy review and interview, the governing body failed to ensure the annual review of written policies and procedures related to communication with the administrator, medical	S 115		

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S 115	Continued From page 9 director, and medical staff to address problems, including, but not limited to patient care, cost containment, and improved practices. Findings: Review of all facility policies and procedures revealed the signature of S2MedDir dated 01/10/2019 and the signature of S1Adm dated 05/17/2019. On 06/16/2020 at 12:50 p.m., S1Adm reviewed the facility's operational manuals and stated these manuals contained all current policies and procedures. She stated the required annual review of policies and procedures was not done. On 06/16/2020 at 2:30 p.m., a phone interview with S2MedDir revealed she did not perform the annual review of policies and procedures as required. She confirmed her last documented signature in 2019 was the most current review of policies and procedures.	S 115		
S 117	4421-C - 16-18 Governing Body 16. ensuring that the outpatient abortion facility procures emergency medical equipment and medications that will be used to provide for basic life support until emergency medical services arrive and assume care; 17. ensuring that the outpatient abortion facility orders and maintains a supply of emergency drugs for stabilizing and/or treating medical and surgical complications for intra- operative and post-operative care on the licensed premises, subject to the approval by the medical director; and 18. ensuring that the outpatient abortion facility develops, implements, enforces, monitors, and	S 117		

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S 117	Continued From page 10 annually reviews written policies and procedures to ensure that products of conception are disposed of in compliance with the Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA), and with any other applicable federal, state, and local statutes, laws, ordinances, and department rules and regulations. This Rule is not met as evidenced by: Based on policy review and interview, the governing body failed to ensure that an annual review of written policies and procedures was done to ensure that products of conception are disposed of in compliance with the Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA), and with any other applicable federal, state, and local statutes, laws, ordinances, and department rules and regulations. Findings: Review of all facility policies and procedures revealed the signature of S2MedDir dated 01/10/2019 and the signature of S1ADM dated 05/17/2019. On 06/16/2020 at 12:50 p.m., S1Adm reviewed the facility's operational manuals and stated these manuals contained all current policies and procedures. She stated the required annual review of policies and procedures was not done. On 06/16/2020 at 2:30 p.m., a phone interview with S2MedDir revealed she did not perform the annual review of policies and procedures as required. She confirmed her last documented	S 117		

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S 117	Continued From page 11 signature in 2019 was the most current review of policies and procedures.	S 117		
S 145	4423 - D-1 Staffing Requirements, Qualifications D. Nursing Staff. The outpatient abortion facility shall provide nursing services and shall employ qualified nursing staff to meet the needs of the patients. 1. Registered Nurse. The outpatient abortion facility shall have a registered nurse (RN) who is responsible for the overall direction of all nursing staff and nursing services provided. a. Qualifications. The RN shall: i. have a current, unrestricted Louisiana registered nurse license; and ii. be in good standing with the Louisiana State Board of Nursing. This Rule is not met as evidenced by: Based on record review and interview, the outpatient abortion facility failed to ensure the Registered Nurse provided nursing care and services consistent with the accepted nursing standards of practice when the Registered Nurse failed to follow the physician's standing orders by not obtaining a CBG on 1 (Patient #14) of 1 diabetic records reviewed from a total sample of 20 patient records reviewed. Findings: Review of the signed job description in the personnel folder for S5DON revealed as responsibility number 3; nurse was to administer injections, dispense medications, transcribe or	S 145		

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S 145	Continued From page 12	S 145		

call in all prescriptions as directed by the physician's standing orders or verbal orders. Further review of the personnel record failed to reveal a skills check and/or competency of a capillary glucose meter use.

Review of the Nursing Procedures: Scope of Practice for Registered Nurses revealed as one of the duties of registered nurses was operating under standing orders if the physician has made the orders specific to the individual patient.

Review of the medical record for Patient #14 revealed she was a 35-year-old with a procedure date of 08/21/2019. Further review revealed she had a past medical history of Diabetes Mellitus Type 2. Further review of the pre-operative and operative medical record stated with the pre-operative vital signs "If applicable Glucose" with a blank line for result value. Written on the line was the notation, "N/A".

