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		

STATEMENT OF DEFICIENCIES
(Printed 7/02/2020)

AND

PLAN OF CORRECTION
(Submitted 7/15/2020)

WOMENS HEALTH CARE CENTER, INC. (WHCC)
2701 GENERAL PERSHING STREET, NEW ORLEANS LA 70115 (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:BO0004641

SURVEY COMPLETED 6/17/2020

SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

ID PREFIX TAG 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

PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)

ID PREFIX TAG S 000

The Outpatient Abortion Facility (OAF) acknowledges the initial comments in this section as accurate. Two (2) inspectors or agents from the Louisiana Department of Health (LDH) presented to the facility on 3/12/2020 to perform the annual licensing survey in conjunction with complaints received. Complaints were referenced as 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. Alleged deficiencies related to complaint LA00054458 are further outlined in the breakdown tagged as S107, S111, S115, S117, S177. The OAF will address each of these tagged sections in detail under their respective headings and paragraphs below.

COMPLETE DATE

ID PREFIX TAG S 000

See individual sections for dates of completion

SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

ID PREFIX TAG S 107 4421 A-B Governing Body

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 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 (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 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 for unlicensed personnel before hire, and every 6months 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.

PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)

ID PREFIX TAG S 107

1. WHCC had operated under a good faith belief that the sited deficiency was not applicable to the OAF, as outlined. Accordingly, WHCC disputes that it was not in compliance with all applicable federal, state, and local statutes, laws, rules, regulations, and ordinances in regard to LAC: Title

48, Chapter 92, Direct Service Worker Registry. According the of LAC: Title 48, Chapter 92, Direct Service Worker (DSW) is defined as "an unlicensed person who provides personal care or other services and supports to persons with disabilities or to the elderly to enhance their well-being, and who is involved in face-to-face direct contact with the person and is compensated through state or federal funds. Functions performed may include, but are not limited to, assistance and training activities of daily living, personal care services, and job-related supports." The OAF does not believe it has any applicants or employees that match this definition or perform the duties described in the statute's definition of DSW. Also, LAC 48: I. Chapter 44 that provides that basis of standards for abortion facilities does not have the term "Direct Service Worker" to describe or define non-licensed staff members of an abortion facility.

Out of an abundance of caution however, WHCC has adopted a policy and procedure for the OAF administrator to perform the prescribed checks pre-hire and semiannually of the Direct Service Worker Registry and/or Adverse Action Site. While this alleged deficiency is disputed, it has nevertheless been addressed in accordance with LAC: Title 48, Chapter 92, Direct Service Worker Registry, so that it will not recur in the future.

2. Regarding documentation for the WHCC governing body, the OAF acknowledges that the information for one member, S12GB, was not maintained in the appropriate fashion on the premises. The facility acknowledges that identifying information for each member of the governing body that included name, contact information, address, and terms of membership should be accurately documented in accordance to LAC 48: I. Chapter 44 Subchapter B. Administration and Organization §4421. Governing Body. The review of a list of Governing Board of Directors dated January 03, 2020, provided by S1Adm as current, revealed the members included S12GB. The facility has corrected this error regarding the S12GB. This was performed by the clinic administrator. Going forward, WHCC administrator will review on a regular basis any changes to the governing body, and thereby ensure each member's name, contact information, address and terms of membership is maintained on the premises, as required.

The facility's current practice of including and maintain such information for the current board members will be enforced by the clinic administrator to preclude the possibility of this particular deficiency from recurring. See "SUPPORTING DOCUMENTS TO ENDORSE STATED COMPLETION OF PLAN OF CORRECTION" section for current and updated information about the board members, as well as the newly adopted policy and procedure for pre-hire and semiannual review of the Direct Service Worker Registry and/or Adverse Action Site.

COMPLETE DATE
ID PREFIX TAG S 107
July 15, 2020

SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)
ID PREFIX TAG 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, 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 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 policies and procedures.

PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)

ID PREFIX TAG S 111

WHCC acknowledges that the required signatures of the director of nursing, medical director and the clinic administrator were not present in the facility's operational manual indicating that annual review of

the facility policies and procedures was performed. The facility promptly performed the required annual review, and documented the required signatures to confirm participation of all mandated parties, including the medical director and the director of nursing. This immediate remedy measure rectifies, satisfies, and aligns compliance with LAC 48: I. Chapter 44 Subchapter B. Administration and Organization §4421. Governing Body.

The clinic administrator is responsible calendaring and coordinating the future annual collaboration of the medical director and director of nursing to meet this requirement. Accordingly, WHCC will ensure this review takes place annually and all required signatures are properly documented. The clinic administrator will ensure that this deficiency does not recur by performing annual audits of the facility's operation manual to evaluate and ensure adherence.

COMPLETE DATE
ID PREFIX TAG S 111
July 9, 2020

SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)
ID PREFIX TAG 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 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.

PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)

ID PREFIX TAG S 115

WHCC acknowledges that the required signatures of the director of nursing, medical director and the clinic administrator were not present in the facility's operational manual indicating that annual review of the facility policies and procedures was performed. The facility promptly performed the required annual review, and documented the required signatures to confirm participation of all mandated parties, including the medical director and the director of nursing. All identified concerns or potential problems were addressed, including, but not limited to issues impacting patient care, cost containment, and improved practices. This immediate remedy measure rectifies, satisfies, and aligns compliance with LAC 48: I. Chapter 44 Subchapter B. Administration and Organization §4421. Governing Body.

The clinic administrator is responsible calendaring and coordinating the future annual collaboration of the medical director and director of nursing to meet this requirement. Accordingly, WHCC will ensure this review takes place annually and all required signatures are properly documented. The clinic administrator will ensure that this deficiency does not recur by performing annual audits of the facility's operation manual to evaluate and ensure adherence.

COMPLETE DATE

ID PREFIX TAG S 115

July 9, 2020

SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

ID PREFIX TAG 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 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 signature in 2019 was the most current review of policies and procedures.

PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)
ID PREFIX TAG S 117

WHCC acknowledges that the required signatures of the director of nursing, medical director and the clinic administrator were not present in the facility's operational manual indicating that annual review of the facility policies and procedures was performed. The facility promptly performed the required annual review, and documented the required signatures to confirm participation of all mandated parties, including the medical director and the director of nursing. There were no actual non-compliance issues detected with regard to OSHA or EPA. This immediate remedy measure rectifies, satisfies, and aligns compliance with LAC 48: I. Chapter 44 Subchapter B. Administration and Organization §4421. Governing Body.

The clinic administrator is responsible calendaring and coordinating the future annual collaboration of the medical director and director of nursing to meet this requirement. Accordingly, WHCC will ensure this review takes place annually and all required signatures are properly documented. The clinic administrator will ensure that this deficiency does not recur by performing annual audits of the facility's operation manual to evaluate and ensure adherence with all applicable authorities and regulations.

COMPLETE DATE
ID PREFIX TAG S 117
July 9, 2020

SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)
ID PREFIX TAG 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 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 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.

PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)

ID PREFIX TAG S 145

The OAF acknowledges and recognizes two (2) main components to the context of this deficiency:

1) 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."
2) The "review of the personnel record failed to reveal a skills check and/or competency of a capillary glucose meter use."

The OAF acknowledges and recognizes that this deficiency occurred where S5DON did not carry out the order of obtaining a CBG on a diabetic patient (Patient #14) as ordered in S3MD Standing orders. To rectify this deficiency, S5DON was retrained by S3MD, S2MedDir and the S1Adm. In accordance with facility protocol and with LAC 48: I. Chapter 44 Subchapter B. Administration and Organization §4423. Staffing Requirements, Qualifications, and Responsibilities.

In this specific instance, S3MD gave S5DON a verbal order to disregard the standing order to perform the CBG on patient #14 but the documentation of this verbal order was not properly documented.

In order to prevent recurrence of this component of the deficiency, the governing body (via internal communications) has instructed and encouraged the physician to be more diligent in ensuring that all standing orders are carried out except where written orders to the contrary is documented by the physician. This would provide the needed oversight that caused this component of the deficiency to occur in the first place. As the physician's medical and clinical judgment should dictate what assessment modalities are appropriate for all patients admitted to the facility, the physician should ensure that all clinically relevant and necessary tests specific to each patient's clinical presentation are performed.

