

2018-07-25 14:25

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**John Bel Edwards**  
GOVERNOR



**Rebekah E. Gee MD, MPH**  
SECRETARY

**State of Louisiana**  
Louisiana Department of Health  
Bureau of Legal Services

July 25, 2018

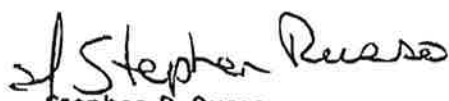
Representative H. Bernard LeBas  
Louisiana House of Representatives  
P.O. Box 370  
Ville Platte, LA 70586-0370

Via Facsimile Only

Dear Representative LeBas:

Enclosed please find the Statement of Deficiencies per your records request. Please contact me at 225-342-1115, if you have any questions.

Sincerely,

  
Stephen R. Russo  
Executive Counsel

Enclosure

2018-07-25 14:26

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Health Standards Section

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  B00004641	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING: _____	(X3) DATE SURVEY COMPLETED  C 06/19/2018
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NAME OF PROVIDER OR SUPPLIER  WOMENS HEALTH CARE CENTER INC	STREET ADDRESS, CITY, STATE, ZIP CODE 2701 GENERAL PERSHING STREET NEW ORLEANS, LA 70115
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(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	<p>Initial Comments</p> <p>Complaint #LA00048525 and Complaint #LA00048580. Tags S0109 and S0193 were cited as a result of Complaint #LA00048525. Tag S0253 was cited as a result of Complaint #LA00048580.</p> <p>Abbreviations:</p> <p>CFR Code of Federal Regulations RS Revised Statute</p> <p>Definitions:</p> <p>License-a Louisiana Controlled Dangerous Substances (CDS) License</p> <p>Controlled Dangerous Substance or Controlled Substance-any substance defined, enumerated, or included in federal or state statute or regulations, 21 CFR §1308.11 - 15 or R.S. 40:964</p>	S 000		
S 193	<p>4431-G-2-3 Pre-Operative, Intra-Operative, Post-Operative</p> <p>2. Oral Information from a Physician or Qualified Person</p> <p>a. When an initial contact is made by a person seeking to schedule an abortion for herself, a minor, or other adult woman, regardless of the means of contact, the physician who is to perform the abortion or any qualified person acting on behalf of the physician shall inform the person of the internet address of the department's abortion alternatives and informed consent website which includes links to mental health counseling.</p> <p>3. Oral Information Provided by Physician, Referring Physician, or Qualified Person</p> <p>a. At least 24 hours before a scheduled</p>	S 193		

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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NAME OF PROVIDER OR SUPPLIER  <b>WOMENS HEALTH CARE CENTER INC</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>2701 GENERAL PERSHING STREET NEW ORLEANS, LA 70115</b>
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S 193	<p>Continued From page 1</p> <p>abortion the physician who is to perform the abortion, the referring physician, or a qualified person shall inform the pregnant woman seeking an abortion, orally and in-person that:</p> <ul style="list-style-type: none"> <li>i. medical assistance may be available for prenatal care, childbirth, and neonatal care and that more detailed information on the availability of such assistance is contained on the department's website and printed materials;</li> <li>ii. a pamphlet is available that describes the unborn child and contains a directory of agencies that offer an abortion alternative;</li> <li>iii. the father of the unborn child is liable to assist in the support of the child, even if he has offered to pay for the abortion. In the case of rape this information may be omitted;</li> <li>iv. the pregnant woman seeking an abortion is free to withhold or withdraw consent to the abortion at any time before or during the abortion without affecting her right to future care or treatment and without loss of any state or federally funded benefits to which she might otherwise be entitled.</li> </ul> <p>This Rule is not met as evidenced by: Based on observation and interview, the facility failed to ensure when an initial contact is made by a person seeking to schedule an abortion for herself, a minor, or other adult woman, regardless of the means of contact, the physician who is to perform the abortion or any qualified person acting on behalf of the physician shall inform the person of the Internet address of the department's abortion alternatives and informed consent website which includes links to mental</p>	S 193		

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NAME OF PROVIDER OR SUPPLIER  WOMENS HEALTH CARE CENTER INC	STREET ADDRESS, CITY, STATE, ZIP CODE 2701 GENERAL PERSHING STREET NEW ORLEANS, LA 70115
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S 193	<p>Continued From page 2</p> <p>health counseling for 5 (#6-#10) of 5 (#6-#10) sampled patients reviewed for oral information out of a total sample of ten patients (#1-#10).</p> <p>Findings:</p> <p>On 06/18/2018 at 11:15 AM, the observations made upon entrance and tour of the facility revealed Women's Rights and Pregnancy Resources posters in rooms throughout the facility, including all patient rooms and waiting rooms, which listed the Hotline 1-866-729-1788 and www.PregnancyInfo.la.gov on the posters.</p> <p>On 06/18/2018 at 11:30 AM, an auditory review of the facility's automated telephone recording, including all available options, was conducted in the presence of S1Administrator. The automated recording did not provide the internet address of the department's abortion alternatives and informed consent website which includes links to mental health counseling.</p> <p>During an interview on 06/18/2018 at 11:43 AM, S4Administrative Assistant stated she was trained by S2Former Administrator regarding what information to obtain and provide during initial contact with patients in October 2017, including how to speak to patients over the phone and obtaining the correct contact information. S4Administrative Assistant confirmed that she was primarily responsible for answering calls and scheduling appointments when the initial telephone contact was made by a person seeking to schedule an abortion. S4Administrative Assistant revealed that S1Administrator, S6Medical Assistant, and any other available staff also answered telephone calls. She stated that she did not provide the internet address of the department's abortion alternatives and informed</p>	S 193		