Review of the Surgical Abortion Order for the attending physician S3MD revealed under pre-operative nursing interventions and medications, "Obtain CBG on diabetic patients and patients exhibiting S/S of hypoglycemia".

In an interview on 06/12/2020 at 2:00 p.m. with S1Adm, she reviewed the policy and procedure binders and stated there is no policy related to diabetic patients and/or when to perform a capillary blood glucose on a patient. There was only a short procedure for the process for blood glucose testing which included the steps for performing the capillary blood glucose.

In an interview on 06/12/2020 at 2:26 p.m., S5DON stated they only use the glucometer if a patient is already a diabetic and they would do a

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S 145	Continued From page 13 glucose when doing initial vital signs. When S5DON was shown the medical record of Patient #14, she stated, "it was me who did the initial set of vital signs and I did not do a glucose; I must have missed it." S5DON confirmed she had added the "N /A", without a physician's order to delete or omit the order. In an interview on 06/15/2020 at 1:45 p.m., S3MD verified the standing order sheet with her name included an order to obtain a CBG on diabetic patients. She verified a CBG was not done on Patient #14, who was a diabetic.	S 145		
S 153	4423 E-2 Staffing Requirements, Qualifications 2. Training. Upon hire, and at a minimum, annually, all employees shall be provided training in each job skill as delineated in their respective job description. a. Medical training of a licensed medical professional shall only be provided by a medical professional with an equivalent or higher license. b. Training of a non-licensed employee related to the performance of job skills relative to medical and clinical services shall only be provided by a licensed medical professional consistent with the applicable standards of practice. c. All training programs and materials used shall be available for review by HSS. d. The administrator shall maintain documentation of all of the training provided in each employee's personnel files.	S 153		

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S 153	Continued From page 14 This Rule is not met as evidenced by: Based on record review and interview the facility failed to ensure employees were provided training in each medical and clinical job skill as delineated in their job description(s) by a licensed medical professional consistent with applicable standards of practice and that training was documented in each employee's personnel files. This deficient practice was evidenced when S1Adm, an unlicensed staff member, with no documentation of ultrasound training, surgical technician training, or training in surgical instrument processing, provided training and competency evaluation(s) for S6Tech in sterile instrument processing; and an annual competency and evaluation for S7US in ultrasonography skills. Findings: Review of facility policy and procedure titled, "Personnel Employee Competency" (no number, no date), provided by S1Adm as current revealed, in part, new employee skills would be measured with competency evaluations 0-120 days after initial hire. The assessment would be evidenced-based and applied to their particular knowledge, skills, attitudes, values and most importantly, the actual work performance. Continuous training would be provided by the clinic through in-services, participation in risk management conferences, annual professional seminars, and continuing education courses. In an interview 06/05/2020 at 11:30 a.m. S6Tech reported she was taught decontamination and sterilization by S1Adm on hire, and S1Adm conducted her competency skills evaluation. 6Tech reported she did not have any training or experience as a surgical scrub or instrument	S 153		

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S 153	Continued From page 15 technician prior to her current position at the facility. In an interview on 06/15/2020 at 12:00 p.m. with S1Adm, she stated she had a surgical tech certification from a local community college and she would bring it 06/16/2020. In an interview on 06/16/2020 at 9:35 a.m. with S1Adm, she stated she did not bring the certificate for surgical tech education. Review of the personnel file for S6Tech on 06/17/2020 at 10:00 a.m. with the assistance of S1Adm revealed a hire date of 04/01/2020 and her competencies were evaluated on 04/01/2020 by S1Adm. S1Adm confirmed she oriented S6Tech to sterile processing on hire and evaluated S6Tech's skills in instrument processing. Review of the personnel file for S1Adm on 06/17/2020 at 10:00 a.m. with the assistance of S1Adm revealed a hire date of 10/16/2017 and failed to reveal certification, training or prior experience as a surgical scrub technician, an instrument processing technician, or ultra sound technician. Further review revealed no license in the medical field. S1Adm confirmed her personnel file contained no documented evidence of training or experience in surgical scrub, surgical instrument processing, or ultrasonography. Review of the personnel file for S7US on 06/17/2020 at 10:00 a.m. with the assistance of S1Adm revealed a hire date of 02/23/2012 and her competencies were checked off on 09/23/2019 by S1Adm. S1Adm confirmed she evaluated S7US's annual competencies on	S 153		

