The Virginia League for Planned Parenthood

June 21, 2012

Hand Delivered

Kathaleen Creegan-Tedeschi
Supervisor, Acute Care Licensing
Office of Licensure and Certification
Virginia Department of Health
9960 Mayland Drive, Suite 401
Henrico, VA 23233-1485

Dear Ms. Creegan-Tedeschi:

Enclosed, please find our plan of corrective action for the deficiencies noted in the Licensure Inspection Report received by the Virginia League for Planned Parenthood on June 11, 2012 for our Initial Abortion Facility Licensure survey, completed on May 18, 2012.

In addition to our responses on the report form, we have included the following attachments:

A. A meeting agenda from a Patient Services Staff training
B. A copy of our monthly quality assurance report/checklist
C. A copy of the attestation provided by our architect

Please feel free to call me at (804) 482-6161 with any questions.

Sincerely,

Paulette McElwain
President and CEO

Enclosures

201 Hamilton Street, Richmond, VA 23221 | Phone 804 355 4358 | Fax 804 355 5216 | www.vlpp.org

State of Virginia

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IOENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	FTAF-010	A. BUILDING _____ B. WING _____	05/18/2012

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

(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
T 100	12 VAC 5- 412 Initial comments An announced Initial Licensure Abortion Facility inspection was conducted at the above referenced facility on May 17, 2012 through May 18, 2012 by two (2) Medical Facilities Inspectors from the Virginia Department of Health's, Office of Licensure and Certification. The facility was out of compliance with the State Board of Health 12 VAC 5-412, Regulations for Abortion Facility's effective December 29, 2011. Deficiencies were identified, cited, and will follow in this report.	T 100	T 275: Service Managers conducted a review of medication lot tracking logs on 5/21/12 to confirm that no Estrace vaginal cream had been dispensed on or after 1/1/12, thereby ensuring that no patients had received expired product. All expired products identified during the inspection were immediately removed and properly discarded. It is VLPP policy for staff to confirm product has not expired at the time of use or dispensing. Every medication or device given to a patient is recorded in a lot tracking log, which includes a notation of the expiration date.	05/21/12
T 275	12 VAC 5-412-260 C Administration, storage and dispensing of dru C. Drugs maintained in the facility for daily administration shall not be expired and shall be properly stored in enclosures of sufficient size with restricted access to authorized personnel only. Drugs shall be maintained at appropriate temperatures in accordance with definitions in 18 VAC 110-20-10 This RULE: is not met as evidenced by: Based on observation and staff interview, the clinic staff failed to ensure drugs and supplies available for administration were properly stored and not expired in 3 of 3 examination rooms, and one physician's station locked cabinet Medications and procedure supplies were found to be expired and/or not dated when opened. The findings included: During the tour of the clinic conducted 5/17/12 at 10:45 a.m., the following was observed:	T 275	Service Managers conducted a review of exam rooms, procedure rooms and supply rooms/areas on 5/21/12 to confirm that no opened, multi-use products lacked a date of opening; any unlabeled products were properly discarded. It is VLPP policy for staff to label (write the date with a Sharpie marker or attach a sticker with the date) any multi-use product at the time of opening. Based on current usage rates, no multi-use vial of Lidocaine remains in the clinic for more than a one-week period (typically used within 48 hours), and no multi-use tube of KY jelly remains in the clinic for more than a one-month period (typically used within one week). Routine use of nitra-test paper has been discontinued at VLPP; there was no risk of use of the identified expired product, as it was incorrectly stored in a service area where it would not have been accessed for patient use.	05/21/12

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Paulette Moore	President & CEO	6/20/2012

State of Virginia

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T 275	Continued From Page 1 In examination room #1, one box containing Estrace vaginal cream (An estrogen/hormonal cream used for the treatment of symptoms associated with menopause. Drug Information Handbook for Nursing 2007 Turkoski, Lance, Bonfiglio page 450) was found to be expired 1/2012. A tube of KY brand lubricating jelly used for daily procedures was opened and not dated as to when it was opened. In exam room #2, two (2) tubes of KY brand lubricating jelly were opened and not dated. In exam room #3, four (4) boxes of Estrace vaginal cream were found expired on 1/2012 and two (2) tubes of KY brand lubricating jelly were not dated when opened. In the locked cabinet at the physician's station, one multi-dose vial of Lidocaine 1% solution for injection was found to be opened and not dated. There was a small plastic bin containing 25-30 (twenty-five to thirty) 22 gauge butterfly venous access needles with tubing which had been removed from their protective/sterile packaging The tubing was exposed with no protective cap on the end which would allow bacteria/dust to enter the tubing. Staff member# 3 stated the previous physician "liked to do that in order to have all the needles ready, but should not have opened them all." There was also "nitra-test" paper (3) three packages which had expired 10/2008. All items that were expired and not dated were removed at the time of discovery by staff member #2. On 5/19/12 at 2:30 p.m. the survey team discussed the findings with staff members #1 and #2. No further information was provided by the end of the survey	T 275	T275 (cont). Service Managers conducted a review of exam rooms, procedure rooms and supply rooms/areas on 5/21/12 to ensure that all products in sterile packaging were sealed and intact. It is VLPP policy for all items in sterile packaging to remain sealed/intact until time of immediate/direct use for patient care and to confirm the integrity of the packaging at the time of use. VLPP conducts follow-up visits and tracks all patient complications, including infections, and a review of our complication log identified no reported IV site infections. The Interim Patient Services Director conducted a staff training on 06/04/12 to review handling of multi-use products, products that expire and sterile products. The training consisted of a team scavenger hunt and review of relevant policy and procedures (see Attachment A, Training Agenda). VLPP has developed a monthly QA review by Service Managers to include formal inspection of inventory and supplies for the items discussed in this report (opening dates, expiration dates, sterile packaging) and documentation of same (see Attachment B, VLPP Monthly Manager QA Check/Report).	05/21/12 06/04/12 06/15/12

