State of Virginia

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AF-0002	A. BUILDING _____ B. WING _____	10/04/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VIRGINIA LEAGUE FOR PLANNED PARENTHOOD	201 N. HAMILTON STREET RICHMOND, VA 23221

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T 000	Initial Comments	T 000		

Two (2) Medical Facilities Inspectors from the Virginia Department of Health's Office of Licensure and Certification conducted an unannounced First Trimester Abortion Facility (FTAF) biennial licensure inspection on October 2, 2018 and October 4, 2018. The surveyors conducted observations, interviews and document reviews during the investigation process to determine compliance.

The facility was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Effective 03/22/2017). The deficiencies cited follow in this report.

T 195 12 VAC5-412-220 B Infection Prevention — T 195

Written infection prevention policies and procedures shall include, but not be limited to:

1. Procedures for screening incoming patients and visitors for acute infectious illnesses and applying appropriate measures to prevent transmission of community-acquired infection within the facility;

2. Training of all personnel in proper infection prevention techniques;

3. Correct hand-washing technique, including indications for use of soap and water and use of alcohol-based hand rubs;

4. Use of standard precautions;

5. Compliance with blood-borne pathogen requirements of the U.S. Occupational Safety & Health Administration;

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T 195	Continued From Page 1 6. Use of personal protective equipment; 7. Use of safe injection practices; 8. Plans for annual retraining of all personnel in infection prevention methods; 9. Procedures for monitoring staff adherence to recommended infection prevention practices; and 10. Procedures for documenting annual retraining of all staff in recommended infection prevention practices. This RULE: is not met as evidenced by: Based on observation, interview and document review, it was determined the facility failed to perform safe injection practices by: 1. Not using an aseptic technique to prepare intravenous medication; 2. Not using a filter needle to prepare medication from a glass ampoule. The findings include: On October 4, 2018 at 10:34 a.m., surveyors observed Staff Member #13 withdraw midazolam from a vial and fentanyl from an ampoule in preparation for a surgical abortion. Staff Member #13 removed the storage cap from the single dose vial of midazolam and pierced the septum with a new needle. Staff Member #13 failed to use an aseptic technique by not cleaning the vial septum with an alcohol wipe prior to piercing. After withdrawing the midazolam, Staff Member #13 transitioned to the fentanyl contained in a glass ampoule. Without wiping the exterior portion of the glass ampoule, Staff Member #13 utilized a bare	T 195	Regarding Item T195 # 1. All staff will receive retraining on proper technique for injection administration, per VLPP policy and CDC guidance. Such training will include how to use an aseptic technique to prepare intravenous medication. All staff retraining will be completed by November 29, 2018. Additionally, within two weeks of retraining all staff will be observed for adherence and annual observation will be added to training protocol. Regarding Item T195 #2. VLPP will purchase filtered needles to use with the remaining supply of glass vials. This purchase was made mid-October 2018. After using current supply of glass ampules, VLPP will switch to vials, which do not require use of filtered needles. VLPP will keep a small supply of filtered needles on stock. Additionally, VLPP will update internal policies to include the use of filtered needles whenever using glass needles. This policy will be updated by November 29, 2018.	

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hand to break the top portion of the vial to access the medication inside. Then with a new non-filter needle, Staff Member #13 entered the opening of the glass ampoule and withdrew the required medication for the procedure. Surveyors asked Staff Member #13 about his/her choice to use a non-filter needle to withdraw the medication from the ampoule. Staff Member #13 explained that because it is a single use ampoule a filter needle is not required.

On October 4, 2018 at 11:47 a.m., surveyors asked Staff Member #13 about failing to wipe the septum of the midazolam vial prior to piercing with a needle. Staff Member #13 stated "It's a single dose vial; not going back in [withdrawing additional doses]." Staff Member #13 further explained that because of the single use, a wipe of the septum is not needed.

A review of the facility's policy titled "Pharmaceuticals Policies and Procedures" states in part:

"Injection Guidance
Follow proper infection control practices and maintain aseptic technique during the preparation and administration of injected medications (e.g., perform hand hygiene, wipe the vial top with alcohol, etc.)"