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S 153	Continued From page 16 09/23/2019, although she (S1Adm) did not have ultrasound training. In an interview on 06/17/2020 at 10:40 a.m. with S1Adm, she stated she did not bring a certificate for surgical tech education. No documentation of training or certification in surgical technology, instrument processing, or ultrasonography was provided for S1Adm by the survey exit on 06/17/2020 at 2:30 p.m.	S 153		
S 161	4425 B Patient Med. Record/Reporting Requirements B. Retention of Patient Medical Records. Patient medical records shall be retained by the outpatient abortion facility for a period of not less than seven years from the date of discharge. If the woman is a minor, then the medical record of the minor shall be kept for a minimum of 10 years from the time the minor reaches the age of majority. Patient medical records shall be maintained on the premises for at least one year and shall not be removed except under court orders or subpoenas. Any patient medical record maintained off-site after the first year shall be provided to the department for review no later than 24 hours from the time of the department's request. NOTE: Refer to R.S. 9:2800.9. This Rule is not met as evidenced by: Based on record review and interviews, the	S 161		

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S 161	Continued From page 17 outpatient abortion facility failed to provide, to the department for review, no later than 24 hours from the time of the department's request for 2 (#2; #5) of 2 medical records requested from offsite storage out of a total sample of 20 medical records reviewed. Findings: In an interview on 03/12/2020 at 2:45 p.m. with S1Adm a request for the medical record for Patient #5 was made. S1Adm stated the chart was in off-site storage. She would have to go to off-site storage to retrieve the medical record. In an interview on 06/09/2020 at 9:30 a.m. with S1Adm, after survey had resumed, another request for the medical record for Patient #5 was made. S1Adm reported she would obtain the record for surveyor review. In an interview on 06/12/2020 at 1:00 p.m. with S1Adm, another request for Patient #5's medical record and a request for Patient #2's medical record was made. In an interview on 06/15/2020 at 8:40 a.m. with S1Adm, she stated it was too hot for her to pull the medical records for Patient #2 and Patient #5 from the off-site storage. S1Adm provided the medical record for Patient #5 on 06/16/2020 at 11:40 a.m., 7 days after the 2nd request for the medical record. S1Adm provided the medical record for Patient #2 on 06/16/2020 at 3:00 p.m., 4 days after the initial request for the medical record.	S 161		

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S 177	Continued From page 18	S 177		
S 177	4431 -D Pre-operative,Intra-operative, and Post Opera D. Minors 1. No physician shall perform or induce an abortion upon any pregnant woman who is under the age of 18 years and who is not emancipated judicially or by marriage unless the physician has received the following: a. one of the following documents: (i). a notarized statement, pursuant to applicable state laws, rules, and regulations, signed by either the mother, father, legal guardian, or tutor of the minor declaring that the affiant has been informed that the minor intends to seek an abortion and that the affiant consents to the abortion; or (ii). a court order pursuant to applicable state laws, rules, and regulations; and b. a signed, dated, and timed document obtained by the attending physician and/or licensed nurse, before the administration of any type of anesthesia which indicates if any person has or has not compelled the female child to undergo an abortion against her will. 2. All documentation related to consent and coercion shall be maintained in the medical record. This Rule is not met as evidenced by: Based on record review and interview, the facility	S 177		

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S 177	Continued From page 19	S 177		

failed to ensure that an abortion was not performed or induced upon on any pregnant woman who was under the age of 18 years and who was not emancipated judicially or by marriage unless a notarized statement, pursuant to R.S. 40:1299.35.5, signed by the mother, father, legal guardian, or tutor of the minor declaring that the affiant has been informed that a minor seeking an abortion and that the affiant consents to the abortion or a court order pursuant to R.S. 40:1299.35.5. This deficient practice was evidenced by 1 (#2) of 5 (#1, #2, #3, #11, #12) minors' records reviewed of a total sample of 20. Findings:

Review of the policy titled Patient Care of Minor Patients revealed all patients under the age of 18 will need a parent or legal guardian to accompany them to the clinic. All minor patients will need an ID; this could be school ID, Passport, or any other legal, photo identification. The parent or legal guardian will need proof of identity. All identification proof will be placed in the minor's medical record.
Procedure: the parent or legal guardian of the minor patient will be given a consent for minors which must be notarized before the minor may return to the Clinic for services.