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NAME OF PROVIDER OR SUPPLIER  WOMENS HEALTH CARE CENTER INC		STREET ADDRESS, CITY, STATE, ZIP CODE 2701 GENERAL PERSHING STREET NEW ORLEANS, LA 70116		
(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 193	<p>Continued From page 3</p> <p>consent website to the person initially requesting an appointment over the phone. She stated that information was provided during the patient's first visit to the clinic.</p> <p>At 12:12 PM on 06/18/2018 during an interview with S1Administrator, the facility's telephone rang, S1Administrator answered the phone, then confirmed it was the calling patient's first appointment and informed the caller to report to the provider's facility at 8:30 AM on Thursday morning. The call ended.</p> <p>At 12:13 PM on 06/18/2018 the same phone rang again. S1Administrator answered the phone and verbally confirmed the caller missed her first appointment, instructed the caller to come into the office at 8:30 AM on Thursday morning. She then asked the caller's age, date of her last menstrual period, phone number, zip code, names of any medications used, and stated "you have asthma." S1Administrator informed the caller she would have an ultra sound, counseling, and it will be \$150.00 for the ultra sound and instructed her to wear a sweater.</p> <p>Observation on 06/18/2018 at 2:00 PM revealed S4Administrative Assistant answering an incoming phone call made by a person seeking an appointment for an abortion. S4Administrative Assistant requested the caller's name, age, phone number, zip code, and the date of her last period. S 4 Administrative Assistant provided the caller the date and time of the next available appointment and informed her to bring a valid pictured ID (identification) and a money order for \$150.00. S4Administrative Assistant did not provide the caller with the internet address of the department's abortion alternatives and informed consent website which includes links to mental</p>	S 193		

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NAME OF PROVIDER OR SUPPLIER  WOMENS HEALTH CARE CENTER INC		STREET ADDRESS, CITY, STATE, ZIP CODE 2701 GENERAL PERSHING STREET NEW ORLEANS, LA 70116		
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S 193	Continued From page 4  health counseling. Following the observation of this phone call, an interview was conducted with S4Administrative Assistant on 06/18/2018 at 2:03 PM and she confirmed this was the initial contact with the caller, Patient #6, who was seeking an abortion and she did not inform her of the internet address of the department's abortion alternatives and informed consent website which includes links to mental health counseling.  Observation on 06/18/2018 at 2:06 PM revealed S5Medical Assistant answering an incoming phone call made by a person seeking an appointment for an abortion. S5Medical Assistant requested the caller's name, age, phone number, zip code, and the date of her last period. S5Medical Assistant provided the caller the date and time of the next available appointment and informed her to bring a valid pictured ID and a money order in the amount of \$150.00. S5Medical Assistant did not provide the caller with the internet address of the department's abortion alternatives and informed consent website which includes links to mental health counseling. Following the observation of this phone call, an interview was conducted with S5Medical Assistant on 06/18/2018 at 2:10 and she confirmed this was the initial contact with the caller, Patient #7, who was seeking an abortion and she did not inform her of the internet address of the department's abortion alternatives and informed consent website which includes links to mental health counseling. S5Medical Assistant stated that she was not aware that the information was supposed to be provided when patients called to schedule an appointment and stated that the information was provided to patients during the initial face to face visit.	S 193		

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S 193	<p>Continued From page 5</p> <p>On 06/18/2018 at 2:20 PM, an observation was made of S4Administrative Assistant providing a walk-in person information regarding abortions, including the department's internet address for abortion alternatives and informed consent.</p> <p>On 06/18/2018 at 4:00 PM, an interview with S1Administrator revealed she received two phone calls earlier from persons seeking to schedule appointments for abortions. When asked if she informed the two callers, who were seeking to schedule appointments for abortions, of the internet address of the department's abortion alternatives and informed consent website which includes links to mental health counseling, S1Administrator replied that the staff informs patients of the department's abortion alternatives and informed consent website which includes links to mental health counseling during the first visit and the information was posted throughout the facility. Upon further review of the regulatory language and the revised statute, S1Administrator revealed the facility was not aware that the website should be provided on initial contact, regardless of the means of contact. She verified that she had not been providing this information to persons seeking to schedule abortions by telephone and the current automated recordings did not list information regarding the internet address of the department's abortion alternatives and informed consent website.</p> <p>On 06/19/2018 at 9:44 AM, an interview with Patient #8 revealed she called to schedule an appointment for an abortion. Patient #8 revealed she was not informed of the internet address of the department's abortion alternatives and informed consent website which includes links to</p>	S 193		