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T 400	Continued From Page 2	T 400		
T 400	12 VAC 5-412-380 local and state codes and standards Abortion faculties shall comply with state and local codes, zoning and building ordinances, and the Uniform Statewide Building Code. In addition, abortion facilities shall comply with Part 1 and sections 3.1-1 through 3.1-8 and section 3.7 of Part 3 of the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute, which shall take precedence over Uniform Statewide Building Code pursuant to Virginia Code 32.1-127.001. Entities operating as of the effective date of these regulations as identified by the department through submission of Reports of Induced Termination of Pregnancy pursuant to 12 VAC 5-550-120 or other means and that are now subject to licensure may be licensed in their current buildings if such entities submit a plan with the application for licensure that will bring them into full compliance with this provision within two years from the date of licensure. Refer to Abortion Regulation Facility Requirements Survey workbook for detailed facility requirements. This RULE: is not met as evidenced by: Based on interview and facility tour it was determined the facility failed to have an architect attestation and failed to meet FGI (AIA) Guidelines for Chapters 3.1 and 3.7. The findings include: 1. On May 17, 2012 a facility tour was conducted with the Administrator and the Director of Clinical Services, between 9:00a.m. and 11:30 a.m. During the facility tour there was no evidence that the facility met the state and local codes and building ordinances.	T 400	T 400: The report states that, "During the facility tour there was no evidence that the facility met the state and local codes and building ordinances." This is incorrect. An architect's attestation was presented to the surveyors at the time of inspection as evidence that VLPP's building is fully compliant with current state and local codes and building ordinances. A copy of that letter is attached. This specific issue is addressed in the first paragraph of the letter (Attachment C). Additionally, the same architect's letter verifies that VLPP's building is fully compliant with the applicable sections of Part 1 and section 3.7. As noted in this report, there are two items from section 3.1 of the 2010 FGI Guidelines that must be addressed to come into full compliance: 1) 3.1-8.2.4.1 of the 2010 FGI Guidelines require that patient care areas must have return air ducting. This item does not affect patient safety and will be brought into compliance within 24 months of the date that VLPP's Abortion Facility License is issued. 2) Per 3.1-8.3.3.1 of the 2010 FGI Guidelines VLPP's emergency electrical system requires a small modification. A new number-10 bonding jumper will need to be installed. This item does not affect patient care and will be brought into compliance within 24 months of the date that VLPP's Abortion Facility License is issued.	N/A Within two years of licensing. Within two years of licensing.

State of Virginia

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T 400	Continued From Page 3	T400		

The facility failed to have an attestation from a licensed Architecture that the first floor of facility met the required FGI (AIA) guidelines. A letter from the Architecture. dated May 14, 2012, stated under HVAC Return Air Systems, stated that rooms 124, 126 and 127 had a return-air ducted system. The remaining spaces the first floor will require return-air duct installation. A new number-10 bonding jumper will require instillation to meet. the code for emergency electrical service.

The Administrator acknowledged that the HVAC return system and the the emergency electrical service still needed work to meet the Code of Virginia. This interview occurred in the facility's conference room, on May 17, 2012, at 09:30a.m.

Patient Services Staff Meeting/Training Agenda
June 4, 2012 10 AM

1. Review of OLC inspection results

2. Challenge: Team Scavenger Hunt

   - 1 single use medication
   - 1 single use item (non-medication)
   - 1 multi-use medication
   - 1 multi-use item (non-medication)
   - 1 medication or device that expires within 12 months
   - 1 item (non-medication) that expires within 6 months
   - 1 sterile item in original packaging
   - 1 non-sterile item that is used on patients

3. Policy/Procedure Review

A. Label multi-use items with date of opening (e.g. write on with Sharpie); once opened, expiration is within 28 days unless otherwise specified by manufacturer.