Review of the medical record for Patient #2 revealed she was a 15-year-old on 04/08/2019, when an abortion procedure was performed by S3MD. Continued review of the medical record revealed a copy of Patient #2's identification card, presented for ID, indicated her age of 15 years at the time that the procedure was performed. Further review revealed no notarized form verifying the legal guardian for Patient #2 was informed that the minor Patient #2 was seeking an abortion and provided the legal guardian's

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S 177	Continued From page 20 consent for the procedure. In an interview on 03/12/2020 at 2:40 p.m. with S1Adm, she verified that Patient #2 was admitted to the abortion clinic on 04/02/2019 for consultation by S2MedDir and had an abortion procedure on 04/08/2019 by S3MD. S1Adm confirmed that Patient #2 was 15 years old at the time the abortion procedure was performed by S3MD. S1Adm verified there was no notarized form of Patient #2's legal guardian's knowledge that Patient #2 was seeking an abortion and her legal guardian provided consent to the abortion in the medical record of Patient #2. In an interview on 06/16/2020 at 3:00 p.m. with S1Adm, she verified there was no notarized form in the chart of Patient #2.	S 177		
S 205	4435 A-B Intra-operative Procedures A. The outpatient abortion facility shall ensure that emergency medical equipment and supplies as required by the governing body, medical director and medical staff are available for intra-operative care and shall include, but are not limited to: 1. surgical or gynecologic table; 2. surgical instrumentation; 3. emergency drugs for stabilizing and/or treating medical and surgical complications as approved by the medical director; 4. oxygen; 5. intravenous fluids; and 6. sterile dressing supplies. B. The outpatient abortion facility shall ensure that the medical equipment required for an abortion shall be maintained and immediately available to the physician in the procedure and/or	S 205		

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S 205	Continued From page 21 post-anesthesia recovery area to provide emergency medical care and treatment. This Rule is not met as evidenced by: Based on record reviews, observations, and interviews, the outpatient abortion facility failed to ensure that equipment and supplies were maintained and available for intra-operative and/or post-operative care. This was evidenced by failure of the facility to have control solutions and a log book to monitor and maintain the proper functioning of the facility's capillary blood glucose meter. Findings: Review of the policy and procedure regarding physical environment stated, "the physical environment maintained by this facility will: maintain a safe and sanitary environment that will be equipped and maintained to protect the health and safety of patients and staff at all times." ..."The environment will .... have the necessary equipment and supplies maintained. and immediately available to procedure and recovery room." Review of the "Procedure for Blood Glucose Testing" presented by S1Adm as current and the only policy related to blood glucose testing revealed under procedure step 10 stated to clean and calibrate glucometer according to manufacturer's specifics. Review of the policy titled "Infection Control Operation Manual" revealed that operations manuals are supplied by equipment manufacturers for the proper use and care of	S 205		

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S 205	Continued From page 22 equipment, materials, and supplies. The manuals are available to appropriate personnel at all times, and are stored in the lab or the Administrator's office. This laboratory will adhere to the manufacturer's policy and protocol concerning all lab equipment. In an interview on 06/12/2020 at 2:15 p.m. with S1Adm, she stated they do not have any controls nor a log book for the controls for the blood glucose meter. In an interview on 06/12/2020 at 2:26 p.m. with S5DON, she verified they do not have any controls for the blood glucose monitor. In an interview on 06/15/2020 at 9:05 a.m. with S1Adm, she verified the manufacturer's guide was the guide provided for and related to the facility's blood glucose meter. She further verified the resource guide recommended the use of at least 2 control solutions for the blood glucose meter and these tests ensured that the glucometer was working properly and the user's technique was good. The resource guide further stated the control tests should be performed including, but not limited to, before using the system for the first time; for practice to ensure that testing technique is good; when opening a new vial of strips; if results seem unusually high or low based on the patient's condition; and whenever a check on the performance of the system was needed.	S 205		
S 243	4447 B Infection Control A. The outpatient abortion facility shall develop, implement, enforce, monitor, and annually review, with the approval of the medical director,	S 243		