The OAF will implement an addendum to the policy for emergency medical protocols specifically addressing the management of clinical scenarios suggestive of glucose disturbances in patients admitted to the clinic for counseling, medical abortions or surgical abortion procedures. Upon review of the patient's past medical history or clinical presentation, the physician will indicate appropriate intended management via physician orders that are clinically relevant and aligned with accepted standards of medical practice. The physician will be responsible for ensuring that the order is processed and executed. The physician will document all orders, sign, date and time all orders according to existing facility protocol. For the purposes of this deficiency, the addendum will specifically address Diabetic patients with reported history of current insulin therapy. The addendum policy is attached to the section "SUPPORTING DOCUMENTS TO ENDORSE STATED COMPLETION OF PLAN OF CORRECTION." (see under ID PREFIX TAG S145). In addition, an in-service for the staff on this update to the policy has been performed by S3MD and a copy is also attached to for review.

To address the second component of the deficiency with respect to skills check/ competency of capillary glucometer use, the facility conducted an in-service training for glucometer use, capillary blood glucose assessment, equipment care and controls training for all medical staff on July 6, 2020. Retraining will occur annually.

COMPLETE DATE
ID PREFIX TAG S 145
July 6, 2020

SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

ID PREFIX TAG 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.

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 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 ultrasound 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 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.

PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)

ID PREFIX TAG S 153

The OAF recognizes that its own policy for quality improvement through staff training was not properly executed. WHCC's existing policies require annual employee evaluations to be performed by the director of nursing, the medical director or facility designated medical professional with equivalent or higher qualifications. The clinic administrator will be responsible for ensuring that the policy is executed by coordinating and scheduling the evaluations by appropriately licensed medical personnel in accordance with LAC 48:1 Subchapter B §4423. Staffing Requirements, Qualifications, and Responsibilities.

S1Adm does, in fact, hold a surgical tech certification, though it was not located in the appropriate personnel file during the survey. An original copy of the certificate has been ordered from the issuing authority, and is anticipated to be received on or about July 27, 2020. Once received, the certificate will be placed and maintained in S1Adm's personnel file to her competency and qualification for that skillset.

In order to prevent recurrence, the clinic administrator will perform audits of current employee folders annually to ensure that the above stated designated individuals have executed the terms of the quality assurance policies, as specified by WHCC policy.

COMPLETE DATE
ID PREFIX TAG S 153
July 6, 2020

SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

ID PREFIX TAG 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 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.

PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)

ID PREFIX TAG S 161

The timeline as described in this statement of deficiency is disputed. WHCC maintains that all medical records requested were turned over for review in a timely fashion. The S1Adm does not recall any requests for medical charts on 3/12/2020. The surveyors presented to the facility and stated that they would randomly pull medical records/charts from the in-house file storage area. The surveyors were granted entry into the storage area where the medical records are housed. The S1Adm recalls that the surveyors did not present a list of patient charts to be pulled (as this was the usual protocol) but requested to inspect the file storage area and get the charts they wanted. On 6/4/2020, when the survey resumed, the surveyors presented S1Adm with 2 typed pages of information they needed. On the first page, it stated in part "please provide the following within 1 hour", and "Daily roster (and services provided i.e. counseling, abortion procedures, etc.) for the last 3 months and February and April

2019." S1Adm provided this information to the lead surveyor within the one-hour time frame. Later that afternoon, the surveyor then presented S1Adm with a handwritten note containing five patient names from 5/26/2020 date of service. Since these were patients that were seen within one month of the survey re-start date of 6/4/2020, these charts were housed in the filing storage area and were presented to the surveyor contemporaneously. On the same day, 6/4/2020, S1Adm was given a second handwritten note (on a yellow post-it paper) with the date 4/4/19 and names of 2 patients written on it. S1Adm explained to surveyor that since those charts were over one year old, those charts will be housed off-site and so, the charts could not be furnished for review on 6/4/2020. S1Adm also pointed out that one of the names of the patient that was written on the post-it note was remarkably familiar. S1Adm then told the surveyor that she would be going to get those charts at the close of business to have them ready for review for 6/5/2020. S1Adm also requested that the surveyor make a specific written request for the medical record of one out of two of the patients from 4/4/19. The surveyor then asked S1Adm why she made such a request. S1Adm explained that it would be in the interest of the OAF to have a written request because the surveyor was requesting a chart of a known "anti-abortion protester known for invading abortion clinics nationwide and has connections with domestic terrorist groups such as Army of God," and that "the Louisiana medical board had initiated an in-depth investigation as a result of baseless complaints that patient made against the clinic." The surveyor asked S1Adm what the outcome of the investigation was. S1Adm replied stating "the investigation was closed about a year ago." The surveyor then said "If the board already looked into this, then I guess we don't need her chart." The surveyor then requested the chart for another patient from 4/4/2019 encounter date and said, "get this one instead." On 6/5/2020, S1Adm presented 2 patient medical records for review to the surveyor. It is the position of the OAF that S1Adm presented all medical records requested by surveyors within 24hours of the request being made.

Therefore, the OAF was in compliance with patient medical records as delineated by the department in this section. It is WHCC's position that compliance with LAC 48: I. Chapter 44 Subchapter B. Administration and Organization §4425. Patient Medical Records and Reporting Requirements has been maintained and assured.

COMPLETE DATE – Timely Addressed during site survey
ID PREFIX TAG S 161
N/A

SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)
ID PREFIX TAG 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 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 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.

PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)

ID PREFIX TAG S 177

The OAF acknowledges that on 3/12/2020, the surveyors requested to inspect the patient medical record storage area and were granted access. The OAF acknowledges that the surveyor exited the

storage area with about 5 to 7 charts. The surveyors then asked S1Adm where the notarized verification of legal guardianship was for the chart belonging to Patient #2. The OAF acknowledges that the notarized verification of legal guardianship was not present in the chart when it was presented to S1Adm by the surveyors. Since WHCC strictly adheres to the documentation protocols governing minors seeking pregnancy termination, this was a curious anomaly. The file contents may have been displaced as they were moved. The OAF firmly implements its own policy for minors seeking abortion and strictly complies with the regulations set forth in LAC 48: I. Chapter 44 Subchapter C. Pre-operative, Intra-operative, and Post-Operative Procedures §4431. Screening and Pre-Operative Services.

The OAF will continue to implement its existing policy concerning minors seeking abortion care as supported by the findings of the surveyors that 4 out of 5 charts of a randomly selected sample had all the appropriate documentation in the record. It has been the policy of the OAF to have the parent/legal guardian sign all the consents in the minor patient record at the time of patient check-in. The notarized verification of legal guardianship would have had to be in the chart prior to the parent/legal guardian signing the consents for abortion on the day of the medical or surgical abortion procedure.

In order to avoid recurrence of missing notarized verification of legal guardianship forms, the facility will implement a 4-point stapling of the notarized form to the corresponding patient chart. This would prevent inadvertent misplacement of the form within the record and also leave a trace of removal if the form in question is absent. The clinic administrator is responsible for ensuring that the staff who perform the patient check-in duties are familiar with the proper minor check-in methodology. An in-service has been conducted to re-acquaint the staff members responsible for patient check-in on the satisfactory implementation of existing OAF policy on minors seeking abortion.

COMPLETE DATE
ID PREFIX TAG S 177
July 6, 2020

SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

ID PREFIX TAG 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 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 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.

PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)

ID PREFIX TAG S 205

The facility's operational manual pertaining to blood glucose meter use directs that the OAF should use the manufacturer guide for performing quality control testing and system maintenance for cleaning/disinfecting. The manufacturer's guide explains that there are 2 ways of performing quality control testing. One way is to use the internal automatic self-test

(https://www.northcoastmed.com/pdf/manuals/nipro/truemetrix/True-Metrix-User-Guide.pdf). Supporting findings for this method of quality control practice can be found by clicking on these links: https://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html

https://www.fda.gov/medical-devices/vitro-diagnostics/blood-glucose-monitoring-devices#:~:text=In%20general%2C%20you%20prick%20your,passes%20through%20the%20test%20strip.

Upon interview with the surveyors, S1Adm asserted that the OAF currently used the device's automatic self-quality control assessment. S1Adm explained that, the glucometer device runs it own auto control assessment as described in the manufacturer's manual. Therefore, it is the OAF position that this aspect of blood glucose meter quality control was currently implemented. Therefore, the OAF was in compliance of blood glucose meter quality control as accepted standards of practice were in place in accordance with facility policy, current CDC/FDA guidelines and LAC 48: I. Chapter 44 Subchapter C. Pre-operative, Intra-operative, and Post-Operative Procedures §4435. Intra-operative Procedures.

COMPLETE DATE
ID PREFIX TAG S 205
N/A

SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)
ID PREFIX TAG 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, 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 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 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 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 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 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.

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 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:

-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 31 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 contamination/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.

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 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 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 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.

PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)

ID PREFIX TAG S 243

The OAF acknowledges the deficiency in this section as falling short of the rules and regulations set forth in LAC 48: I. Chapter 44 Subchapter D. Physical Environment §4447. Infection Control. In response to the immediate jeopardy finding during the survey, the facility has put in place updated effective processes to ensure sanitary equipment and supplies used for surgical and medical care of patients. In context of the identified deficiencies, used/contaminated instruments brought into the decontamination station will be first washed with appropriate detergents under running hot water. The instruments that contain any screws that can be removed/unscrewed will be separated. The screws and instruments will be washed until all visible soil or discoloration is no longer visible. Next, the cleaned instruments will be disinfected with chemical germicides by soaking in a holding tray for 10 minutes. Lastly, the cleaned and disinfected instruments will be rinsed, placed and packaged in the sterilization bags/pouches (with appropriate indicator strips) and sterilized in the autoclave per autoclave protocol. After the autoclave cycle is completed, the sterilized instruments will be removed and allowed to completely dry in a clean holding area before being stored in the clean supply room. Furthermore, the decontamination/sterilization station area will be partitioned into clearly designated dirty/contaminated/used instrument area, washing station, clean/disinfected area, and sterilized area. A dirty-to-clean workflow is the foundation for design of a sterile processing area. Simply put, it requires a one-way traffic pattern for instruments or devices in which items move from a contaminated state to a decontaminated state. This one-way workflow is essential to preventing cross-contamination as items move through the process. This will ensure a clarified workflow to processing area and aid with preserving the integrity of the instrument disinfection and sterilization process. On 6/4/2020, survey team identified 2 sterilized bags with instruments that contained moisture in it dated 5/29/2020. The survey team noted that these bags were found in the instrument storage area. In context of the identified deficiency, the facility will immediately implement the following:

- All sterilized bags removed from the autoclave after autoclave cycle is completed 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.

On 6/5/2020, survey team identified 2 rolling tables with contaminated instruments, used supplies and a disposable vacuum container and attached tubing with blood and bodily fluids, sitting uncovered in the decontamination/ sterilization room. In the context of the identified deficiency, 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 of from the procedure room to the decontamination station. The trays will remain covered in the decontamination/sterilization room (under the designated area for dirty/contaminated/ used instrument area) until the technician responsible for the instrument processing is ready to process the contents of the used tray. On 6/5/2020, the survey team observed a clinic staff member rolling an uncovered tray containing a suction canister with attached tubing, containing blood and body fluids and instruments, and gauze contaminated with blood and body fluids into the decontamination/sterilization room. In context of the identified deficiency, the facility will immediately implement the strict use of coverings for trays that are being transported to the decontamination/sterilization. The coverings will be such that the contents of the tray being transported cannot be seen or identified. The trays shall remain covered and placed the designated area for dirty/contaminated/ used instruments until the technician is ready to process the contents of the used tray. On 6/5/2020, the survey team observed a plastic vacuum canister being washed and wiped down by the technician, with the wording on the side of the plastic vacuum canister which read, "Caution: Do Not Reuse." In the context of the identified deficiency, the facility will switch to the use of only reusable suction canisters. The facility will follow the suggested manufacturers guidelines or current CDC Guidelines for cleaning/disinfection of the reusable suction canisters. The facility will immediately dispose of all used plastic vacuum canisters that read "Caution: Do Not Reuse." On 6/5/2020, the survey team observed that the 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 recleaning, reported by the technician to be rust. In the context of the identified deficiency, the facility will immediately implement that instruments and all attachments (like screws) with any discoloration of any kind that is not removable with the cleaning step of the processing will be immediately discarded/removed from use entirely. If an instrument with such noted discolorations as described by surveyors is believed to be from rust deposition or rust staining, then the instrument will be treated with appropriate rust removal agents until satisfactory visible absence of such staining is achieved. Afterwards, the instruments that have undergone the de-rusting process will be cleaned, disinfected and sterilized per the instrument processing protocol adapted. On 6/5/2020, the survey team observed staff coming into the decontamination room to obtain cleaned plastic vacuum containers for use in another procedure. In the context of the identified deficiency, the facility will immediately implement the use of only reusable bottle vacuum canisters in lieu of using plastic vacuum canisters for all surgical uterine aspiration procedures. The facility will only use the suggested manufacturers guidelines or current CDC guidelines for cleaning/disinfection of the reusable suction canisters. The facility will immediately dispose of all used plastic vacuum canisters that read "Caution: Do Not Reuse." During the survey period of 6/4/2020 to 6/15/2020, the survey team's review of the personnel files for staff performing decontamination and sterilization revealed no documentation of formal training for decontamination, sterilization, or storage of surgical equipment or instruments. In the context of the identified deficiency, the facility will immediately implement that the required documentation of formal training in decontamination, sterilization and storage of instruments will be placed in the employee folder within the first 90 days of hire or resumption of such duties. The facility will implement annual performance evaluation or skill checklist of any staff member or technician who may be assigned to work in the central processing station. The annual performance evaluation or skill checklist will be performed by the clinic administrator, the director of nursing or other qualified designated staff member. The current technician has completed 2 training courses provided by the

National Abortion Federation (NAF) on-line learning titled "Infection Prevention 1- Principles of Infection Prevention" and "Infection Prevention 2- Instrument Processing." These courses were completed on 10/3/2019. The facility will ensure that documentation certifying satisfactory completion of these courses that are pertinent to the subject matter is placed in the employee's personnel file. During the survey period of 6/4/2020 to 6/15/2020, the survey team observed that decontamination and sterilization staff had no evidence of skill competency evaluation completed by a qualified professional with training and/or expertise in repossessing (sic) of instruments. In the context of the identified deficiency, the facility will immediately implement annual performance evaluation or skill checklist of any staff member or technician who may be assigned to work in the central processing station. The annual performance evaluation or skill checklist will be performed by either the clinic administrator, the director of nursing or other qualified designated staff member who are qualified professionals with training and/or expertise in instrument processing. The facility will perform and document for surveyor review a performance evaluation for the current technician designated to form the duties of instrument processing. During the survey period of 6/4/2020 to 6/15/2020, the survey team observed that the facility failed to have processes in place for the cleaning, decontamination, packaging, sterilization and storage of surgical instruments. No documentation of monitoring and surveillance of the processing of surgical instruments and equipment was provided. In the context of the deficiency noted herein, the facility will immediately implement an updated infection control policy that highlights and documents industry standard guidelines for instrument and equipment cleaning processes. In the following 12 months of this IJ component, the facility will implement and ensure that there is a monthly review of this policy by the Medical Director and Clinic Administrator. The facility's updated policy to reflect the identified deficiency is immediately available for surveyor's review. In the context of this summary identified herein, the facility will immediately implement an updated policy elucidating the logistical breakdown of the decontamination/sterilization station area. The area will be partitioned into dirty/contaminated/used instrument area, washing station, clean/disinfected area, and sterilized area. This will ensure a clarified workflow to processing area and aid with preserving the integrity of the instrument disinfection and sterilization process. During the survey period of 6/4/2020 to 6/15/2020, the survey team observed that staff members did not receive formal training or competency evaluations by a professional with formal experience or training in instrument processing. In the context of this identified deficiency, the facility will immediately provide necessary training to the designated technician and competency/performance evaluation of said staff member by the a professional with formal experience in surgical instrument processing. During the survey period of 6/4/2020 to 6/15/2020, the survey team observed that the facility failed to have processes in place for the cleaning, decontamination, packaging, sterilization and storage of surgical instruments. In the context of the deficiency identified, the facility will immediately address deficiency and implement updated infection control policies and practices that address cleaning, decontamination, packaging, sterilization and storage of surgical instruments. The facility will immediately implement instrument processing, workflow and sterility assurance measures.

Upon receipt of the notification of the immediate jeopardy situation on 6/15/2020 at 5:20pm, the facility has initiated, instituted and implemented the following to address the component deficiencies outlined. Through clinic administrator, with review and approval of the medical director, ensured the following:

1) **Instrument Processing Area and Work Flow**

The instrument processing work flow must follow the CDC guidelines, with the following sequential steps: disposal of sharps (done by physician prior to tray transport); covered transportation of used tray; disposal of single-use disposable instruments and waste; sorting of instruments and handpieces; cleaning; sterilization and storage. The instrument processing area has immediately been redesigned for this work flow and traffic pattern. The area set aside for cleaning and sterilization of instruments should promote a one-directional workflow to avoid the risk of cross-contamination of sterilized items via contact with contaminated items and equipment. The facility now has designated separate areas (spaces) within the sterilization room for receiving, decontamination, cleaning, drying, inspection, packaging, sterilization and storage, to help maintain one-directional flow during instrument processing.

2) Transporting

Instruments will be transported from the patient treatment area to the sterilization area after disposable sharps have been placed in an appropriate sharps container by the physician immediately after use. OSHA requires the transport of used sharp instruments in rigid puncture-proof containers with rigid sides and bottom. Handling of contaminated instruments should be minimized during transportation to the instrument processing area. The used tray will be covered entirely before the tray leaves the room and during the transportation path to the processing area. The used trays will remain properly covered in the area designated for receiving contaminated instruments until the technician is ready for instrument and specimen processing. Personnel should wear utility gloves when handling used trays during the removal, transport, cleaning and packaging processes. Biohazardous waste are always disposed of in the appropriate receptacle in accordance with state and local medical waste regulations.

3) Receiving, Sorting and Cleaning

All instruments will be cleaned immediately after use. The instruments will be washed with detergent and running hot water, visually inspected for any discoloration or staining, presoaked in the chemical germicide.

4) **Preparation and Packaging**

The facility will ensure that technician is trained (by staff member with qualifying instrument processing knowledge) to place loose decontaminated instruments in the pouch or wrap made of material intended for the particular type of sterilization process. According to the CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities 2008, wrap or packaging for instruments may consist of "peel-open pouches (e.g., self-sealed or heat-sealed plastic and paper pouches), roll stock or reels (i.e., paper-plastic combinations of tubing designed to allow the user to cut and seal the ends to form a pouch), and sterilization wraps (woven and nonwoven)." The packaging material used by the facility allows for penetration of the sterilant, prevents contamination during handling, provides an effective barrier to microbial penetration and maintain the sterility of the processed item after sterilization. When loading packages into the sterilizer, correct loading is enforced for sterilization to occur and packages must remain intact without being pierced or damaged during loading. In accordance with the CDC Guidelines, a chemical indicator is be placed inside each wrapped package. If this indicator cannot be seen from the outside of the package, another indicator (e.g., indicator tape) should be placed on the outside of the package.

5) Storage

Sterile pouches or wrap will maintain asepsis of instruments for prolonged periods, provided they are not compromised by becoming wet or torn. Studies have indicated that instruments remain sterile in packs for prolonged periods but may show signs of contamination if not handled properly. Therefore, there is no evidence to suggest that packs of instruments should be routinely resterilized solely based on

the length of time in storage. The event-related shelf-life practice, as described in the 2008 CDC guideline, recognizes this and the fact that packs will remain sterile unless compromised. Instruments must only be removed from the sterilizer after completion of the full sterilization cycle and, if wet during sterilization, after the packaging is dry. Storage will be in low/no-moisture areas and dust free. The facility will store them in enclosed cabinets or drawers to maintain sterility. All the items in packs that become torn or remaining items in packs that have been opened to remove one or more items in the pack should be reprocessed, beginning with the cleaning step of the process.

6) Sterility Assurance and Documentation

Sterility assurance provides operators with the knowledge that sterilization procedures are effective or that corrective action is required. It should be noted that most failures in sterilization are due to operator error and not to any inherent defect in the sterilization device as consistent with this deficiency. The facility will continue to ensure sterility using biologic indicators, which are required to evaluate the effectiveness of sterilization.

Documentation will be maintained for all sterilizers and sterilization procedures and will be initialed by the operator. Maintenance records for the sterilizer will include the sterilizer's serial and model numbers, dates and details for maintenance/servicing, and sterilization cycles immediately following maintenance/servicing. All sterilization cycles must be fully recorded, and the time, date and sterilizer used must be noted on external packaging prior to sterilization and storage of the package. Against each sterilization cycle in the record, the operator should record charts, note gauges and attach printouts demonstrating mechanical monitoring of appropriate time, temperature and pressure. All spore test results must be thoroughly documented for the specific sterilizer, with date, time and results noted.

7) Training of Scrub room technician

The facility will immediately provide necessary training to the designated technician and competency/performance evaluation of scrub room technician by a professional with formal experience in surgical instrument processing in accordance with the LAC 48: I. Chapter 44 guidelines for maintaining performance standards and ensuring quality assurance.

The OAF has also invested in the purchase of new examination tables that are devoid of rust formations "where the foot and leg rests retracted." The OAF has discarded the "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." The OAF has also discarded all cloth covered rolling chairs in the procedure rooms. The OAF has also discarded the white plastic garbage can described by the surveyor. The removal of these items from the premises immediately addresses this finding of deficiency. The clinic administrator is responsible for ensuring that all examination tables are without rust formations. As part of the cleaning/maintenance log, the appearance of rust will be included and assessed to ensure that recurrence is avoided.

COMPLETE DATE

ID PREFIX TAG S 243

June 17, 2020 - Immediate Jeopardy removal

July 6, 2020 – New examination table purchase

SUPPORTING DOCUMENTS TO ENDORSE STATED COMPLETION OF PLAN OF CORRECTION

ID PREFIX TAG S 107

S107

Women's Health Care Center
2701 General Pershing St.
New Orleans, La. 70115

Governing Board

Governing Board Of Directors

[redacted]

President

[redacted]

Recording Secretary

[redacted]

S107

WOMEN'S HEALTH CARE CENTER, INC.
2701 General Pershing Street
New Orleans, Louisiana 70115

GOVERNING BOARD
CONTACT INFORMATION

[redacted]

Updated 07/01/2020

S 107

WOMENS HEALTHCARE CENTER, INC
ADDENDUM TO EMPLOYMENT POLICY
Re: Direct Service Worker Registry and/or Adverse Action Site.

PURPOSE:
To ensure each unlicensed direct care staff person employed by the outpatient abortion facility (OAF) is in good standing and without restrictions with the Direct Service Worker (DSW) Registry and/or Adverse Action Site before hire and every 6 months for the duration of employment.

METHODOLOGY:

1) The clinic administrator (OAF) will perform a search query of all unlicensed staff members as defined by LAC 48:I Ch 92 Subchapter A 9201 through the website: adverseactions.ldh.la.gov/SelSearch
2) The search will be performed prior to completion of employment agreement.
3) The search will be performed in the month of June and December of each year.
4) A printout of the search query shall be placed in the personnel folder for the respective employee
5) An audit sheet will be maintained that shows the dates when the search query was performed.

RESPONSIBLE PARTY:
Clinic administrator [redacted]

APPROVED BY:
(Signature) [redacted]

MEDICAL DIRECTOR

S111

WOMEN'S HEALTH CARE CENTER, INC.
2701 GENERAL PERSHING ST.
NEW ORLEANS, LA 70115

STATEMENT OF FACT

I, [redacted] Medical Director of Women's Health Care Center, Inc. have reviewed and approved the policies and procedures in the OPERATIONAL MANUALS of this clinic.

The Operational Manuals include:

THE ADMINISTRATIVE MANUAL
THE PERSONNEL MANUAL
THE PATIENT CARE MANUAL
THE OSHA/ INFECTION CONTROL/ EMERGENCY MANAGEMENT MANUAL
THE NURSING PROCEDURES MANUAL

2019

[redacted] 1/10/19
MEDICAL DIRECTOR DATE

[redacted] 1/10/19
ADMINISTRATOR DATE

2020

[redacted] 7/9/20
MEDICAL DIRECTOR DATE

[redacted] 5/13/19
ADMINISTRATOR DATE

[redacted] 7/9/20
Director of Nursing

5111

WOMEN'S HEALTH CARE CENTER, INC.
2701 GENERAL PERSHING STREET
NEW ORLEANS, LOUISIANA 70115

BOARD OF DIRECTORS MEETING
Spetember 13, 2019

Attended by: [redacted]

The meeting was held at Women's Health Care Center.

TOPIC OF DISCUSSION

On this day DR [redacted] has been approved to join staff at Women's Health Care Center Inc.

Approval was unanimous

[redacted]

9/13/19
Date

Sep 2019
Date

7/9/20
Date

S177

WOMEN'S HELATH CARE CENTER, INC.

INSERVICE SIGN-IN SHEET

TOPIC: Patient check-in process

Re: minor patient's seeking abortion

PRESENTED BY: [redacted]

DATE: July 06, 2020

ATTENDED BY:

1. [redacted]
2.
3.
4.
5.
6. _____
7. _____
8. _____

ID PREFIX TAG S 145

S145

WOMEN'S HELATH CARE CENTER, INC.

INSERVICE SIGN-IN SHEET

TOPIC: Glucose meter use, capillary blood glucose assessment and Equipment Quality Control & System maintenance

PRESENTED BY: [redacted]

DATE: July 06, 2020

ATTENDED BY:

1. [redacted]
2.
3.
4.
5.
6.
7. _____
8. _____

Women's Health Care Center, Inc

Addendum to Policy and Procedure for Emergency Medical Conditions

Re: Patients with past medical history of diabetes mellitus currently on insulin therapy and patients with clinical evidence of glucose disturbance

OBJECTIVES: To monitor blood glucose levels if medically indicated and as ordered by the clinic physician.

1. Type one and Type two diabetics reporting current insulin use will be identified on counselling day and instructed by either the physician or the nurse to bring their personal glucometer and insulin supplies with them on procedure day.
2. The physician may order a STAT blood glucose on patients presenting with symptoms of glucose disturbances on procedure day.

Method of Testing For patients with their own glucometer:

1. If the patient is a known diabetic and has brought their own blood glucose supplies to clinic, the patient will be asked to take a blood glucose level during intake vitals and as medically indicated after that. The nurse will provide the patient with an alcohol swab and 2 x 2 gauze. The nurse will ensure that the patient disposes of their sharps into the sharp's container. The nurse will then record the value in the patient chart and on the surgical roster.

Method of Testing Using the Facility's True Metrix Pro Professional Glucose System Glucometer:

1. Gather supplies: Glucometer, test strips, lancet, alcohol swab, 2x2 gauze, sharps container within arm's length, rubber gloves.
2. Clean monitor prior to use and perform hand hygiene.
3. Remove one strip from under the glucometer lid.
4. Put gloves on and clean the side of one finger with the alcohol swab. Avoid punctures to the touch pads of the fingers.
5. Allow alcohol to dry.
6. insert the flat edge of the strip into the glucometer.
7. Wait for the blood drop to appear on the screen.
8. Lance the prepared site and dispose of lancet into the sharp's container.
9. Wipe the first drop of blood and touch the second drop of blood with the tip of the strip that is inserted into the glucometer.
10. Give the patient 2x2 gauze to apply pressure while the monitor reads the value
11. Dispose of the strip into the sharp's container
12. Clean the monitor with disinfectant wipes or alcohol-containing wipes.
13. Remove gloves and perform hand hygiene
14. Record the value on the chart and on the surgical roster.

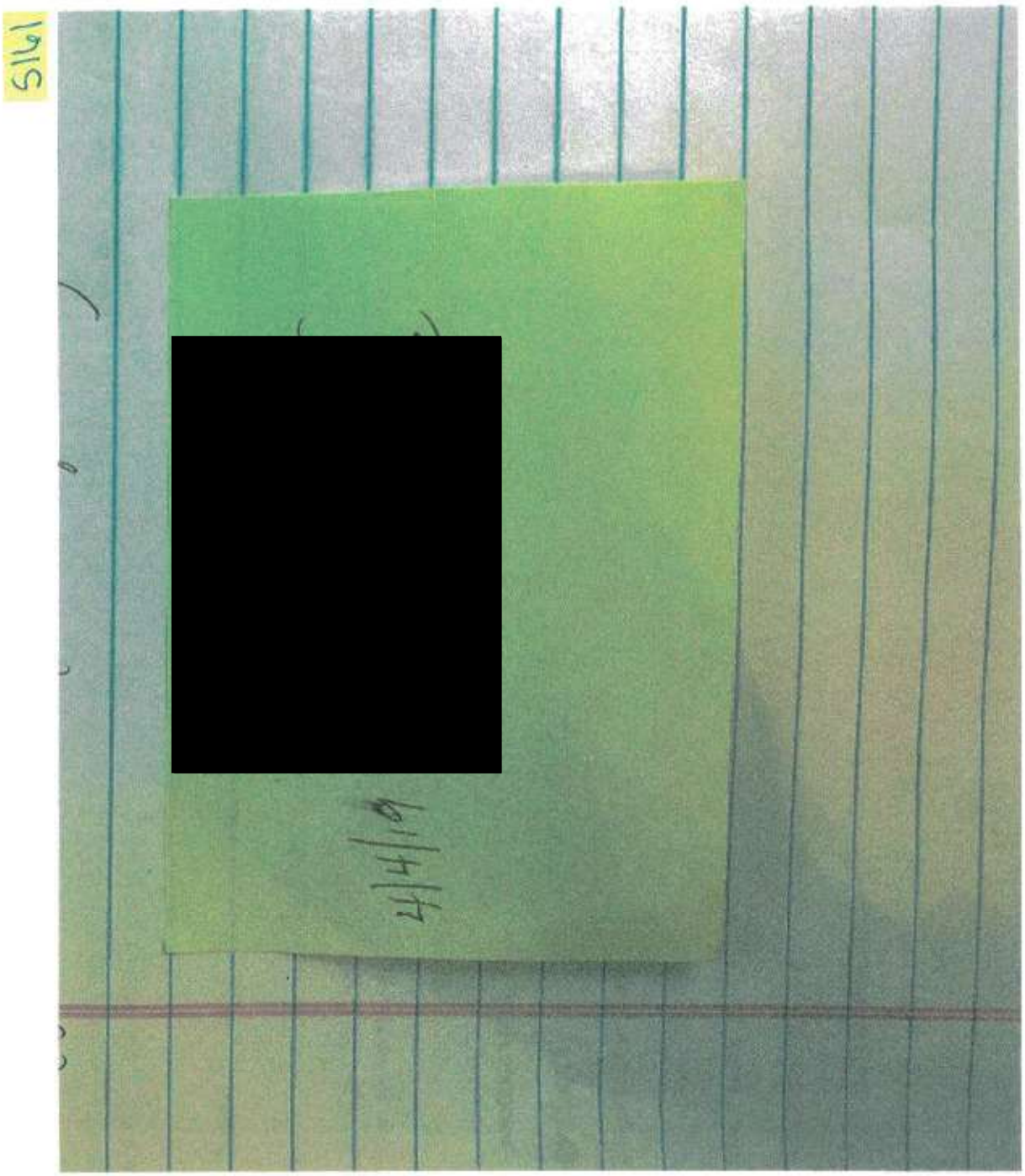
BLOOD SUGAR LEVELS

mg/dl	Fasting min/max	2 hrs post meal
normal	70/100	<140
Diabetes	70-130	<180

Medical Director: [redacted]

Signed copy in operations binder
Signature and date

ID PREFIX TAG S 161



ID PREFIX TAG S 205

https://www.fda.gov/medical-devices/vitro-diagnostics/blood-glucose-monitoring-devices#:~:text=In%20general%2C%20you%20prick%20your,passes%20through%20the%20test%20strip.

https://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html

https://www.northcoastmed.com/pdf/manuals/nipro/truemetrix/True-Metrix-User-Guide.pdf

ID PREFIX TAG S 243

POLICY AND PROCEDURE
INFECTION CONTROL
MEDICAL EQUIPMENT AND SURIGICAL INSTRUMENT CLEANING POLICY
CENTRAL PROCESSING POLICY

POLICY:

Purpose

1. To ensure that all employees are knowledgeable regarding the cleaning methods, instrument processing and sterilization processes for reusable equipment and surgical instruments.
2. To prevent transmission of infectious materials from reusable equipment through adherence to infection control guidelines.

Procedure:

Per CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 recommendations summarize that the designated central processing area be divided into distinct areas for the following steps:

- Receiving
- Cleaning and decontamination
- Preparation
- Packaging
- Sterilization
- Storage

Therefore, the instrument processing work flow must follow the above stated guidelines, with the following sequential steps: disposal of sharps (done by physician prior to tray transport); transportation of used tray; disposal of single-use disposable instruments and waste; sorting of instruments and equipment; cleaning; sterilization and storage. The instrument processing area is designed for this workflow and traffic pattern. The area set aside for cleaning and sterilization of

instruments should promote a one-directional workflow to avoid the risk of cross-contamination of sterilized items via contact with contaminated items and equipment. The facility would maintain designated separate areas (spaces) within the sterilization room for receiving, decontamination, cleaning, drying, inspection, packaging, sterilization and storage, to help maintain one-directional flow during instrument processing.

The following steps will be utilized by central processing technician for reusable equipment/surgical instrument handling and processing:

1. Decontamination process: After each use, trays with contaminated/used surgical instruments and equipment would be transported to the designated receiving area. All instruments (vaginal speculums, cannister/tubing connections, dilators, cups, needle extenders, etc) must be disassembled as appropriate. All disposable and single use items with gross contamination must be discarded in the biologic waste disposal. (For the purposes of an out-patient procedural facility, see table below in the Other section for categorization of instrument/equipment type). Rinse with hot water to remove gross tissue and blood *until the instrument/equipment is completely free of all discoloration, debris or staining.* The equipment/instrument is then washed/scrubbed with appropriate detergent and hot water *until the instrument/equipment is completely free of all discoloration, debris or staining. In the event that an instrument/equipment is noted to be discolored/damaged, such must be immediately discarded, and clinic supervisor notified to aid maintain adequate inventory.*

2. Disinfection process: The decontaminated instruments should be either sprayed or soaked until completely saturated with a liquid-based germicide/disinfectant (see disinfectant type section below) solution for three (3) to ten (10) minutes. The instruments should be rinsed with water and allowed to dry. *For reusable collection bottles, the facility will adapt the guidelines form the 2008 CDC recommendations for semicritical patient care item disinfection. Therefore, the reusable collection bottles will undergo high-level disinfection processing with appropriate sterilant and disinfectant type.*

3. Sterilization process: Equipment/Instruments that have been decontaminated and disinfected are placed in a sterilization pouch with internal indicator inside to ensure validity of sterilization. For instruments to be autoclaved, place instruments in the autoclave and follow autoclaving policies while operating.

4. Storage process: Prior to storing sterilized instruments/equipment, *visual inspection of each package must be done to ensure the complete absence of moisture,* or compromise to packaging during handling. The sterilized instruments should be stored in the clean supply room on the shelves and bins provided. *At all times, all sterilized packages should never be kept/stored or left in close proximity to any contaminated trays to avoid the risk of cross-contamination. Strict adherence to the one-directional workflow of the processing station is required.*

For the purposes of this facility, the following equipment will be decontaminated, disinfected, and sterilized after each use:

1. All Surgical instruments

2. All Vaginal speculums

For the purposes of this facility, the following reusable equipment will be decontaminated and disinfected after each use.

1. Glass reusable suction/collection cannisters

Responsible Party and Quality Improvement:
The Clinic administrator, Director of Nursing or other qualified agent of the facility with instrument processing knowledge and experience will be responsible for training, performance evaluation of personnel responsible for instrument/equipment processing/scrub room technician.

This policy will be evaluated every month by the medical director and clinic administrator beginning June 15, 2020 and ending June 15, 2021. Acknowledgment of policy review would be kept with this policy. Afterwards, policy review should be done per quality improvement protocol.

Other:
Disinfectant type: Facility will follow guidelines from FDA regarding Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices retrieved from https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices-information-manufacturers/fda-cleared-sterilants-and-high-level-disinfectants-general-claims-processing-reusable-medical-and. According to https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf many disinfectants are used alone or in combinations (e.g., hydrogen peroxide and peracetic acid) in the health-care setting. These include alcohols, chlorine and chlorine compounds, formaldehyde, glutaraldehyde, *ortho*-phthalaldehyde, hydrogen peroxide, iodophors, peracetic acid, phenolics, and quaternary ammonium compounds. Commercial formulations based on these chemicals are considered unique products and must be registered with EPA or cleared by FDA. In most instances, a given product is designed for a specific purpose and is to be used in a certain manner. Therefore, users should read labels carefully to ensure the correct product is selected for the intended use and applied efficiently. The facility will utilize disinfectants that contain one or a combination of the following

- Alcohol
- Chlorine and chlorine compounds
- Formaldehyde
- Glutaraldehyde
- Hydrogen peroxide
- Iodophors
- Ortho-phthalaldehyde (OPA)
- Peracetic acid
- Peracetic acid and hydrogen peroxide
- Phenolics
- Quaternary ammonium compounds
- Other germicides

OSHA Bloodborne Pathogen Standard: In December 1991, OSHA promulgated a standard entitled "Occupational Exposure to Bloodborne Pathogens" to eliminate or minimize occupational exposure to bloodborne pathogens. One component of this requirement is that all equipment and environmental and working surfaces be cleaned and decontaminated with an appropriate disinfectant after contact with blood or other potentially infectious materials. Even though the OSHA standard does not specify the type of disinfectant or procedure, the OSHA original compliance document suggested that a germicide must be tuberculocidal to kill the HBV. To follow the OSHA compliance document a tuberculocidal disinfectant (e.g., phenolic, and chlorine) would be needed to clean a blood spill. However, in February 1997, OSHA amended its policy and stated that EPA-registered disinfectants labeled as effective against HIV and HBV would be considered as appropriate disinfectants ". . . provided such surfaces have not become contaminated with agent(s) or volumes of or concentrations of agent(s) for which higher level disinfection is recommended." When bloodborne pathogens other than HBV or HIV are of concern, OSHA continues to require use of EPA-registered tuberculocidal disinfectants or hypochlorite solution (diluted 1:10 or 1:100 with water). Studies demonstrate that, in the presence of large blood spills, a 1:10 final dilution of EPA-registered hypochlorite solution initially should be used to inactivate bloodborne viruses to minimize risk for infection to health-care personnel from percutaneous injury during cleanup.

Indications for Sterilization, High-Level Disinfection, and Low-Level Disinfection

Indications for sterilization and disinfection: by ID number and category.		
#	Recommendation	Category
3.a.	Before use on each patient, sterilize critical medical and surgical devices and instruments that enter normally sterile tissue or the vascular system or through which a sterile body fluid flows (e.g., blood). See recommendation 7g for exceptions.	IA
3.b.	Provide, at a minimum, high-level disinfection for semicritical patient-care equipment (e.g., gastrointestinal endoscopes, endotracheal tubes, anesthesia breathing circuits, and respiratory therapy equipment) that touches either mucous membranes or nonintact skin.	IA
3.c.	Perform low-level disinfection for noncritical patient-care surfaces (e.g., bedrails, over-the-bed table) and equipment (e.g., blood pressure cuff) that touch intact skin (see Recommendation 5g).	II

(adapted from https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf)

Semicritical Items

Semicritical items contact mucous membranes or nonintact skin. This category includes respiratory therapy and anesthesia equipment, some endoscopes, laryngoscope blades [24], esophageal manometry probes, cystoscopes [25], anorectal manometry catheters, and diaphragm fitting rings. These medical devices should be free from all microorganisms; however, small numbers of bacterial spores are

permissible. Intact mucous membranes, such as those of the lungs and the gastrointestinal tract, generally are resistant to infection by common bacterial spores but susceptible to other organisms, such as bacteria, mycobacteria, and viruses. Semicritical items minimally require high-level disinfection using chemical disinfectants. Glutaraldehyde, hydrogen peroxide, *ortho*-phthalaldehyde, and peracetic acid with hydrogen peroxide are cleared by the Food and Drug Administration (FDA) and are dependable high-level disinfectants provided the factors influencing germicidal procedures are met (Table 1). When a disinfectant is selected for use with certain patient-care items, the chemical compatibility after extended use with the items to be disinfected also must be considered. High-level disinfection traditionally is defined as complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores. The FDA definition of high-level disinfection is a sterilant used for a shorter contact time to achieve a 6-$\log_{10}$ kill of an appropriate *Mycobacterium*species. Cleaning followed by high-level disinfection should eliminate enough pathogens to prevent transmission of infection. [26, 27]

References

https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf

https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices-information-manufacturers/fda-cleared-sterilants-and-high-level-disinfectants-general-claims-processing-reusable-medical-and

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References

https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf

https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices-information-manufacturers/fda-cleared-sterilants-and-high-level-disinfectants-general-claims-processing-reusable-medical-and

[redacted]

7/15/20

STATEMENT OF DEFICIENCIES
(Printed 7/02/2020)
(Revisions Requested via Email 7/28/2020)

AND

PLAN OF CORRECTION
(Submitted 7/15/2020)
(Supplemented 7/30/2020)

WOMENS HEALTH CARE CENTER, INC. (WHCC)
2701 GENERAL PERSHING STREET, NEW ORLEANS LA 70115 (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:BO0004641

SURVEY COMPLETED 6/17/2020

ID PREFIX TAG S 161
Portion(s) of summary statement of deficiencies

"This Rule is not met as evidenced by: Based on record review and interviews, the 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."

Provider's Plan of Correction

This deficiency is currently being disputed. Nevertheless, the OAF provides this supplemented plan of correction. The timeline as described in this statement of deficiency is disputed. WHCC maintains that all medical records requested were turned over for review in a timely fashion. The S1Adm does not recall any requests for medical charts on 3/12/2020. The surveyors presented to the facility and stated that they would randomly pull medical records/charts from the in-house file storage area. The surveyors were granted entry into the storage area where the medical records are housed. The S1Adm recalls that the surveyors did not present a list of patient charts to be pulled (as this was the usual protocol) but requested to inspect the file storage area and get the charts they wanted.

On 6/4/2020, when the survey resumed, the surveyors presented S1Adm with 2 typed pages of information they needed. On the first page, it stated in part "please provide the following within 1 hour", and "Daily roster (and services provided i.e. counseling, abortion procedures, etc.) for the last 3 months and February and April 2019." S1Adm provided this information to the lead surveyor within the one-hour time frame. Later that afternoon, the surveyor then presented S1Adm with a handwritten note containing five patient names from 5/26/2020 date of service. Since these were patients that were seen within one month of the survey re-start date of 6/4/2020, these charts were housed in the filing storage area and were presented to the surveyor contemporaneously. On the same day, 6/4/2020, S1Adm was given a second handwritten note (on a yellow post-it paper) with the date 4/4/19 and names of 2 patients written on it. S1Adm explained to surveyor that since those charts were over one year old, those charts will be housed off-site and so, the charts could not be furnished for review on 6/4/2020. S1Adm also pointed out that one of the names of the patient that was written on the post-it note was remarkably familiar. S1Adm then told the surveyor that she would be going to get those charts at the close of business to have them ready for review for 6/5/2020. S1Adm also requested that the surveyor make a specific written request for the medical record of one out of two of the patients from 4/4/19. The surveyor then asked S1Adm why she made such a request. S1Adm explained that it would be in the interest of the OAF to have a written request because the surveyor was requesting a chart of a known "anti-abortion protester known for invading abortion clinics nationwide and has connections with domestic terrorist groups such as Army of God," and that "the Louisiana medical board had initiated an in-depth investigation as a result of baseless complaints that patient made against the clinic." The surveyor asked S1Adm what the outcome of the investigation was. S1Adm replied stating "the investigation was closed about a year ago." The surveyor then said "If the board already looked into this, then I guess we don't need her chart." The surveyor then requested the chart for another patient from 4/4/2019 encounter date and said, "get this one instead." On 6/5/2020, S1Adm presented 2 patient medical records for review to the surveyor. It is the position of the OAF that S1Adm presented all medical records requested by surveyors within 24hours of the request being made.

Therefore, the OAF was in compliance with patient medical records as delineated by the department in this section. It is WHCC's position that compliance with LAC 48: I. Chapter 44 Subchapter B. Administration and Organization §4425. Patient Medical Records and Reporting Requirements has been maintained and assured.

The OAF will prevent this alleged deficiency from recurring by providing patient records within the required time frame as stated by law. The clinic administrator will be responsible for obtaining the requested records, making a record of date and time of receipt of request, retrieving such records and making a record of the date and time of submission of the requested records. If the records are stored at the off-premises storage unit, the clinic administrator will assign a staff member to go off premises to retrieve such records within the allotted time frame as specified by law. The clinic administrator will ensure the archiving policy is properly implemented.

COMPLETE DATE
July 29, 2020

ID PREFIX TAG S 205

Portion(s) of summary statement of deficiencies

"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 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."

Provider's Plan of Correction

Please note that the OAF is currently disputing this section of the deficiency report. Nevertheless, OAF submits this supplemented Plan of Correction, which adds a second quality control measure. The facility's operational manual pertaining to blood glucose meter use directs that the OAF should use the manufacturer guide for performing quality control testing and system maintenance for

cleaning/disinfecting. The manufacturer's guide explains that there are 2 ways of performing quality control testing. One way is to use the internal automatic self-test (https://www.northcoastmed.com/pdf/manuals/nipro/truemetrix/True-Metrix-User-Guide.pdf). Supporting findings for this method of quality control practice can be found by clicking on these links: https://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html

https://www.fda.gov/medical-devices/vitro-diagnostics/blood-glucose-monitoring-devices#:~:text=In%20general%2C%20you%20prick%20your,passes%20through%20the%20test%20strip.

The department of health and hospital states in recent communication that "the links and reference materials were reviewed. Please review the materials again, as they do indicate quality control testing using control solutions is required." The manufacturer states "Quality Control Testing is used to detect errors that may occur due to test system errors, product defects, adverse environmental conditions and variance in operator performance. Ongoing Quality Control Testing is also used to detect any performance issues of the system over time. Facility Quality Control Testing Policy and Procedure should adhere to the manufacturer's instructions for use and regulatory guidelines. TRUE METRIX™ PRO is a no-coding system, which means the meter does not have to be coded to each lot of test strips. To assure accurate and reliable results, TRUE METRIX™ PRO offers two kinds of Quality Control Tests. These tests ensure that the TRUE METRIX™ PRO System is working properly and the user's testing technique is good." The OAF interprets and understands this to mean that there are two kinds of quality measures that the device uses. The OAF therefore understands this to mean that either kind of control testing is appropriate. The OAF understands that the two kinds of quality control are auto-self check and liquid control testing. The OAF determines that the auto check is a reliable and suitable quality control measure as defined by the manufacturer.

An excerpt from the FDA website provided above states in part "How can you check your meter's performance? There are three ways to make sure your meter works properly:

1. Use liquid control solutions:
    - every time you open a new container of test strips
    - occasionally as you use the container of test strips
    - if you drop the meter
    - whenever you get unusual results

- To test a liquid control solution, you test a drop of these solutions just like you test a drop of your blood. The value you get should match the value written on the test strip vial label.

2. Use electronic checks. Every time you turn on your meter, it does an electronic check. If it detects a problem it will give you an error code. Look in your meter's manual to see what the error codes mean and how to fix the problem. If you are unsure if your meter is working properly, call the toll-free number in your meter's manual, or contact your health care provider.
3. Compare your meter with a blood glucose test performed in a laboratory. Take your meter with you to your next appointment with your health care provider. Ask your provider to watch your testing technique to make sure you are using the meter correctly. Ask your health care provider to have your blood tested with a laboratory method. If the values you obtain on your glucose

meter match the laboratory values, then your meter is working well and you are using good technique."

The OAF's interpretation and understanding of the FDA's guidance is that there a three ways of quality control measures for a glucometer. One of the three ways is that an electronic check can be run automatically by the device itself. This specification is resonated by the manufacturer as well. Therefore, the OAF determines that electronic check/auto-self check method is reliable and suitable quality control measure that aligns with acceptable standards.

Upon interview with the surveyors, S1Adm asserted that the OAF currently used the device's automatic self-quality control assessment. S1Adm explained that, the glucometer device runs its own auto control assessment as described in the manufacturer's manual. Therefore, it is the OAF position that this aspect of blood glucose meter quality control was currently implemented.

Pending informal dispute resolution decision, the OAF will additionally implement liquid quality control testing of the glucometer device. The liquid controls that will be used are as specified by the manufacturer. A control logbook will be maintained to document when controls are run. The liquid controls will be performed (as recommended by the manufacturer):

- Before using the system for the first time.
- For practice to ensure that testing technique is good.
- When opening a new vial of test strips.
- If results seem unusually high or low based on the patient's condition.
- If strip vial has been left open or exposed to extreme heat, cold or humidity.
- Whenever a check on the performance of the system is needed.
- If meter damage is suspected (meter dropped, crushed, wet, etc.)

The quality assurance policy will be updated to include glucometer liquid control testing. The clinic administrator will be responsible for implementing and executing this quality measure. In addition to the above stated reasons for performing the liquid controls, the D.O.N will perform monthly liquid controls, document performance in the assigned logbook and submit to the clinic administrator to ensure proper policy implementation and execution. This is will assure compliance.

The pertinent clinic staff/members that will be responsible for using the blood glucose measuring device have completed the TRUE METRIX PRO training program suggested by the device manufacturer. The training checklist and post-training test have been placed in their respective employee files.

COMPLETE DATE
July 29, 2020

Training Checklist

TRUE METRIX™ PRO Blood Glucose System Training Checklist (Please print)

Name_____ **Date** ___/___/___

Title_____

Facility _____

1. The Facility Personnel has completed the following:

____ Read the Owner's Booklet
____ Read the test strip Instructions for Use
____ Read the Control Solution Instructions for Use
____ Read the sections in the Comprehensive Resource Guide located prior to the Training Program section

2. The Facility Personnel understands the following:

____ Use of the TRUE METRIX™ PRO System in a clinical setting
____ System specifications
____ Limitations and critical safety information, including that the TRUE METRIX™ PRO System must not be used for certain patients (neonate)

3. Familiarization with the components of the system.

a. Meter

____ Location of serial number for the meter
____ Review of meter buttons and functions

b. Test strips

____ Identifies lot number
____ Writes open date on test strip vial label
____ Understands the use by dates, both printed and written
____ Reviews proper handling of test strips including recapping of the test strip vial immediately after removing test strip
____ Demonstrates proper insertion of the test strip into the meter

c. Control Solution

____ Identifies lot number
____ Writes open date on control solution bottle label
____ Understands the use by dates, both printed and written
____ Identifies control test level
____ Identifies control test ranges

Training Checklist cont.

Name_____

4. Quality Control Tests

____ Understands manufacturer's instructions for quality control testing
____ Understands the purpose of the automatic self-check of the meter upon insertion of test strip into Test Port
____ Understands the purpose of control tests, the frequency of testing, and the number of control solution levels to be tested
____ Understands the testing temperature range and what may result if testing temperature is out of range
____ Identifies correct (unopened vs. opened) use by dates on the control solution bottle
____ Identifies the correct control test range for the control solution level and understands the troubleshooting if the control test result is not within the acceptable range
____ Demonstrates the procedure using the control solution
____ Records the control test result on the TRUE METRIX™ PRO Quality Control Testing Data Form

5. Blood Collection

____ Understands the proper technique of capillary blood collection for both fingertip and forearm samples
____ Understands when fingertip should be used instead of forearm
____ Demonstrates the ability to obtain a sufficient amount of blood for testing from both a fingertip and forearm
____ Understands facility's procedure on obtaining blood samples
____ Understands the importance of the use of the recommended type of blood collection tube for collecting a venous blood sample for the testing on the TRUE METRIX™ PRO Blood Glucose Monitoring System

6. Demonstration of Blood Glucose Testing

____ Demonstrates proper blood glucose testing procedure for the TRUE METRIX™ PRO System
____ Understands the proper blood application to the Sample Tip and the significance of the symbols in the Display

7. Patient Blood Glucose Test Results

____ Demonstrates the proper documentation of test results
____ Understands that use of Memory, Averages, and Ketone Test Reminder features may not be appropriate for multiple-patient facilities
____ Proper disposal of biohazardous materials (contaminated biological materials and sharps) per facility policy and procedures

8. Care, Cleaning/Disinfection, Storage of System

____ Understands recommended procedures for cleaning and disinfecting the TRUE METRIX™ PRO Meter
____ Understands facility policy and procedure for Medical Device Cleaning and Disinfection
____ Demonstrates battery replacement
____ Understands proper storage of meter, test strips, and control solution

Training Post Test

TRUE METRIX™ PRO Blood Glucose System Training Written Test (Please print)

Name_____ **Date** ____/____/____

Title_____

Facility Name _____

Address_____

Phone/Fax _____

True or False

1. It is recommended that healthcare personnel complete the training program prior to using the TRUE METRIX™ PRO Blood Glucose Monitoring System for the first time in a facility.

   _____True _____False

2. The TRUE METRIX™ PRO System can be used on neonates.

   _____True _____False

3. Quality Control Testing should be performed per your facility's policies and procedures.

   _____True _____False

4. Any control solution can be used with the TRUE METRIX™ PRO System.

   _____True _____False

5. Capillary blood testing of critically ill patients with reduced peripheral blood flow (for example: shock, severe hypotension, severe dehydration, hyperglycemia with hyperosmolarity, with or without ketosis) should be tested with the TRUE METRIX™ PRO System.

   _____True _____False

6. If the meter becomes soiled, wipe it off with PDI Super Sani Cloth Wipes.

   _____True _____False

7. The battery should be replaced with an AAA alkaline battery.

   _____True _____False

Training Post Test cont.

TRUE METRIX™ PRO Blood Glucose System Training Written Test (Please print)

Name_____

Multiple Choice (choose only one answer for each question)

1. Training on the use of the TRUE METRIX™ PRO System consists of reviewing the following:

    a) The Comprehensive Resource Guide
    b) The Owner's Booklet
    c) Test strip Instructions for Use
    d) Control solution Instructions for Use
    e) All of the above

2. If a point-of-care blood glucose test is ordered on a patient, the healthcare professional performing the test must:

    a) Identify treatment(s) patient may be on or starting
    b) Identify drug therapy(ies) patient may be on or starting
    c) Identify and use appropriate point-of-care blood glucose testing system
    d) All of the above

3. The TRUE METRIX™ PRO System utilizes the following enzyme to test for glucose:

    a) Glucose oxidase (GO)
    b) GDH-FAD
    c) GDH-NAD
    d) GEH-PDQ

4. The following sample(s) is/are appropriate for testing on the TRUE METRIX™ PRO System:

    a) Capillary whole blood from fingertip or forearm
    b) Venous whole blood collected in a Sodium Flouride tube
    c) Plasma
    d) Urine
    e) Venous whole blood collected using ONLY a sodium heparin tube.
    f) a and c
    g) b and d
    h) a and e

5. The following recommended Quality Control Tests are performed on the TRUE METRIX™ PRO:

    a) One level of control solution and a patient sample
    b) One level of control solution
    c) A low level of control solution and a high level of control solution
    d) Meter automatic self-test and a minimum of 2 levels of control solution

Quality Control Testing Data Form

QUALITY CONTROL TESTING DATA FORM

Meter Serial Number ________________ (see number on Meter label below the bar code) *Note any problems in Troubleshooting section below.

Date	Time	Test Strips			Control Solution - Level ______					Control Solution - Level ______					Control Solution - Level ______					Initials	*
		LOT	EXP	Date Opened	LOT	EXP	Date Opened	Acceptable Range	Result	LOT	EXP	Date Opened	Acceptable Range	Result	LOT	EXP	Date Opened	Acceptable Range	Result		

*TROUBLESHOOTING

Date	Problem	Action	Initials

ID PREFIX TAG S243

Portion(s) of summary statement of deficiencies

"S243 Infection Control:

- Who will monitor the processing of instruments (including, but not limited to, decontamination, packaging, sterilization, and storage), the workflow of the sterile processing area, the transport of contaminated instruments/supplies, use and processing of glass suction canisters? How will they monitor and how often?
- With regards to the rust formation on exam tables, how often will the administrator examine the table as part of the cleaning/maintenance log?"

Provider's Plan of Correction

In addition to the OAF plan of correction delineated in the immediate jeopardy response and the previously submitted plan of correction, the OAF will monitor the scrub room/instrument processing (workflow, instrument and glass suction canisters) area via live camera feed that will be monitored by the clinic administrator to ensure compliance. The transport of the contaminated instruments to the processing area will be monitored with competency/skill/performance evaluations which are conducted annually per facility policy. This will ensure compliance of proper instrument transport and prevent recurrence of this deficiency.

The examination tables will be visually examined for rust formation as part of the daily cleaning log and monthly maintenance logs. The logs have been updated to reflect "visual inspection of exam tables for rust formation." As per facility policy, the clinic administrator is responsible for implementation of the quality assurance policy.

COMPLETE DATE

June 17, 2020 - Immediate Jeopardy removal
July 6, 2020 – New examination table purchase
July 29, 2020 – daily cleaning log update, monthly maintenance log update

[redacted]

7/30/20