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NAME OF PROVIDER OR SUPPLIER  WOMENS HEALTH CARE CENTER INC		STREET ADDRESS, CITY, STATE, ZIP CODE 2701 GENERAL PERSHING STREET NEW ORLEANS, LA 70115		
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S 193	Continued From page 6  mental health counseling during her initial telephone contact to schedule her appointment.  On 06/19/2018 at 9:50 AM, an interview with Patient #9 revealed she initially called to schedule an appointment for an abortion and denied being provided information or the internet address of the department's abortion alternatives and informed consent website which includes links to mental health counseling.  On 06/19/2018 at 10:20 AM, an interview with Patient #10 revealed she called to schedule an appointment for an abortion. Patient #10 revealed she was not informed of the internet address of the department's abortion alternatives and informed consent website which includes links to mental health counselling during her initial telephone contact to schedule her appointment.	S 193		
S 253	4451 A-C Pharmaceutical Services  A. All outpatient abortion facilities shall have a controlled dangerous substance (CDS) license issued by the Louisiana Board of Pharmacy and a Drug Enforcement Agency (DEA) registration in accordance with applicable state and federal laws. B. The outpatient abortion facility shall develop, implement, enforce, monitor, and annually review written policies and procedures that govern the safe storage, prescribing, dispensing, preparing and administering of drugs and biologicals on the licensed premises. C. Storage Areas. The outpatient abortion facility shall provide a designated secure storage area for storing drugs and biologicals. 1. The designated storage area shall be constructed and maintained to prevent	S 253		



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S 253	Continued From page 7  unauthorized access, 2. The designated storage area shall adhere to the manufacturer's suggested recommendations for storage of drugs. 3. Locked areas that are used to store medications including controlled substances, shall conform to all applicable federal and state laws, and the outpatient abortion facility's policies and procedures.  This Rule is not met as evidenced by: Based on observation, staff interview, and review of records, the outpatient abortion facility failed to ensure that S7Medical Doctor/Medical Director who procured/ordered a controlled dangerous substance (CDS) had a current CDS license issued by the Louisiana Board of Pharmacy in accordance with applicable state law R.S 40:973.  Findings:  During an interview with S1Administrator (Adm) on 6/18/18 beginning at 11:15 AM, S1Adm explained that the facility had two physicians on staff who provided services, S7Medical Doctor/Medical Director (MD) and S8MD. S1Adm explained that S7MD was the facility's Medical Director and had been providing services at the facility for an extended period. S1Adm was questioned about medications of which the facility utilized for patient care services in the facility, medications for patient administration,	S 253		

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NAME OF PROVIDER OR SUPPLIER  WOMENS HEALTH CARE CENTER INC	STREET ADDRESS, CITY, STATE, ZIP CODE 2701 GENERAL PERSHING STREET NEW ORLEANS, LA 70116
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S 253	<p>Continued From page 6</p> <p>prescription and/or, dispensing. S1Adm informed that the facility did not dispense medications but, medications were stored on site, administered and prescribed to patients by the facility staff.</p> <p>On 6/18/18 at 11:55 AM, S1Adm provided lists of medications utilized by the facility. Review of the list of medications revealed the facility's list of medications for the STAT KIT ACLS COMPLIANCE UPGRADE 2018 (Emergency Cart/Crash Cart List) maintained in the facility, provided by S1Adm on 6/19/18 at 8:30 AM, contained the medication Midazolam (Versed). Observation of the facility's Emergency Cart verified the facility possessed and had on hand, two vials of Midazolam (Versed), 2 milligram/injection with an expiration date of 12/2018. The quantity observed in the Crash Cart matched the kit's inventory accountability forms.</p> <p>A review of state law R.S 40:973 revealed in part: Every person who conducts research with, manufactures, distributes, procures, possesses, prescribes, or dispenses any controlled dangerous substance within this state or who proposes to engage in the research, manufacture, distribution, procurement, possession, prescribing, or dispensing of any controlled dangerous substance within this state shall obtain a controlled dangerous substance license issued by the Board of Pharmacy in accordance with the rules and regulations promulgated by it prior to engaging in such activity.</p> <p>La R.S. 40:964 identified Versed (Midazolam) as a schedule IV drug.</p> <p>During a review of records and interview on</p>	S 253		

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S 253	Continued From page 9  06/19/2018 at 1:45 PM, S1Adm verified that the Versed in the provider's crash cart was ordered by S7MD and Versed was a scheduled medication as identified by the Louisiana Board of Pharmacy. S1Adm provided a copy of S7MD's DEA registration and Controlled Dangerous Substance (CDS) License via the Louisiana Board of Pharmacy. S1Adm verified that S7MD's CDS license had an address other than that of the facility and the license was expired as of 05/01/2018. S1Adm verified that the Versed on hand and available to facility staff within the Crash Cart was procured by S7MD and S7MD did not possess a current CDS license.	S 253		