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S 243	Continued From page 23 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: 1. alcohol based hand rub and hand hygiene; 2. use of all types of gloves; 3. decontamination of equipment between each patient use, including, but not limited to, chairs and procedure room tables; 4. linen cleaning, if applicable; 5. waste management including, but not limited to, the requirements of Part XXVII of LAC Title 51, Public Health/Sanitary Code; 6. environmental cleaning; 7. reporting, investigating, and monitoring of surgical infections; 8. sterilization procedures and processes, if applicable; 9. single use devices; 10. disinfecting procedures and processes; and 11. breaches of infection control practices. This Rule is not met as evidenced by: Based on record review, observation and interview the outpatient abortion facility failed to 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 prevention of infections and communicable diseases of patients	S 243		

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S 243	Continued From page 24 and personnel. This deficient practice was evidenced by failure to develop and implement specific policies/procedures for: a) transportation of contaminated surgical instruments, equipment, and supplies; b) workflow in the decontamination room, where the sterilization also took place, to prevent mixing dirty and clean processes; c) decontamination of equipment between each patient use, including procedure tables and chairs; d) prevention of reusing single-use supplies; and e) storage of sterilized and processed surgical instruments. An Immediate Jeopardy situation was found to exist and notification was made to S1Adm on 06/15/2020 at 5:20 p.m. Findings: Review of the infection control policy and procedure binder provided by S1Adm as containing all of the facility's current policies and procedures related to Infection Control, revealed no facility specific policy and procedure(s) written, with the approval of the medical director, for transportation of contaminated instruments from their point of use to the cleaning/decontamination room, cleaning/decontamination processes including separating clean and dirty in the decontamination room, the cleaning, disinfection, packaging of instruments for sterilization, and storage of instruments and equipment after decontamination and sterilization. Review of AORN Guidelines for Perioperative Practice (2018 Edition) revealed in part the following: - (Environmental Cleaning: V.I.d.) Items that are contaminated with blood or tissue and that	S 243		

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S 243	Continued From page 25 release blood, body fluids, or other potentially infectious materials in a liquid or semi-liquid state if compressed, and items that are caked with dried blood, body fluids, or other potentially infectious materials must be placed in closable, leak-proof containers or bags that are color coded, labeled, or tagged for easy identification as biohazardous waste. Leak-proof containers prevent exposure of personnel to blood, body fluids, and other potentially infectious materials and prevent contamination with infectious microorganisms, prevent exposure of personnel to infectious waste, and prevent contamination of the environment. - Contaminated instruments must be contained during transport to a decontamination area (Instrument Cleaning; Recommendation IV) -Instruments should be cleaned and decontaminated in an area separate from locations where clean items are handled (Sterilization and Disinfection; Instrument Cleaning, Recommendation V) The sterile processing area should have separate clean and decontamination spaces... (Instrument Cleaning; Recommendation V.a.) -Personnel working in the decontamination area and handling contaminated instruments must wear PPE, to include...a mask and eye protection or a full face shield... (Instrument Cleaning; Recommendation VI) -Surgical Instruments should be inspected and evaluated for cleanliness and correct working order after decontamination and if soiled or defective, should be removed from service until they are cleaned or repaired (Instrument Cleaning; Recommendation X) -Items to be sterilized should be packaged in a manner that facilitates sterilization and provides for an aseptic presentation of the package contents (Sterilization and Disinfection/packaging	S 243		

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S 243	Continued From page 26 systems; Recommendation IV) Preventing water retention can help avoid the occurrence of wet packs and sterilization failure (IV.f) An observation on 06/05/2020 from 11:30 a.m.-11:50 a.m., in the reprocessing/sterilization room, revealed 2 rolling tables with instruments and supplies, not covered or in a container, that were contaminated with blood and body fluids and a vacuum container with blood and body fluids with an attached contaminated tubing on top of the table. S7US was observed to roll another tray/table with a suction canister containing blood and body fluid and instruments contaminated with blood, body fluids and gauze, all uncovered on top of the table, into the decontamination and sterilization room to the area identified by S6Tech as the dirty area. Next to the uncovered, contaminated instrument tables were clear, clean tables, which were located next to the cabinet containing the autoclave and tables with unused sterile "peel pack" instrument packs for autoclaving cleaned and decontaminated instruments. This "dirty area" containing dirty tables with contaminated instruments and supplies was within 2-3 feet of empty instrument tables identified by S6Tech as having been cleaned and disinfected. These clean tables were located within a few feet behind S6Tech as she rinsed and washed contaminated instruments and prepared contents of the vacuum containers in a glass bowl over an illumination light so that S3MD could perform a gross examination of the contents. This illumination light was to the right of the decontamination sink, in close proximity to the counter space reported by S6Tech to be the "clean area". The counter space also held the table top steam autoclave and sterilization pouches that would be used to contain	S 243		