The Centers for Disease Control and Prevention (CDC) provides the following guidance regarding Safe Practices for Medication Injections

"How should I draw up medications?
Parenteral medications should be accessed in an aseptic manner. This includes using a new sterile syringe and sterile needle to draw up medications while preventing contact between the injection materials and the non-sterile environment. Proper

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T 195	Continued From Page 3 hand hygiene should be performed before handling medications and the rubber septum should be disinfected with alcohol prior to piercing it." The American Society of Health-system Pharmacists (ASHP) provides the following guidance when preparing medication from a glass ampoule based in part on standards set by the United States Pharmacopeia in chapter 797. "To minimize particulate contamination, 5 micron filter straws or filter needles must be used when withdrawing contents of ampuls."	T 195		
T 260	12 VAC5-412-240 D Medical Testing and Laboratory Services All tissues removed resulting from the abortion procedure shall be managed in accordance with requirements for medical waste pursuant to the Regulated Medical Waste Management Regulations (9VAC20-120). This RULE: is not met as evidenced by: Based on observation, interview and document review, it was determined the facility failed to comply with Regulated Medical Waste Management Regulation 9VAC20-120-360 by not labeling medical waste with the date first placed in storage on the outer packaging. The findings include: During a tour of the facility on October 2, 2018 at 10:23 a.m., Staff Member #5 walked surveyors to the refrigerator used for the storage of products of conception (POC). Staff Member #5 opened the	T 260	Regarding item T260 VLPP began labeling all bagged medical waste on October 8, 2018 with the collection date and will continue to do so. VLPP management will check periodically to ensure that all waste has been labeled. Additionally, VLPP's internal policy will be updated to note that per Regulated Medical Waste Management policy 9VAC20-120-360 labeling appropriately requires that medical waste containers in storage at the facility must be labeled with the collection date.	

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T 260	Continued From Page 4 refrigerator and surveyors observed a single red bio-hazard bag that Staff Member #5 advised is used for the storage of medical waste from multiple procedures. Surveyors noticed the bag did not contain a label indicating the date the facility placed the medical waste in storage. Surveyors asked Staff Member #5 if the facility labels medical waste placed in the refrigerator with a date first stored. Staff Member #5 advised "they [the facility] does not place a date on the bag." A review of the facility's policy titled "Containment and Disposal of RMW" states in part: "All regulated medical waste will be placed in containers which are:... labeled appropriately."	T 260		
T 370	12 VAC5-412-320 B Required Reporting The abortion facility shall report the following events to OLC: 1. Any patient, staff or visitor deaths. 2. Any serious injury to a patient. 3. Medication errors that necessitate a clinical intervention other than monitoring; and 4. A death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the abortion facility grounds; This RULE: is not met as evidenced by: Based on interview and document review, it was determined the facility staff failed to report a serious injury to the Office of Licensure and Certification (OLC) for one (1) of one (1) events	T 370	As discussed with inspectors on the final day of the inspection, VLPP defines serious adverse events as any untoward occurrence that results in: 1. Patient death 2. Life threatening adverse or device reaction 3. 3. Prolonged hospitalization (> 48 hours) 4. Persistent or significant disability To ensure that all incidents are reported as indicated, the Medical Director will audit all patient cases with ER referrals within 24 hours and report to COO/CEO who will report cases to OLC as appropriate. The three with meet monthly and review any cases to ensure appropriate reporting occurred.	

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T 370	Continued From Page 5 from January 2017 through September 2018. The findings included: During the entrance conference on October 2, 2018 at 10:32 a.m. with Staff Member #9, the surveyors requested a list of patients transferred from the facility for additional medical care and any patients meeting the criteria for events reportable to OLC. Staff Member #9 reported only one patient was transferred from the facility for additional medical treatment. Staff Member #9 reported the facility did not have any events that met the criteria for reporting to OLC. The transferred patient was included in the survey sample and designated Patient #11. A review of Patient #11's medical record documented a surgical abortion in [redacted]. Patient #11's medical record indicated at the end of the procedure the physician noted [redacted] and the physician requested a patient transfer from the facility to a local hospital. Patient #11's medical record documented the patient required [redacted]. During an interview conducted on October 2, 2018 at 5:03 p.m. with Staff Member #14, a physician, the surveyor asked what might be considered a serious injury. Staff Member #14 stated, "A serious injury is any injury that requires another procedure or additional medical treatment." The surveyor asked whether Patient #11's case would be considered a serious injury. Staff Member #14 reported remembering Patient #11's case. Staff Member #14 stated, "It was a serious injury. We did follow up with the patient. The patient did require [redacted] but was home and doing well when we called."	T 370		

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The surveyor inquired whether OLC had been notified of the event. Staff Member #14 reported the surveyors would have to follow up with Staff Member #10.

At approximately 4:45 p.m. on October 2, 2018 during a telephone interview, with Staff Member #10. The surveyor requested documentation by the facility regarding notification of OLC related to Patient #11's case.

During an interview on October 4, 2018 at 9:03 a.m., the surveyor asked whether the facility had notified OLC and to review the documentation regarding Patient #11's case. Staff Member #10 stated, "No, I did not notify the State [OLC]. I could not find a place to confidentially upload the information other than through behavioral health services." Staff Member #10 requested to "see the regulation related to the requirement." The surveyors reviewed the regulation with Staff Member #10. Staff Member #10 agreed that the regulation requires serious injuries to be reported to OLC as one of the four reportable events.