Examples for discussion:

- KY Jelly Tubes
- Lidocaine Vials
- Microcuvette Bottles

B. All staff members are responsible for checking expiration date at the time of using a product or retrieving medication; managers will conduct monthly review of stock.

C. Items in sterile packages must remain sealed until time of use or are no longer considered sterile.

Attachment B
Tag # 275

VLPP MONTHLY MANAGER QA CHECK/REPORT

(to be completed and submitted to supervisor by the 10th of the following month)

Month/Year:_____ **By:**_____

*Note: Any "no" responses must be explained on reverse.

1. Was the refrigerator temperature checked every day the center was open?

Location	Checked	WNL
Reception	yes no	yes no
Lab	yes no	yes no
Recovery Room	yes no	yes no

2. Was the room temperature checked every day the center was open?

Location	Checked	WNL
FP/PC Lab	yes no	yes no
AB Lab	yes no	yes no

3. Was the lot currently in circulation tested prior to use?

Test Kit	Lot Testing Recorded	WNL
HSPT	yes no	yes no
LSPT	yes no	yes no
Glucose strips	yes no	yes no
Microcuvettes	yes no	yes no
Rapid HIV	yes no	yes no
Urine dipstick	yes no	yes no

4. Were Rh controls performed every day Rh testing was performed?

Location	Checked	WNL
AB Lab	yes no	yes no
	yes no	yes no
	yes no	yes no

5. Was the autoclave spore test performed each week?

Location	Result Recorded	WNL
Sterilization Room	yes no	yes no

6. Was the autoclave cleaning/flushing performed this month? yes no

7. Was the emergency cart reviewed for adequate stock and expiration dates? yes no

8. Inventory Review (to include cabinets, drawers, refrigerators, etc.):

- Multi-use products were dated upon opening and are within designated shelf life
- Medications and other related products are not expired
- Sterile packages have not been compromised (e.g. partially opened)
- Stock is organized so that oldest products (with earliest expiration dates) will be used first

COMMENTS:

FP/PC Service Area	Initials
Reception area refrigerator	
Reception hallway cabinet	
Exam Room 4	
Exam Room 5	
Exam Room 6	
Exam Room 7 (lab)	
Exam Room 8	
Exam wing hallway cabinets	

AB Service Area	Initials
Exam Room 1	
Exam Room 2	
Exam Room 3	
Lab	
Procedure hallway cabinets	
Recovery Room	
Procedure Room 1	
Procedure Room 2	

***Record any QA deficiencies for the month below:**

Finding:

Immediate actions taken:

Follow-up actions taken:

Attachment C
Tag # 400

Baskervill 115
1897 2012

May 14, 2012

Ms. Paulette M. McElwain
CEO/President
Virginia League for Planned Parenthood, Incorporated
201 N. Hamilton Street
Richmond, Virginia 23221

Re: 201 N. Hamilton Street

Dear Ms. McElwain:

In 2008, Baskervill provided architectural and engineering services for the proposed Alteration and Additions for Virginia League for Planned Parenthood, located at 201 N. Hamilton Street, Richmond, Virginia 23221. The City of Richmond issued a building permit and upon completion of the project, a Certificate of Occupancy for the project. In issuing the Certificate of Occupancy, the City agreed that the building design met all zoning and applicable building codes in the City Zoning Ordinance and the 2006 Edition of the Uniform Statewide Building Code.

In 2011, at the request of Virginia League for Planned Parenthood, Baskervill reviewed the building for compliance with the Guidelines for Design and Construction of Health Care Facilities the applicable sections (Part 1 and sections 3.1 and 3.7 of Part 3), 2010 Edition. In our review of the building's electrical and mechanical systems we found the following items not in compliance with the guidelines:

3.1-8.2.4.1 HVAC Return Air Systems:
- The first floor of the building has a return-air ducted system in Rooms 124, 126 & 127. The remaining spaces on the first floor will require return-air duct installed from the existing return air duct to each individual room.

3.1 – 8.3.3.1 Emergency electrical service:
- A new number-10 bonding jumper will require installation to meet code.

Our review found that VLPP's facility is compliant with the applicable sections of the 2010 edition of the Guidelines for Design and Construction of Health Care Facilities.

As mentioned above, one of the key features of the building design is the HVAC system for two treatment rooms. The treatment rooms have been designed with positive air pressure, 4 outdoor air changes per hour, 20 total air changes per hour, all return air is exhausted and the supply air has a 30-60% relative humidity with 68-75 degree air temperature. This separate mechanical system is fully ducted (supply and return air).

If you have any additional questions concerning the building design please feel free to contact me.

Sincerely,

Bruce W. Tyler AIA, LEED ap
Principal

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JUN 21 2012
VDH/OLC

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