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instruments for sterilization and storage. One of the cleaned rolling tables held some loose sterilization pouches in which decontaminated and cleaned instruments would be placed. Further observation of cleaned instruments waiting to be packaged for sterilization revealed a brownish red coloring on the screw at the hinge, and within the hinge, on a surgical instrument (clamp) that was not removable with re-cleaning. S6Tech reported this was just rust, and that blood was not ok, but rust was ok on instruments.

Further observation on 06/05/2020 from 11:30 a.m.- 11:50 a.m., in the reprocessing/sterilization room revealed cleaned single use plastic vacuum canisters stacked to the left of the sink with the plastic lids. Further observation revealed S6Tech washing out a plastic vacuum canister and lid, after emptying blood and body fluids, then wiping with a disinfecting wipe. Observation of the plastic canisters revealed wording on the side of the canister that read, "CAUTION DO NOT REUSE." S6Tech reported that she cleaned the plastic vacuum canisters with soap and water, then wiped with disinfecting wipes. S6Tech confirmed the vacuum canisters are reused and not discarded after each use.

In an interview on 06/05/2020 at 12:02 p.m. S1Adm reported the plastic vacuum canisters were not a "single-use" item and were re-used after cleaning. S1Adm, after reviewing the suction canister with the surveyor, confirmed the canister had "CAUTION DO NOT REUSE" on the side of the canister.

An observation on 06/05/2020 at 1:00 p.m. of S7US revealed she entered the sterilization/reprocessing room and took 3 disposable suction canisters and lids which were

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WOMENS HEALTH CARE CENTER INC	2701 GENERAL PERSHING STREET NEW ORLEANS, LA 70115

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S 243	Continued From page 28 recently cleaned by S6Tech for use in resetting procedure rooms. In an interview on 06/05/2020 at 1:05 p.m. S1Adm verified the plastic suction canisters and lids which the facility reuses were labeled, "CAUTION DO NOT REUSE." An observation on 06/12/2020 at 1:40 p.m. of S6Tech in the sterilization/reprocessing room revealed she took a plastic suction canister and lid labeled "CAUTION DO NOT REUSE", emptied the blood and body fluid contents, then washed the canister and lid with soapy water, rinsed them, and wiped them with a disinfecting wipe. In an interview on 06/12/2020 at 1:40 p.m. S6Tech stated she was unaware if any new plastic suction canisters were ordered. She further stated the facility was still reusing the plastic suction canisters and lids. In an interview on 06/15/2020 at 2:30 p.m. S5DON reported that she could not answer as to if the facility re-used the plastic vacuum containers, and that the surveyors would have to ask the administrator about that. Review of the facility policy and procedure titled, "Housekeeping: Examination Rooms and Recovery Room", no date, provided by S1Adm as current, revealed in part that examination rooms and the recovery room would be cleaned daily to maintain a clean environment and prevent infections. Further review revealed the examination tables would be cleaned between patient use. Additional review revealed after each patient the table or chair would be sprayed with a disinfectant.	S 243		

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S 243	Continued From page 29 An observation on 06/04/2020 at 10:50 a.m. in Exam/Procedure Room #8 revealed rust at the end of the examination/procedure table, near the area into which the footrests retracted. A brownish spot was observed on the foot step at the end of the table which was easily removed with an alcohol swab. A white plastic covered garbage can was noted to have a brownish substance on the lid, easily removed with an alcohol swab. S1Adm, present for the observations confirmed the findings, and reported procedures were performed in the room the day before and the room should have been cleaned and disinfected after the procedures. An observation on 06/04/2020 at 10:55 a.m. in a room used for exams, procedures, and ultrasounds, as well as some lab testing, revealed rust at the end of the exam table (where the foot and leg rests retracted), a portable goose neck exam light with dust on the base of the light and wheel well, and a piece of hair on the base of the lamp. Further observation revealed a rolling chair with a cloth covered seat and back cushions. S1Adm, present for the observations, confirmed the findings, and confirmed the rust on the exam table prevented the tables from being properly disinfected and the cloth chair could not be cleaned and disinfected with permeable cloth covering. An observation on 06/04/2020 at 10:38 a.m., in the room which contained the sterile instruments storage closet, revealed 2 processed peel packs each containing 2 large metal dilators, and with a date of 05/29/2020 in thin light ink written on the paper portion of the packaging. Further observation revealed a section of multiple beads of moisture inside the packets on top of the instruments. These packages of sterilized	S 243		

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S 243	Continued From page 30 instruments were obtained from one of several plastic bins holding packs of sterile instruments. When both instrument packages were turned over, the paper side of the package was noted to be wet and saturated through to the outside. S1Adm, present for the observation confirmed the findings, and verified the instruments should have been dried before moving to storage area. S1Adm reported the facility followed AORN standards. In an observation on 06/05/2020 at 12:40 p.m. in the decontamination/sterilization room revealed cleaned instruments being put into peel pack sterilization pouches with a chemical indicator. Further observation revealed brown-reddish substance on the adjustment screw of the speculum and area surrounding the screw. S6Tech verified the observation and reported it was "just rust and rust was OK." In an interview on 06/05/2020 at 11:35 a.m. S6Tech reported her process was to soak instruments in warm water for 10 minutes. She reported she was not sure if it had to be a certain temperature. The tech further reported she wiped the instruments, then would rinse the instruments, then soak them in disinfectant for 10 minutes, then rinse and put them to dry. An Immediate Jeopardy situation was found to exist and notification was made to S1Adm 06/15/2020 at 5:20 p.m. The facility failed to have an effective process in place to ensure sanitary equipment and supplies were available for use for patient care. Observations made on 06/04/2020 and 06/05/2020 included the following, in part:	S 243		

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S 243	Continued From page 31 -sterile packages of instruments stored in the sterile instrument storage area with moisture in 2 sealed processed peel packs with a date of 05/29/2020 written on the paper portion of the packages; - 2 rolling tables with contaminated instruments, used supplies, and a disposable vacuum container and attached tubing with blood and body fluids, sitting open and uncovered in the decontamination/sterilization room. -observation of S7US rolling an uncovered tray containing a suction canister with attached tubing, containing blood and body fluids, instruments, and gauze contaminated with blood and body fluids into the decontamination/sterilization room; -observation of used plastic vacuum canisters washed and wiped down by S6Tech, with wording on the side of the plastic vacuum canister which read, "CAUTION DO NOT REUSE"; -Instruments packaged to be sterilized with brown-reddish discoloration, instruments with brownish red coloring on the screw at the hinge, and within the hinge, not removable with re-cleaning, reported by S6Tech to be rust and that this was OK; -staff coming into the decontamination room to obtain cleaned plastic vacuum containers for use in another procedure. Review of personnel files for staff performing decontamination and sterilization revealed no documentation of formal training for decontamination, sterilization, or storage of surgical equipment or instruments. Decontamination and Sterilization staff had no evidence of current skill competency evaluation(s) completed by a qualified professional with training and/or expertise in repossessing of instruments.	S 243		

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S 243	Continued From page 32 On 06/16/2020 at 10:30 a.m. a plan of removal of the IJ was presented and reviewed. The plan of removal was not accepted and S1Adm was advised that their plan of removal did not include any policies developed and approved by the Medical Director, with specifics of the cleaning and decontamination process, such as detergents or enzymatic to be used, and the QA guidelines did not provide specifics as to what will be monitored, by whom, and when. The IJ remained in place on 06/16/2020 at 4:45 p.m. A second POR was provided to the survey team on 06/17/2020 at 11:40 a.m. but did not include policies and procedures approved by S2MedDir. On 06/17/2020 at 1:40 p.m. a POR was presented to survey team with policies and procedures approved by S2MedDir. The following POR was accepted and the IJ lifted on 06/17/2020 at 1:50 p.m.: The OAF, with involvement from S1Adm, S2MedDir, and S3MD, developed a plan in-part as follows to ensure that process(es) are put into place to ensure the use of sanitary equipment and supplies for surgical and medical care of patients: - Development of a policy and procedure for the cleaning and central processing of medical equipment and surgical instruments, decontamination, high-level disinfection, low-level disinfection, and sterilization, storage process, and inspection of surgical instruments. - A Quality Assurance program that will have the clinic administrator, DON or other qualified agent of the facility with instrument processing knowledge and experience be responsible for training and performance evaluation of personnel	S 243		

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S 243	Continued From page 33 responsible for instrument/equipment processing/scrub room technician. The policy will be evaluated each month by the medical director and clinic administrator beginning June 15, 2020 and ending June 15, 2021, with acknowledgment of policy review to be kept with the policy - The OAF will follow FDA guidelines regarding Sterilants and High Level Disinfectants. The policy and procedure defined noncritical, semi-critical, and critical equipment and the level of disinfection required for each category of equipment. - Instruments will be inspected and any parts able to be separated will be during processing. The instruments will be cleaned until all visible soil or discoloration was no longer visible before proceeding to the sterilization process per the autoclave protocol, including the use of biological, chemical, and mechanical indicators. - Decontamination/sterilization areas will be partitioned into clearly designated dirty/contaminated/used instrument area, washing area, clean/disinfected area, and sterilized area, requiring a one-way traffic design from dirty to clean. - All sterilizer bags removed from the autoclave after sterilization cycle complete, will be left to air dry in a designated clean area until visibly dry and absence of moisture is confirmed prior to being transported to the clean storage area. - The facility will immediately implement the use of coverings over the trays carrying instruments and supplies that have been used for a surgical or medical case during transportation from the procedure room to the decontamination station, and will remain covered until the technician is ready to process the contents of the used tray. - The facility will immediately dispose of all used plastic vacuum containers, and will	S 243		

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S 243	Continued From page 34 immediately implement the use of only reusable bottle vacuum canisters for all uterine aspiration procedures, and will follow CDC guidelines for cleaning/disinfection of the reusable suction containers. - Will ensure documentation of formal training for decontamination and sterilization, and storage of surgical equipment is placed in the personnel files within the first 90 days of hire or resumption of such duties. The training documentation for online courses for Infection Prevention and Instrument Processing completed by S6Tech will be immediately placed in her personnel file. The annual performance evaluation or skill checklist will be performed by S3MD. Documentation of this evaluation was dated and signed by S3MD 06/15/2020 at 7:58 p.m. - All instruments will be cleaned immediately after use. The instruments will be washed with detergent (or other antibacterial enzymatic cleaner) and running hot water, visually inspected for any discoloration or staining, presoaked in the chemical germicide. Observations were made by the survey team on 06/17/2020 at 12:50 p.m. which included trays transported from the procedure rooms to decontamination area with contaminated equipment, supplies, and instruments covered. S6Tech was observed to be wearing proper PPE. The room was observed to be divided into specific identifiable clean and dirty areas. S6Tech was observed to clean and start the disinfection process and was able to verbalize the process correctly. S8RN was observed to come to the door of the processing room to see if she could bring in a tray of contaminated instruments, and was told to wait a minute until the tech could complete the current disinfection of the tray she was currently finishing, and the work space. The	S 243		

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S 243	Continued From page 35 tray was observed to be covered. The survey team reviewed the policies and procedures developed and noted they were signed by S2MedDir and 1Adm. A review of the Personnel file for S6Tech was reviewed and found to contain training documentation of online course completed 10/03/2019 (Infection Prevention 2-Instrument Processing, by NAF). Further review revealed skill competencies for Autoclave operations, maintenance and cleaning, Scrub Room competencies, and proper packaging of specimens evaluated by S3MD and found to perform all skills with competent knowledge.	S 243		

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S 000	Initial Comments Complaint Survey for intake #LA00055261, with a Focused Infection Control survey. NOTE: This Event ID #5EHF11 for LA00055261 was investigated under Event ID #OKEZ11 with the re-licensing survey, exit date 6/17/2020.	S 000		

DHH/Health Standards Section

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE