**EXHIBIT 1**
Legal Opinion to ISDH

I, Mandy [redacted]:

1. On November 28, 2014, I went to the Women's Pavilion for my counseling appointment.

2. I was there for counseling regarding an abortion, but on my way into the Women's Pavilion, I talked to a woman on the sidewalk by the name of Ellen Master. She presented alternatives to abortion, such as adoption, and offered me financial, legal, and medical assistance to eliminate the pressure on me to have an abortion.

3. I went inside to my counseling appointment, considering what Mrs. Master had told me. But during the counseling visit the abortionist asked me to sign-off on some paperwork and gave me a pill.

4. Upon my exit from the Women's Pavilion, I talked again to Mrs. Master, and, although I wanted to consider these options, I informed Mrs. Master that it was too late because the abortionist had already given me the abortion pill that I took in his office.

5. This all occurred over a two hour period during my first visit to the abortionist on November 28, 2014.

Mandy [redacted]

12/1/15 Date

EXHIBIT 2
Legal Opinion to ISDH

Natural Family Planning • Theology of the Body Training • Natural Family Planning • A Haven for Healing • Health-First • Life Support • Facts-First • Silent No More • Health-First • TLC Advocates • A Haven For Healing • Health-First • Facts-First • Life Support • Holy Family Adoption Agency • Natural Family Planning • 40 Days For Life, South Bend • Holy Family Adoption Agency • Health-First • Silent No More • TLC Advocates • TLC Advocates • Health-First • Natural Family Planning • Facts-First • Life Support

# Answer the *C.A.L.L.* Campaign

## Citizens Against Licensing Lawlessness

**For Immediate Release**

Contact: Shawn Sullivan, Esq.
SullyatLaw@sbcglobal.net
Cell: (574) 286-7860
Fax: (574) 233-7862

## State Health Department, Citizen Group Call for Closure of South Bend Abortion Clinic

**Summary of Release**: Concerned citizens and representatives of the non-profit entities located at the Life Center in South Bend, which is next to the abortion clinic, are initiating a campaign "Answer the C.A.L.L. (Citizens Against Licensing Lawlessness)." According to the spokesperson for Answer the C.A.L.L.,Shawn Sullivan, Esq., the campaign is in response to the continued lawlessness of Dr. Ulrich "George" Klopfer. In just the past few months, the entities at the Life Center have reported violations to the Indiana State Department of Health (ISDH), and the ISDH just recently filed a complaint against the abortion clinic seeking a revocation of its license. The ISDH's complaint is based on a multitude of violations that turned up from ISDH's survey of the abortion clinic in late October 2014. Dr. Laura McGuire, M.D., after reviewing the complaint, stated that the abortionist's "practices can cause injury or even death." Adding these violations to the past five years' worth of violations, the two recent criminal prosecutions brought against Dr. Klopfer and the abortion clinic, as well as the voluminous complaints to the Indiana Attorney General's office, the Answer the C.A.L.L. campaign is demanding that pubic officials close the abortion clinic before something tragic occurs. Sullivan says: "Because no one concerned about the well-being of the patients and their loved ones should ignore the evidence any longer, we are specifically calling upon our public officials to immediately act to protect the public and not wait until South Bend has a disaster on its hands."

SOUTH BEND, Indiana, February 18, 2015: Representatives from several local non-profit organizations revealed today that the Indiana State Department of Health (ISDH) has asked an Administrative Law Judge to revoke the license of the South Bend abortion clinic known as the Women's Pavilion. The clinic is operated by Dr. Ulrich "George" Klopfer, The non-profits, located at The Life Center, 2018 Ironwood Circle in South Bend – adjacent to the abortion clinic – monitor the operations of the clinic and have filed complaints with the ISDH. Along with other concerned citizens, representatives from the non-profits have formed an action group called "Answer the C.A.L.L. (Citizens Against Licensing Lawlessness)." As evidence of this lawlessness, the Answer the C.A.L.L. cite the recent non-profits' complaints against the Women's Pavilion, the two recent criminal actions -- one in Lake County and the other in St. Joseph County, thousands of complaints filed with the Attorney General's office, the pending review of Dr. Klopfer's Medical License (re-scheduled for March 26, 2015), and the recent survey of the ISDH showing numerous serious violations of the state's medical rules for surgical abortion clinics.

The recent complaint by the ISDH is made up of the violations found in late October 2014, when the ISDH completed an on-site survey of the facilities. The multitude of violations all relate to patient care and safety. As Dr. Laura McGuire, M.D., a local physician, stated: "The violations set forth here are not just a matter of improper paperwork; these kinds of practices can cause injury or even death. Identical violations year after year signal a lack of genuine corrective action, and ultimately, a lack of desire to adhere to acceptable medical standards. The violations are inexcusable, and the failure to promptly remedy them is appalling." A glance at the 48 pages of violations reveals some unsettling information putting the patients at great risk:

> *[T]hese kinds of practices can cause injury or even death.*
>
> Dr. Laura McGuire, M.D.

1. Failure to have qualified staff overseeing the sedation (conscious sedation) of patients and failing to have qualified staff monitoring the patients in recovery;
2. Failure to have laboratory services, such as blood work and pregnancy testing, performed at a certified facility;
3. Using expired medications (from 2012) and explaining that the common medicines are on "backorder" although unable to substantiate such a claim with any documentation;
4. Failure to have an infection control plan;
5. Failure of personnel to have basic CPR training certification;
6. Failure to have immunization documentation regarding the staff that deals with the patients;
7. Failure to have an emergency plan in the event of loss of power;
8. Failure to have an evacuation plan in the event of an emergency with Dr. Klopfer stating that it "is all up here" (pointing to his head);
9. Failure to comply with numerous certification, training, and licensing of staff, including an RN without her medical license, and failing to complete annual competency assessments for professional staff;

10. Failure to develop written policies governing surgical abortion services that are designed to assure "appropriate standards of medical and patient care;"

Dr. Klopfer has refused to develop and submit a "plan of correction" for the above-listed deficiencies, despite being repeatedly asked to do so. In fact, according to Shawn Sullivan, attorney and spokesperson for Answer the C.A.L.L., a number of the violations cited in the 2014 survey were also found in the surveys done in 2010 and 2012. "This," says Sullivan, "is what gave rise to our awareness and action campaign. The mounting evidence of Dr. Klopfer's lawlessness would cause any reasonable person to demand the closure of such an operation before there is a disaster. This situation is a time bomb. We don't need to wait until we have a catastrophe like that in the Kermit Gosnell case or the Brian Finkel case. We should not continue to ignore all of the signs as to where this situation is headed." Sullivan surmised that when you consider that Dr. Klopfer had some of these same violations in 2010 and 2012, which he never corrected, and he continues to receive more citations from ISDH, and the non-profit entities monitoring Dr. Klopfer's operations are seeing an increased disregard for the law, "it is clear that he is going to operate in this lawless fashion until he is stopped or there is horrific climax to the situation. In no other situation would we place the women of our community at such great risk and tolerate so many health and safety violations. Any restaurant with this many health violations would have been shut down many years ago."

Sullivan noted that in addition to the "Answer the C.A.L.L." campaign that the non-profits at the Life Center would continue to monitor Dr. Klopfer's activities. He added that the "Answer the C.A.L.L." campaign is designed to draw attention to the issue and "call upon on our public officials and the citizens of the community to ensure that this lawless activity ceases immediately and that all licenses are revoked before it is too late."

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Bio for Shawn Sullivan: Mr. Sullivan is an attorney in South Bend and the founder and Director of the Life Center at 2018 Ironwood Circle, South Bend, IN 46615. He is a 1993 *Cum Laude* graduate of Harvard Law School, and a 1989 *Summa Cum Laude* graduate of the University of Dayton.

**EXHIBIT 3**
Legal Opinion to ISDH

Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
*Governor*

Jerome M. Adams, MD, MPH
*State Health Commissioner*

June 26, 2015

REGARDING THE APPLICATION FOR LICENSE TO OPERATE AN ABORTION CLINIC:

Women's Pavilion
2010 Ironwood Circle
South Bend, IN 46635

**NOTICE OF DENIAL OF LICENSE**

To: Dr. Ulrich Klopfer, DO
Women's Pavilion
2010 Ironwood Circle
South Bend, IN 46635

The Director of the Division of Acute Care, Indiana State Department of Health (hereinafter referred to as "Director"), upon review and recommendation of the Abortion Clinic Licensing Program ("Program"), hereby issues this Notice of Denial of License ("Notice").

TLC Advocates

At the time of this Notice, the applicant's current licensure is pending revocation following a complaint survey conducted on June 03, 2015. During the complaint survey deficiencies demonstrating non-compliance were cited. The program believes these deficiencies provide further evidence of the clinic's inability to comply with and follow existing state law and that such behavior is an intentional and willful act.

Based on the clinic's survey history of non-compliance, ongoing non-compliance, untimely and unacceptable plans of correction and pending license revocation, the application for licensure for the above-referenced abortion clinic (seeking licensure following the expiration of the current license on June 30, 2015) has been denied.

If you wish to seek administrative review of this action pursuant to Indiana Code § 4-21.5-3-5, you must file a petition for review within eighteen (18) days after the date of this Notice.

A petition for review must be in writing and must include facts demonstrating that:

The petitioner is a person to whom the order is specifically directed;
The petitioner is aggrieved or adversely affected by the order; or
The petitioner is entitled to review under any law.

**If the petition for review is not filed timely, this action becomes a FINAL ORDER.**

Any petition for review should be submitted in writing to:

Court Administrator
Office of Legal Affairs, #3H
Indiana State Department of Health
2 North Meridian Street
Indianapolis, IN 46204-3006

Upon receipt of a timely filed petition for review, an administrative proceeding will be conducted by an Administrative Law Judge appointed by the Indiana State Department of Health.

This action does not prohibit the applicant from re-applying for licensure in the future.

Respectfully,

Terry L. Whitson
Assistant Commissioner
Health Care Quality and Regulatory Commission

Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

June 26, 2015

4A-07
Alyson Cox
16620 Holly Oak Dr
Westfield, IN 46074

RE: Complaint Allegation #: IN00170828

Dear Alyson Cox:

An investigation of your complaint filed with the Acute Care Division was completed on June 3, 2015 and found that your complaint was substantiated. This means the allegation(s) of your complaint was confirmed. The enclosed document is the survey report written as the result of the investigation.

When a complaint is investigated, surveyors typically interview a variety of people, review records and other documents, and make observations. Each concern of your complaint was investigated. The evidence obtained by the surveyors identified there was a violation of state requirements. These violations (deficiencies) are listed on the left-hand portion of the survey report included with this letter. The Division will review the survey findings and recommend an appropriate enforcement action.

This complaint is now closed. Should you have any questions about the report of the investigation, do not hesitate to contact us. You will need the Complaint Allegation Number identified above.

Thank you for your concern regarding the care provided to the patients in Indiana and your desire to ensure patients receive the quality care required by state regulations.

Sincerely,

John Lee, RN, MBA
Nurse Surveyor Supervisor
Program Director, Hospitals, ASC's
317/233-7487

Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

June 29, 2015

4A-07
Jennifer Borek
South Bend, IN
By Email

RE: Complaint Allegation #: IN00165426

Dear Jennifer Borek:

An investigation of your complaint filed with the Acute Care Division was completed on June 3, 2015 and found that your complaint was substantiated. This means the allegation(s) of your complaint was confirmed. The enclosed document is the survey report written as the result of the investigation.

When a complaint is investigated, surveyors typically interview a variety of people, review records and other documents, and make observations. Each concern of your complaint was investigated. The evidence obtained by the surveyors identified there was a violation of state requirements. These violations (deficiencies) are listed on the left-hand portion of the survey report included with this letter. The Division will review the survey findings and recommend an appropriate enforcement action.

This complaint is now closed. Should you have any questions about the report of the investigation, do not hesitate to contact us. You will need the Complaint Allegation Number identified above.

Thank you for your concern regarding the care provided to the patients in Indiana and your desire to ensure patients receive the quality care required by state and/or federal regulations.

Sincerely,

John Lee, RN, MBA
Nurse Surveyor Supervisor
Program Director, Hospitals, ASC's
317/233-7487

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 011127 | A. BUILDING: _____ B. WING _____ | 06/03/2015 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| WOMEN'S PAVILION | 2010 IRONWOOD CIR SOUTH BEND, IN 46635 |

| (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 |
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| T 000 | INITIAL COMMENTS<br><br>The visit was for a licensure complaint investigation.<br><br>Complaint Number:<br>IN 00170828<br>Substantiated: deficiencies related to the allegations are cited<br><br>Date: 6-03-15<br><br>Facility Number: 011127<br><br>QA: cjl 06/12/15 | T 000 | | |
| T 022 | 410 IAC 26-4-1 GOVERNING BODY<br><br>410 IAC 26-4-1(c)(1)<br><br>(c) The governing body shall do the following:<br>(1) Assume responsibility for:<br>(A) determining;<br>(B) implementing; and<br>(C) monitoring;<br>policies governing the clinic ' s operation.<br><br>This RULE is not met as evidenced by:<br>Based on document review and interview, the governing body failed to ensure that policies governing all clinical services were implemented and maintained, including a policy/procedure for the medical abortion services being provided by the facility for 10 of 10 medical records (MR) reviewed (patient 21, 22, 23, 24, 25, 26, 27, 28, | T 022 | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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| T 022 | Continued From page 1<br>29 and 30).<br><br>Findings:<br><br>1. On 6/3/15 at 4:45 PM, the medical director and clinic physician #50 was requested to provide a copy of a policy/procedure for medical abortion services provided at the clinic and none was provided prior to exit.<br><br>2. Review of the following medical records indicated:<br>a. Patient 21 received medical abortion services on 05/01/15.<br>b. Patient 22 received medical abortion services on 04/29/15.<br>c. Patient 23 received medical abortion services on 05/13/15.<br>d. Patient 24 received medical abortion services on 05/29/15.<br>e. Patient 25 received medical abortion services on 05/26/15.<br>f. Patient 26 received medical abortion services on 04/21/15.<br>g. Patient 27 received medical abortion services on 05/01/15.<br>h. Patient 28 received medical abortion services on 05/15/15.<br>i. Patient 29 received medical abortion services on 05/27/15.<br>j. Patient 30 received medical abortion services on 05/27/15.<br><br>3. During an interview on 6/3/15 at 4:45 PM, the medical director and clinic physician #50 confirmed that no policy/procedure regarding medical abortion services was available. | T 022 | | |

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| T 024 | Continued From page 2 | T 024 | | |
| T 024 | 410 IAC 26-4-1 GOVERNING BODY<br><br>410 IAC 26-4-1(c)(2)<br><br>(c) The governing body shall do the following:<br>(2) Ensure that:<br>(A) clinic policies are followed so as to provide quality health care in a safe environment; and<br>(B) the clinic complies with:<br>(i) this article;<br>(ii) IC 16-21; and<br>(iii) IC 16-34.<br><br>This RULE is not met as evidenced by:<br>Based on document review and oral responses by the facility physician during interview, the governing body failed to ensure that medical abortion services provided at the clinic are in compliance with Indiana Code (IC) 16-34-2-1.1 for 10 of 10 medical records (MR) reviewed (patient 21, 22, 23, 24, 25, 26, 27, 28, 29 and 30) regarding requirements for counseling and providing information about the risks and alternatives to the use of an abortion inducing drug at least eighteen (18) hours before an abortion inducing drug is dispensed, prescribed, administered or otherwise given to a pregnant woman.<br><br>Findings:<br><br>1. Review of Indiana Code (IC) 16-34-2-1.1 indicates the following: | T 024 | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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| T 024 | Continued From page 3<br>Voluntary and informed consent required; viewing of fetal ultrasound and hearing auscultation of fetal heart tone<br>Sec. 1.1. (a) An abortion shall not be performed except with the voluntary and informed consent of the pregnant woman upon whom the abortion is to be performed. Except in the case of a medical emergency, consent to an abortion is voluntary and informed only if the following conditions are met:<br>(1) At least eighteen (18) hours before the abortion and in the presence of the pregnant woman, the physician who is to perform the abortion, the referring physician or a physician assistant (as defined in IC 25-27.5-2-10), an advanced practice nurse (as defined in IC 25-23-1-1(b)), or a certified nurse midwife (as defined in IC 34-18-2-6.5) to whom the responsibility has been delegated by the physician who is to perform the abortion or the referring physician has informed the pregnant woman orally and in writing of the following:<br>(A) The name of the physician performing the abortion, the physician's medical license number, and an emergency telephone number where the physician or the physician's designee may be contacted on a twenty-four (24) hour a day, seven (7) day a week basis.<br>(B) That follow-up care by the physician or the physician's designee (if the designee is licensed under IC 25-22.5) and is available on an appropriate and timely basis when clinically necessary.<br>(C) The nature of the proposed procedure or information concerning the abortion inducing drug.<br>(D) Objective scientific information of the risks of and alternatives to the procedure or the use of an abortion inducing drug, including:<br>(i) the risk of infection and hemorrhage; | T 024 | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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| T 024 | Continued From page 4<br>(ii) the potential danger to a subsequent pregnancy; and<br>(iii) the potential danger of infertility.<br>(E) That human physical life begins when a human ovum is fertilized by a human sperm.<br>(F) The probable gestational age of the fetus at the time the abortion is to be performed, including:<br>(i) a picture of a fetus;<br>(ii) the dimensions of a fetus; and<br>(iii) relevant information on the potential survival of an unborn fetus;<br>at this stage of development.<br>(G) That objective scientific information shows that a fetus can feel pain at or before twenty (20) weeks of postfertilization age.<br>(H) The medical risks associated with carrying the fetus to term.<br>(I) The availability of fetal ultrasound imaging and auscultation of fetal heart tone services to enable the pregnant woman to view the image and hear the heartbeat of the fetus and how to obtain access to these services.<br>(J) That the pregnancy of a child less than fifteen (15) years of age may constitute child abuse under Indiana law if the act included an adult and must be reported to the department of child services or the local law enforcement agency under IC 31-33-5.<br>(2) At least eighteen (18) hours before the abortion, the pregnant woman will be informed orally and in writing of the following:<br>(A) That medical assistance benefits may be available for prenatal care, childbirth, and neonatal care from the county office of the division of family resources.<br>(B) That the father of the unborn fetus is legally required to assist in the support of the child. In the case of rape, the information required under this clause may be omitted. | T 024 | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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| T 024 | Continued From page 5<br>(C) That adoption alternatives are available and that adoptive parents may legally pay the costs of prenatal care, childbirth, and neonatal care.<br>(D) That there are physical risks to the pregnant woman in having an abortion, both during the abortion procedure and after.<br>(E) That Indiana has enacted the safe haven law under IC 31-34-2.5.<br>(F) The:<br>(i) Internet web site address of the state department of health's web site; and<br>(ii) description of the information that will be provided on the web site and that are;<br>described in section 1.5 of this chapter.<br>(3) The pregnant woman certifies in writing, on a form developed by the state department, before the abortion is performed, that:<br>(A) the information required by subdivisions (1) and (2) has been provided to the pregnant woman;<br>(B) the pregnant woman has been offered by the provider the opportunity to view the fetal ultrasound imaging and hear the auscultation of the fetal heart tone if the fetal heart tone is audible and that the woman has:<br>(i) viewed or refused to view the offered fetal ultrasound imaging; and<br>(ii) listened to or refused to listen to the offered auscultation of the fetal heart tone if the fetal heart tone is audible; and<br>(C) the pregnant woman has been given a written copy of the printed materials described in section 1.5 of this chapter.<br>(4) At least eighteen (18) hours before the abortion and in the presence of the pregnant woman, the physician who is to perform the abortion, the referring physician or a physician assistant (as defined in IC 25-27.5-2-10), an | T 024 | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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| T 024 | Continued From page 6<br>advanced practice nurse (as defined in IC 25-23-1-1(b)), or a midwife (as defined in IC 34-18-2-19) to whom the responsibility has been delegated by the physician who is to perform the abortion or the referring physician has provided the pregnant woman with a color copy of the informed consent brochure described in section 1.5 of this chapter by printing the informed consent brochure from the state department's Internet web site and including the following information on the back cover of the brochure:<br>(A) The name of the physician performing the abortion and the physician's medical license number.<br>(B) An emergency telephone number where the physician or the physician's designee may be contacted twenty-four (24) hours a day, seven (7) days a week.<br>(C) A statement that follow-up care by the physician or the physician's designee who is licensed under IC 25-22.5 is available on an appropriate and timely basis when clinically necessary.<br>(b) Before an abortion is performed, the provider shall perform, and the pregnant woman shall view, the fetal ultrasound imaging and hear the auscultation of the fetal heart tone if the fetal heart tone is audible unless the pregnant woman certifies in writing, on a form developed by the state department, before the abortion is performed, that the pregnant woman:<br>(1) does not want to view the fetal ultrasound imaging; and<br>(2) does not want to listen to the auscultation of the fetal heart tone if the fetal heart tone is audible.<br><br>2. On 6/3/15 at 4:45 PM, the medical director and clinic physician #50 was requested to provide | T 024 | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 011127 | A. BUILDING: _____ B. WING _____ | 06/03/2015 |

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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 |
|---|---|---|---|---|
| T 024 | Continued From page 7<br>a copy of a policy/procedure for medical abortion services provided at the clinic and none was provided prior to exit.<br><br>3. Review of the following medical records (MR) indicated:<br>a. Patient 21 received medical abortion services on 05/01/15 and lacked documentation demonstrating that the requirements of IC 16-34-2-1.1 were completed at least 18 hours before the abortion.<br>b. Patient 22 received medical abortion services on 04/29/15 and lacked documentation demonstrating that the requirements of IC 16-34-2-1.1 were completed at least 18 hours before the abortion.<br>c. Patient 23 received medical abortion services on 05/13/15 and lacked documentation demonstrating that the requirements of IC 16-34-2-1.1 were completed at least 18 hours before the abortion.<br>d. Patient 24 received medical abortion services on 05/29/15 and lacked documentation demonstrating that the requirements of IC 16-34-2-1.1 were completed at least 18 hours before the abortion.<br>e. Patient 25 received medical abortion services on 05/26/15 and lacked documentation demonstrating that the requirements of IC 16-34-2-1.1 were completed at least 18 hours before the abortion.<br>f. Patient 26 received medical abortion services on 04/21/15 and lacked documentation demonstrating that the requirements of IC 16-34-2-1.1 were completed at least 18 hours before the abortion.<br>g. Patient 27 received medical abortion services on 05/01/15 and lacked documentation demonstrating that the requirements of IC 16-34-2-1.1 were completed at least 18 hours | T 024 | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 011127 | A. BUILDING: _____ B. WING _____ | 06/03/2015 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| WOMEN'S PAVILION | 2010 IRONWOOD CIR SOUTH BEND, IN 46635 |

| (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 024 | Continued From page 8<br>before the abortion.<br>h. Patient 28 received medical abortion services on 05/15/15 and lacked documentation demonstrating that the requirements of IC 16-34-2-1.1 were completed at least 18 hours before the abortion.<br>i. Patient 29 received medical abortion services on 05/27/15 and lacked documentation demonstrating that the requirements of IC 16-34-2-1.1 were completed at least 18 hours before the abortion.<br>j. Patient 30 received medical abortion services on 05/27/15 and lacked documentation demonstrating that the requirements of IC 16-34-2-1.1 were completed at least 18 hours before the abortion.<br><br>4. At 3:55 PM, 4:05 PM and 4:45 PM, during the interview with the facility physician, #50, physician #50 reported:<br>a. The facility has no log of patients with appointment dates, for either the first visit where lab work and consultation/counseling is done, or for their surgical procedures.<br>b. There is a log book kept for documenting surgical patient procedures on the day of surgery, but no log is kept for medical abortion patients.<br>c. The process for medical abortions includes: At the first appointment, an ultrasound is performed and labs (i.e. pregnancy test, Rh testing, hemoglobin and hematocrit) are done. Also, the "state information" and counseling are done and the patient signs their "releases". Then, the Mifiprex (RU486) is given to the patient and 4 tablets of Misoprostol are sent home with the patient to use vaginally at their convenience at about 48 hours later.<br>d. There is no written policy/procedure related to the medical abortion process at the facility. | T 024 | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 011127 | A. BUILDING: _____ B. WING _____ | 06/03/2015 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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| WOMEN'S PAVILION | 2010 IRONWOOD CIR SOUTH BEND, IN 46635 |

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|---|---|---|---|---|
| T 128 | Continued From page 9 | T 128 | | |
| T 128 | 410 IAC 26-7-1 MEDICAL RECORDS<br><br>410 IAC 26-7-1(c)<br><br>(c) A written or electronic register must be kept of all patients treated that provides the following:<br>(1) Identification data.<br>(2) Treatment rendered.<br>(3) Attending physician.<br>(4) Condition on discharge.<br>(5) Transfers to hospital facility.<br>(6) Other data deemed necessary by the clinic.<br><br>This RULE is not met as evidenced by:<br>Based upon document review and interview, the clinic failed to maintain a patient register of all patients receiving services including medical abortion services at the facility for one facility.<br><br>Findings:<br><br>1. On 6/3/15 at 3:55 PM, the medical director and clinic physician #50 was requested to provide a patient register indicating all patients obtaining medical abortion services at the clinic and none was provided prior to exit.<br><br>2. During an interview on 6/3/15 at 3:55 PM, the medical director and clinic physician #50 confirmed the clinic does not maintain a log of patients with appointment dates, for either the first visit where lab work and consultation/counseling is done, or for their surgical procedures, or any other follow up appointments. Physician #50 confirmed that a | T 128 | | |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 011127 | A. BUILDING: _____ B. WING _____ | 06/03/2015 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
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|---|---|---|---|---|
| T 128 | Continued From page 10<br>register is kept for documenting surgical patient procedures on the day of surgery and confirmed that no register indicating the treatment rendered for patients obtaining medical abortion services was maintained by the clinic. | T 128 | | |

SHAWN F. SULLIVAN
ATTORNEY AT LAW, LTD
1717 East Wayne Street
South Bend, Indiana 46615
*Admitted in Indiana, Illinois, and North Carolina*

Direct Line: (574) 233-7860

**EXHIBIT 4.a**
Legal Opinion to ISDH

**URGENT** Via Email and Priority Mail

March 3, 2016

Greg Zoeller
Indiana State Attorney General
Indiana Government Center
South 302 W. Washington St, 5th Floor
Indianapolis, IN 46204

**Re:** ***Disposition of the 17 Pending TLC Advocate Complaints, dating back to December of 2014, Reporting 54 potential Criminal Violations;***

- **New evidence – witness statements by the mothers mistreated by Dr. Klopfer and or denied informed consent**, starting with the first informed consent complaint filed with the Attorney General in 2014;
- **The audio and testimonial evidence showing Dr. Klopfer's intent to operate a criminal enterprise** (the same evidence that led to 6/3/15 ISDH survey and finding of 10 (out of 10) counts of informed consent violations, I.C. § 16-34-2-1.1, which are now incorporated in the AG's complaint in ***In re* License of George G. Ulrich Klopfer**, D.O., License No. 02000628A, Medical Licencing Board, Cause No. 2014 MLB 0044; and
- **Previously supplied witness statements by third party witnesses testifying to Dr. Klopfer's un-professional conduct in the community.**

Dear Mr. Zoeller,

We write requesting a meeting with your office, to occur in the near future, to discuss the mounting criminal activity associated with Dr. Klopfer's operation of the Women's Pavilion. We hope to immediately meet concerning the pending unresolved 17 complaints filed with your office by the TLC Advocates (dating back to December 2014), new evidence related to them (an example witness statement attached), as well as the audio and testimonial evidence of Dr. Klopfer's clinic being set up to perpetually violate the informed consent law (I.C.§ 16-34-2-1.l(a)(l)) by Dr. Klopfer, and the witness statement pertaining to Dr. Klopfer's unprofessional conduct in the community. I am eager to advise my anxious clients that our Attorney General is as serious about these violations of the Criminal Code as we are and that we have scheduled a meeting to discuss them. We have pleaded with them to be patient with the Attorney General's office, and have distinguished your office with Indiana State Department of Health ("ISDH"), but they are on edge given the speed at which the wheels of justice are turning in regards to Dr.Klopfer.[1]

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[1] Our clients are an ever expanding group. We represent the The Life Center, TLC Advocates, the 860 petitioners who signed the Answer the C.A.L.L. (Citizens Against Licensing the Lawless) Campaign, and the new class of clients consisting of the mothers who were denied the informed consent prior to receiving an abortion. These mothers desired the 18 hours to consider the information required by the state, but they did not receive the information, and they were not accorded 18 hours to consider the information. As an example of this growing constituency, we are attaching the witness statement of the mother associated with the first complaint filed with your office. We hope to open up this confidential litigation file to the AG's

I will not try to provide an exhaustive list of the issues that could potentially be discussed at the meeting we are requesting. It is sufficient to say that my clients are concerned by the recent actions of the ISDH, which refused to investigate 15 of their 17 complaints (the same complaints we submitted to the AG's office) thereby limiting their prosecution of 18-hour rule violations to 10 infractions in May of 2015, and ignoring the 51 violations documented by the TLC advocates in November and December of 2015 and from June to November 2015. My clients are particularly disturbed by ISDH's ignoring of complaints of 18-hour infractions committed immediately following the settlement agreement, i.e., on November 3, 4 and 6, 2015.

The meeting we are requesting will be invaluable to the AG. Obviously our lawyers and our clients can provide information as well as testimonial and documentary information if you would find it useful at your trial in the M.L.B. proceeding, *In re* Klopfer. Equally important, our clients have leads and information that is pertinent to your adverse or cross examination. And of course the meeting we are requesting is necessary for resolving the 17 pending complaints of criminal violations by Dr. Klopfer:

- Ellen Master, AG File 14-CP-63223 (12/2/14) (reported 2 separate and distinct informed consent violations and for one of them there is new evidence, a witness statement);
- Dr. Jennifer Borek, AG File 15-CP-**** (2/9/15) (reported testimony of Dr. Klopfer's intentional practice of violating informed consent laws with all medical abortions);
- Alyson Cox, AG File 15-CP-53691 (4/1/15) (obtained audio evidence of Dr. Klopfer's intentional practice of violating informed consent laws with all medical abortions);
- Pamela Washburn, AG File 15-CP-**** (7/3/15) (reported 1 distinct informed consent violation);
- Mary Ball, AG File 15-CP-**** (7/6/15) (reported 1 distinct informed consent violation);
- Amber Dolby, AG File 15-CP-**** (7/28/15) (reported 2 distinct informed consent violations);
- Ellen Master, AG File 15-CP-58727 (8/26/15) (reported 9 distinct informed consent violations);
- Shawn Master, AG File 15-CP-**** (8/26/15) (reported 10 distinct informed consent violations);
- Pamela Washburn, AG File 15-CP-52011 (11/20/15) (reported 1 abortion without a license);
- Dr. Jennifer Borek, AG File 15-CP-58184 (11/24/15) (reported 4 distinct informed consent violations);
- Nick Keszei, AG File 15-CP-**** (11/24/15) (reported 3 distinct informed consent violations);
- Zach Spaulding, AG File 15-CP-61488 (11/24/15) (reported 3 distinct informed consent violations);
- Jenna Kovatch, AG File 15-CP-****(11/27/15) (reported 5 distinct informed consent violations);
- Dr. Jennifer Borek, AG File 15-CP-****(11/27/15) (reported 6 distinct informed consent violations occurring after appeal of license revocation dismissed);
- Jenna Dyer, AG File 15-CP-**** (11/27/15) (reported the same 6 informed consent violations occurring after appeal of license revocation dismissed);
- Pamela Washburn, AG File 16-CP-51978 (2/10/16) (reported activity, possibly an abortion, without a license).

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office, which would occur as part of the meeting being requested herein.

In closing, if there is any type of stipulation or confidentiality agreement that would facilitate the meeting requested herein, we would gladly oblige. Thank you in advance for your consideration to this request and do not hesitate to call me to discuss this matter.

Sincerely,

Shawn F. Sullivan, IN Bar No. 21472-71
Attorney for TLC Advocates, The Life Center, and those similarly situated
S. F. SULLIVAN, ATTORNEY AT LAW, LTD.,

Ex. 1: Mandy Witness Statement

c: Mike Pence
Office of the Governor
State House
Room 206
Indianapolis, IN 46204-2797

Darren Covington/ Kirk E. Masten
Director, Medical Licensing Board
Indiana Government Center
402 W. Washington St., Room W072
Indianapolis, IN 46204

Lindsey Craig
Family Policy Director
Governor's Office, Room 206
Indianapolis, IN 46204-2797

**EXHIBIT 4.b**
Legal Opinion to ISDH

SHAWN F. SULLIVAN
ATTORNEY AT LAW, LTD

1717 EAST WAYNE STREET
SOUTH BEND, IN 46615
(574) 233-7860 • FAX (574) 233-7862
*Admitted in Indiana, Illinois, and North Carolina*

Via email <rsnyder1@isdh.in.gov>

January 29, 2016

Randall Snyder, Director of Acute Care Division
Indiana State Department of Health (ISDH)
2 North Meridian Street, 4A
Indianapolis, IN 46204

Re: Application for Abortion Clinic License by Women's Pavilion and/or MGK Inc. (Dr. Ulrich "George" Klopfer), 2010 Ironwood Circle, South Bend, IN 46635

Dear Mr. Snyder,

I write on behalf of the TLC Advocates (who have submitted complaints containing 51 informed consent violations), the members and supporters of The Life Center, and the over 900 concerned citizens who have signed the "Answer the C.A.L.L. (Citizens Against Licensing the Lawless)" petition, all of whom are deeply concerned about Dr. Klopfer's abortion clinic re-licensure application, which could be filed as early as February 2, 2016. The lack of administrative enforcement here, with only an 88-day stay of operations,[1] when the clinic admitted 10 informed consent violations (during your June 3, 2015 Survey), as well as indisputable evidence that Dr. Kloper systemically violated the informed consent law, is extremely troubling. But more troubling is the refusal of the ISDH to process our complaints filed after the June 3, 2015 Survey because – according to ISDH – they were "repetitive." This excuse for inaction was matched by the startling claim by the ISDH that they do not have jurisdiction to prosecute the TLC Advocates' reporting of 11 illegal abortions (with each one of the illegal abortions being conducted without informed consent) between November 3 and November 6, 2015.

The harm to women is mounting. The attached statement, as an example, is from the very first informed consent violation reported to the ISDH. While I will only release details regarding these statements over the phone, due to privilege concerns, please know that we continue to gather this type of evidence to demonstrate the damage caused by ISDH's lackadaisical enforcement policies. Sadly, although the laws are set up to protect women from this type of damage, the laws are not being enforced. In this case, despite Dr. Klopfer's intentional and systemic violation of the criminal laws, and despite the complaints of TLC Advocates that have documented 51 illegal abortions along with testimonial evidence and an audio-recording the Women's Pavilion's commitment to intentionally denying informed consent, ISDH ignores the magnitude of the situation to the detriment of Dr. Klopfer's patients. Moreover, in the opinion of our clients, and the legal opinion of our outside counsel, the 11 illegal abortions that we reported as occurring after Dr.

[1] Dr. Klopfer signed the settlement documents on November 2, 2015, and the ISDH immediately began giving him credit for his 90-day suspension from operations even though he was still operating. This is just one more anomaly in a history of lackadaisical enforcement of the law in regards to the Women's Pavilion and Dr. Klopfer.

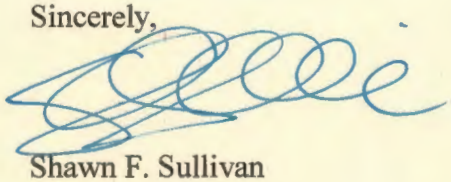
Klopfer had settled with ISDH, but during the extra days of operation that ISDH granted to Women's Pavilion (November 4th through 6th, 2015), are the most poignant violations that should have been investigated by ISDH because those are felonies and represent the doctor's unrepentant, incorrigible, criminal mindset, which should preclude any doctor's ability to apply for a clinic license.[2]

In the case of Dr. Klopfer and Women's Pavilion, however, there are many more reasons that would prompt the reasonable regulatory official to bar Dr. Klopfer from ever obtaining an abortion clinic license again. For starters, his rap sheet of violations with ISDH and prosecutors should have been the basis for extensive fines, especially with his admissions of systemically violating what is a criminal law. How else does the ISDH plan to deter him and deter other abortionists from setting up business plans that systemically violate the law? When the facts of this case become known to all of the populace, this will be a very embarrassing moment for Indiana. And add to that the growing body of injured parties because the ISDH chooses to license the lawless.

I could go on about the awkward nature of the current situation where the ISDH is essentially protecting the abortionist, but already, according to your lead attorney in this matter, Matthew Foster, you consider me to have disdain for the ISDH. I do not harbor disdain for the ISDH. Such a defensive remark to explain my zealous advocacy is churlish and turns the entire matter on its head. It is I, on behalf of thousands of others, that seek to *represent the purpose and rules of ISDH.* Far from disdaining the ISDH, I think the ISDH and its Acute Care Division are essential to protecting the public from lawless abortionists. I think the ISDH holds the premiere responsibility in protecting mothers and enforcing the laws on the books. Unfortunately, though, the current administration of the ISDH are hell-bent on undermining ISDH's own rules. It is the current administration of ISDH and its legal staff that are hell-bent on making a mockery of the abortion laws by refusing to investigate credible complaints and by fostering positions that are more damaging than incompetent. I am seeking, and my clients are pleading – and have been pleading since they launched the Answer the C.A.L.L. campaign last February – that the ISDH simply cease the shenanigans that allow this repeat offender to continue to plague Indiana women and the rule of law.

Please remedy this situation immediately before we have a disaster on our hands in Indiana.

Sincerely,



Shawn F. Sullivan

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[2] By November 2, 2015, when Dr. Klopfer executed the settlement documents, he was already facing Medical Licensing Board allegations that he violated the informed consent law, he had already admitted the 10 informed consent violations found by the ISDH, and he was facing revocation of his license for informed consent violations. That he would immediately violate the informed consent laws that last week of operation, in full view of the TOLC Advocates, while the ink was still drying on the settlement document, in full view of the TLC Advocates, demonstrates that he believes he is beyond authentic prosecution by the ISDH. That ISDH would not investigate these, even when knowing that Dr. Klopfer admitted during the June 3, 2015 survey that violating the informed consent law was his *modus operandi*, proves that ISDH is only feigning regulation of Women's Pavilion and Dr. Klopfer.

I, Mandy [redacted]:

1. On November 28, 2014, I went to the Women's Pavilion for my counseling appointment.

2. I was there for counseling regarding an abortion, but on my way into the Women's Pavilion, I talked to a woman on the sidewalk by the name of Ellen Master. She presented alternatives to abortion, such as adoption, and offered me financial, legal, and medical assistance to eliminate the pressure on me to have an abortion.

3. I went inside to my counseling appointment, considering what Mrs. Master had told me. But during the counseling visit the abortionist asked me to sign-off on some paperwork and gave me a pill.

4. Upon my exit from the Women's Pavilion, I talked again to Mrs. Master, and, although I wanted to consider these options, I informed Mrs. Master that it was too late because the abortionist had already given me the abortion pill that I took in his office.

5. This all occurred over a two hour period during my first visit to the abortionist on November 28, 2014.

Mandy [redacted]

12/1/15 Date

EXHIBIT 4.c
Legal Opinion to ISDH

Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
*Governor*

Jerome M. Adams, MD, MPH
*State Health Commissioner*

July 20, 2015

Mr. Shawn Sullivan
1717 East Wayne Street
South Bend, Indiana 46615

Dear Mr. Sullivan:

The ISDH is in receipt of your letter received on July 17, 2015. Your letter, on behalf of your clients, TLC Advocates, voiced concerns over the ISDH's handling of the regulation of abortion clinics in this state. Specifically, you are dissatisfied over the closure of the TLC Advocate Complaints of Pam Washburn and Mary Ball. As you stated, these complaints relate to violations of Ind. Code § 16-34-2-1.1 concerning timing of the informed consent.

Ms. Pam Washburn and Mary Ball's complaint concerned the same violation identified and investigated by the ISDH on June 3, 2015 with its complaint survey of Women's Pavilion. The division has acted upon the results of the substantiated complaint and an action is pending before an Administrative Law Judge for the ISDH. An additional survey of the same complaint/allegation will not be conducted by the ISDH.

Thank you for your patience as the administrative process runs its course through the required channels.

Respectfully,

Randall Snyder, PT, MBA
Division Director, Acute Care

Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

**EXHIBIT 4.d**
Legal Opinion to ISDH

November 30, 2015

Via Regular Mail & Email (tomborekmci@gmail.com)

Mr. Tom Borek, Legal Assistant
Shawn F. Sullivan, Attorney at Law, LTD
1717 East Wayne Street
South Bend, IN 46615

Re: Complaints Regarding Women's Pavilion

Dear Mr. Borek:

The Indiana State Department of Health ("ISDH") has received your emails of November 23, 2015 and November 30, 2015, which delivered complaints made by several persons about activity at Women's Pavilion in South Bend. Specifically, we received complaints from Nick Keszei, Jennifer Borek, Ellen Master, and Zachary Spaulding on November 23, and from Pamela Washburn, Jennifer Borek, Jenna Kovatch, and Kristine Hunsley on November 30.

ISDH does not presently regulate Women's Pavilion, which is no longer licensed as an abortion clinic. As a courtesy, however, we have forwarded the complaints to the Office of the Indiana Attorney General, which will respond as it deems appropriate. Thank you.

Very truly yours,

Matthew Foster, Litigation Chief
ISDH Office of Legal Affairs

MWF/gb

*An Embarrassing Moment for Hoosiers . .*

# INDIANA STATE DEPARTMENT OF HEALTH ("ISDH") AND OTHER ENFORCEMENT BODIES IN INDIANA ARE PROTECTING AN ABORTION DOCTOR WHO REPEATEDLY AND INTENTIONALLY VIOLATES THE LAW AND ENDANGERS WOMEN

## DEMAND that ISDH and other Indiana agencies and law enforcement ABIDE by the LAW and PROTECT WOMEN!!

**Challenge Indiana Law Enforcement to PROTECT HOOSIERS:**

1. ISDH failed to fine the out-of-state abortionist, Dr. Klopfer, even though Dr. Klopfer admitted to operating his abortion clinic in violation of the criminal laws requiring him to provide mothers with informed consent.
2. ISDH dismissed the informed consent violations and all other violations against Dr. Klopfer without permanent revocation of his clinic license. In fact, Dr. Klopfer still has his medical license and can obtain a clinic license.
3. ISDH has ignored and still refuses to investigate over 48 complaints filed by The Life Center ("TLC"). These complaints show more informed consent violations by Dr. Klopfer and other illegal abortions.

*An Embarrassing Moment for Hoosiers . .*

INDIANA STATE DEPARTMENT OF HEALTH ("ISDH") AND OTHER ENFORCEMENT BODIES IN INDIANA ARE PROTECTING AN ABORTION DOCTOR WHO REPEATEDLY AND INTENTIONALLY VIOLATES THE LAW AND ENDANGERS WOMEN

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**EXHIBIT 5.a**
Legal Opinion to ISDH

# the Life Center

The Life Center ("TLC"), located adjacent to Dr. Klopfer's abortion clinic, does not only serve to report on Dr. Klopfer's violations. TLC actually serves as **the reason** why a mother's **informed consent**, as required by Indiana law, is **so vital** to enabling a mother to make the best choice for her and her family. In order to enable a mother to make an informed choice about abortion – instead of feeling forced to have an abortion -- TLC sidewalk counselors offer **adoption** as well as **medical**, **financial**, and **legal** support, **protection** from those **forcing abortion**, and shelter from domestic violence. In just three years, **102 mothers** hearing this offer by TLC have decided not to go through with their scheduled abortion. That is why Dr. Klopfer and other pro-abortion forces are willing to do anything, including violating the informed consent law, to prevent mothers from considering these and other options. We know mothers want to hear what TLC has to say before going through with an abortion because they have said so. And regretfully, those mothers who were denied informed consent by Dr. Klopfer are lamenting their uninformed choice.

TLC is sponsored and operated by

APOSTOLATE of DIVINE MERCY
in service of HUMAN LIFE

*Making visible the Divine Mercy of Jesus*
*- through public witness, worship, service and education*

Go to www.DivineMercyforLife.net


# the Life Center

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TLC is sponsored and operated by

APOSTOLATE of DIVINE MERCY
in service of HUMAN LIFE

*Making visible the Divine Mercy of Jesus*
*- through public witness, worship, service and education*

Go to www.DivineMercyforLife.net



# the Life Center

The Life Center ("TLC"), located adjacent to Dr. Klopfer's abortion clinic, does not only serve to report on Dr. Klopfer's violations. TLC actually serves as **the reason** why a mother's **informed consent**, as required by Indiana law, is **so vital** to enabling a mother to make the best choice for her and her family. In order to enable a mother to make an informed choice about abortion – instead of feeling forced to have an abortion -- TLC sidewalk counselors offer **adoption** as well as **medical**, **financial**, and **legal** support, **protection** from those **forcing abortion**, and shelter from domestic violence. In just three years, **102 mothers** hearing this offer by TLC have decided not to go through with their scheduled abortion. That is why Dr. Klopfer and other pro-abortion forces are willing to do anything, including violating the informed consent law, to prevent mothers from considering these and other options. We know mothers want to hear what TLC has to say before going through with an abortion because they have said so. And regretfully, those mothers who were denied informed consent by Dr. Klopfer are lamenting their uninformed choice.

TLC is sponsored and operated by

APOSTOLATE of DIVINE MERCY
in service of HUMAN LIFE

*Making visible the Divine Mercy of Jesus*
*- through public witness, worship, service and education*

Go to www.DivineMercyforLife.net

EXHIBIT 5.b
Legal Opinion to ISDH

the Life Center

# Answer the *C.A.L.L.* Campaign

## Citizens Against Licensing the Lawless

**Originally launched on Ash Wednesday 2015 • As of Ash Wednesday 2016, there are 850 signatories**

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**An embarrassing moment for Hoosiers:** A year ago, TLC Legal, on behalf of the above clients, launched the "Answer the C.A.L.L. campaign" to urge the Indiana government – the Governor, the Attorney General, the Medical License Board, county prosecutors, and the Indiana State Department of Health (ISDH) -- to finally hold Dr. Klopfer responsible for decades of operating an illegal abortion clinic in Northern Indiana. Sadly, such a petition was necessitated because the agencies of Indiana essentially encourage Dr. Klopfer to violate the law over and over again.

**In the past two years alone,** Dr. Klopfer has had two criminal cases brought against him and has been cited with numerous health code violations -- from un-monitored post-operation recovery to expired medications to illegal sedation of patients by unlicensed "nurses." After audio evidence was handed to ISDH and Attorney General, Dr. Klopfer was forced to admit that he was intentionally violating the informed consent law when providing abortions, a criminal offense in Indiana. The ISDH charged him with the 10 informed consent violations that Dr. Klopfer admitted, but recently settled that case with him, without a fine, and said he was free to re-apply to re-open his abortion clinic. The ISDH also dismissed another case against Dr. Klopfer without a fine or any other sanction. Meanwhile, the Medical License Board sits idle, and allows Dr. Klopfer to continue practicing while Dr. Klopfer's rap sheet expands. Accordingly, because Dr. Klopfer violates the criminal code in order to deny women the ability to make an informed choice, and because he endangers women's health by failing to adhere to minimum standards of patient care, every person interested in the Rule of Law should sign this petition.

| Name | City/Town | State | Zip | Date |
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**EXHIBIT 6**
Legal Opinion to ISDH

OCTOBER 27, 2017 (/ABBYJOHNSON/2017/9/6/WHOLE-WOMENS-HEALTH-EXPOSED)

# Whole Woman's Health Exposed (/abbyjohnson/2017/9/6/whole-womens-health-exposed)

Detailed inspection reports obtained by And Then There Were None, a group started by former Planned Parenthood director Abby Johnson that helps abortion workers leave their jobs, reveals dozens of health violations levied against Whole Woman's Health, which currently operates 4 abortion facilities in Texas.

Whole Woman's Health is a chain of abortion facilities located mostly in Texas, with clinics also in Maryland, Minnesota and Illinois, who was also the plaintiff in the 2016 Supreme Court case Whole Woman's Health v. Hellerstadt. They won their case, which threw out laws in Texas which would have required abortion facilities to meet common health and safety standards and for abortionists to have admitting privileges to a hospital within 30 miles of the facility.

"As is common in the abortion industry, making a hefty profit is the bottom line and must be achieved over anything else, including the health and safety of patients," said Abby Johnson. "The reports we obtained show a blatant disregard for women's health and safety, as well as the safety of the abortion workers themselves, on the part of Whole Woman's Health. Women deserve this information.

Before the Supreme Court decided in Whole Woman's Health favor, the abortion facility in Austin had shut down and was put up for sale. Abby Johnson toured that facility as a prospective buyer, snapping photos of what appears to be blood on the walls and dirty equipment.

"I was appalled at the state of the Austin Whole Woman's Health," said Ms. Johnson. "It looked more like a prison than an actual facility where patients went for healthcare. Disgusting does not do it justice."

According to the inspection reports, these are some examples of health violations at various Whole Woman's Health facilities from 2011-2017:

· Failed to properly disinfect and sterilize instruments that were used from woman to woman

· Failed to provide a safe and sanitary environment – products of conception were being examined and contaminated instruments were being washed in the same room

· Emergency cart contained expired supplies and medications

· Cracks, rips and tears on the vinyl covers of exam tables

· There was a hole in the cabinet flooring that had "the likelihood to allow rodents to enter the facility"

· Suction machines had numerous rusty spots having the "likelihood to cause infection"

"No wonder Whole Woman's Health took their case all the way to the Supreme Court. They needed to win in order to keep their doors open and make money. They had everything to lose if they didn't win," said Ms. Johnson.

*To speak to Abby Johnson at And Then There Were None, please contact Kristina Hernandez at 908-902-8473.*

PRINTED: 08/03/2017
FORM APPROVED

Texas Department of State Health Services

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 140013 | A. BUILDING: _____ B. WING _____ | 07/24/2017 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| | 8401 NORTH IH 35 SUITE 200 |

| (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 |
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| A 000 | TAC 139 Initial Comments<br><br>Note: The State Form is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be referred to the Office of the Texas Attorney General (OAG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.<br>An entrance conference was held with the Clinic Nurse Manager the morning of 7-24-17. The purpose and process of the initial licensure survey were discussed, and an opportunity given for questions.<br><br>Initial licensure is recommended, with an approved plan of correction.<br><br>An exit conference was held with the Clinic Nurse Manager and the Director of Clinical Services on the afternoon of 7-24-17. Preliminary findings of the survey were discussed, and an opportunity given for questions. | A 000 | | |
| A 126 | TAC 139.41(a) Policy Development and Review<br><br>(a) The licensee shall be responsible for the conduct of the licensed abortion facility and shall assume full legal responsibility for developing, implementing, enforcing, and monitoring written policies governing the facility's total operation, and for ensuring that these policies comply with the Act and the applicable provisions of this chapter and are administered so as to provide health care in a safe and professionally | A 126 | | |

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| | health care in a safe and professionally acceptable environment. These written policies shall include at a minimum the following: | | | |

SOD - State Form

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



PRINTED: 08/03/2017
FORM APPROVED

Texas Department of State Health Services

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 140013 | A. BUILDING: _____ B. WING _____ | 07/24/2017 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| **WHOLE WOMAN'S HEALTH ALLIANCE** | **8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753** |

| (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 |
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| A 126 | Continued From page 1<br><br>This Requirement is not met as evidenced by:<br>Based on a review of documentation and an interview with staff, the licensee failed to be responsible for implementing and enforcing written policies governing the facility's total operation and for ensuring that these policies are | A 126 | | |

administered so as to provide health care in a safe and professionally acceptable environment.

Findings were:

During a tour of the facility on 7-24-17, a random count of Fentanyl (a Schedule II narcotic medication) was performed. 150 ml of Fentanyl was present in boxed vials. 2 ml of Fentanyl was present in an unopened vial (not in a box). 2 syringes, each pre-filled with 0.5 ml of the drug, represented 1 ml of Fentanyl, for a total of 153 ml of Fentanyl. The Fentanyl count on 7-24-17 was verified by staff #7, present during the tour and the narcotic count. The narcotic count sheet indicated that 154 ml of Fentanyl had been present during the closing count conducted on 7-21-17 (which had been verified and signed off on by staff #6 and staff #9). In an interview with staff members #6 & #7, neither member was able to explain the 1 ml Fentanyl discrepancy and both staff stated that no patients had been seen since 7-21-17.

According to https://www.deadiversion.usdoj.gov/schedules/, a Schedule II drug is described as follows: "Schedule II/IIN Controlled Substances (2/2N)

Substances in this schedule have a high potential for abuse which may lead to severe psychological

Texas Department of State Health Services

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| | 140013 | A. BUILDING: _____ B. WING _____ | 07/24/2017 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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| WHOLE WOMAN'S HEALTH ALLIANCE | 8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753 |

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| A 126 | Continued From page 2<br>or physical dependence.<br><br>Examples of Schedule II narcotics include: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®, Percocet®), and fentanyl (Sublimaze®, Duragesic®). Other Schedule II narcotics include: morphine, opium, codeine, and hydrocodone.<br><br>Examples of Schedule IIN stimulants include: amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®).<br><br>Other Schedule II substances include: amobarbital, glutethimide, and pentobarbital."<br><br>Facility policy titled "Medication Therapy Practices" stated, in part:<br>"Controlled Medications Closing Count"<br>1. Each day that Controlled Medications are administered, at the end of the day, two staff will open the safe and count each drug on the Controlled Medication log.<br>... | A 126 | | |

...

8. Any discrepancies between the actual closing count and the anticipated closing count should be resolved and reported to the clinical manager. Discrepancies that cannot be resolved should generate a Narcotics Deviation Report. Deviation reports of concern, i.e. that indicate missing drugs or careless handling, should be shared with the Medical Director/Consultant and included in the Quarterly Review."

The above was confirmed in an interview with staff #6 and staff #7 on the afternoon of 7-24-17.





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| **WHOLE WOMAN'S HEALTH ALLIANCE** | **8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753** |

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| A 257 | Continued From page 3 | A 257 | | |
| A 257 | TAC 139.49(d)(5)(L)((ii)(I - V) Infection Control Standards<br><br>(L) Performance records.<br>(ii) Each sterilizer shall be monitored during operation for pressure, temperature, and time at desired temperature and pressure. A record shall be maintained either manually or machine generated and shall include:<br>(I) the sterilizer identification;<br>(II) sterilization date and time;<br>(III) load number;<br>(IV) duration and temperature of exposure phase (if not provided on sterilizer recording charts);<br>(V) identification of operator(s);<br><br>This Requirement is not met as evidenced by:<br>Based on a review of performance records and interview, the facility failed to ensure that each sterilizer was monitored during operation for pressure, temperature, and time at desired temperature and pressure, as evidenced by the fact that a record was not maintained that included: duration and temperature of exposure phase (if not provided on sterilizer recording charts).<br><br>Finding included:<br><br>Review of the autoclave logs for May, June, and July 2017 revealed that pressure, temperature, and duration of exposure at desired temperature and pressure of the sterilized logs was not documented.<br><br>In an interview on 07/24/17, staff member #7 stated that the new autoclave forms have an area to document the pressure and temperature, | A 257 | | |

Texas Department of State Health Services

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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| | 140013 | A. BUILDING: _____ B. WING _____ | 07/24/2017 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| WHOLE WOMAN'S HEALTH ALLIANCE | 8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753 |

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| A 257 | Continued From page 4<br>however the facility was utilizing old logs that did not contain a prompt to document this information. The new forms also did not have an area to document duration of the exposure phase.<br><br>With no documentation of these elements it is unknown if these loads and instruments were effectively sterilized.<br><br>Facility policy titled "Decontamination, Disinfection, Sterilization, and Storage of Sterile Supplies" states, in part:<br>"Performance Records<br>Performance records for all sterilizers will be | A 257 | | |

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| | maintained for each cycle. And will be retained for two years.(sic) These records will be available for review within two hours during the specified two-year period.<br><br>All sterilizers will be monitored during operation for pressure, temperature, and time at desired temperature and pressure. The performance record will include:<br>-Sterilizer identification number<br>-Sterilization date<br>-Sterilization time<br>-Load number<br>-Pack ID#<br>-Duration and temperature of exposed phase<br>-Identification of operator<br>-Results of biological tests and dates performed<br>-Time/temperature recording charts from each sterilizer"<br><br>The above findings we confirmed on 07/24/17 in an interview with staff member #7. | | | |





| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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NAME OF PROVIDER OR SUPPLIER

**WHOLE WOMAN'S HEALTH ALLIANCE**

STREET ADDRESS, CITY, STATE, ZIP CODE

**8401 NORTH IH 35 SUITE 200**
**AUSTIN, TX 78753**

| (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 |
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| A 315 | Continued From page 5 | A 315 | | |
| A 315 | House Bill 2 Medical and Clinical Services<br><br>A physician must provider the pregnant woman with: a) a telephone number by which the pregnant woman may reach the physician, 24 hours a day to request assistance for any complications that arise from the abortion or ask health-related questions regarding the abortion; and b) the name and telephone number of the nearest hospital to the home of the pregnant woman at which an emergency arising from the abortion would be treated.<br><br>This Requirement is not met as evidenced by:<br>Based on a review of clinical records and an interview with staff, the physician failed to provide the pregnant women with the name and telephone number of the nearest hospital to the home of the pregnant woman at which an emergency arising from the abortion would be treated.<br><br>Findings were:<br><br>During a review of 21 clinical records, 10 of the 21 records (patients #2, #3, #4, #5, #6, #12, #13, #14, #15 and #16) contained no documentation that the patient had been furnished with the name and/or telephone number of the nearest hospital to the home of the pregnant woman at which an | A 315 | | |

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| | to the home of the pregnant woman at which an emergency arising from the abortion would be treated.<br><br>-Patients #2, #3, #4, #5 and #6 had been provided with a hospital name but no telephone number for the hospital.<br><br>-Patients #12, #13, #14, #15 and #16 had been | | | |





| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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| | 140013 | A. BUILDING: _____ B. WING _____ | 07/24/2017 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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| **WHOLE WOMAN'S HEALTH ALLIANCE** | **8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753** |

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| A 315 | Continued From page 6<br><br>provided with neither a hospital name nor a telephone number for the hospital.<br><br>The above was confirmed in an interview with | A 315 | | |

staff #7 on the afternoon of 7-24-17.

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| A 327 | House Bill 2 Medical and Clinical Services<br><br>Physicians must ensure that abortion-inducing drugs are used according to FDA regulations that require the women to visit the physician in person for each of the two doses of the abortion pill, as well as for a follow-up appointment within 14 days. The physician must provide the woman with a copy of the final printed label of the abortion-inducing drug.<br><br>This Requirement is not met as evidenced by:<br>Based on a review of clinical records and an interview with staff, the physician failed to ensure that the patient was scheduled for a follow-up appointment within 14 days.<br><br>Findings were:<br><br>Based on the review of 21 clinical records, 1 of 21 (patient #1) was not scheduled to return to the clinic for a follow-up visit within the required 14 | A 327 | | |

Texas Department of State Health Services

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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| | 140013 | A. BUILDING: _____ B. WING _____ | 07/24/2017 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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| WHOLE WOMAN'S HEALTH ALLIANCE | 8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753 |

| (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 |
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| A 327 | Continued From page 7<br>days (appointment was scheduled for 21 days after).<br><br>The above was confirmed in an interview with staff #7 on the afternoon of 7-24-17. | A 327 | | |

Texas Department of State Health Services

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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| | 140007 | A. BUILDING: _____ B. WING _____ | 11/08/2016 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| WHOLE WOMANS HEALTH OF SAN ANTONIO | 4025 E SOUTHCROSS BLVED BLDG 5 SUITE 30 SAN ANTONIO, TX 78222 |

| (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 |
|---|---|---|---|---|
| A 000 | TAC 139 Initial Comments<br><br>Note: The State Form is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be referred to the Office of the Texas Attorney General (OAG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.<br>An entrance conference was held with the facility co-owner on the morning of 11-7-16. The purpose and process of the licensure resurvey were discussed, and an opportunity given for questions.<br><br>Continued licensure is recommended, with an approved plan of correction.<br><br>An exit conference was held with the facility co-owner and other administrative staff on the afternoon of 11-8-16. Preliminary findings of the survey were discussed, and an opportunity given for questions. | A 000 | REVIEWED<br>DEC 13 2016<br>BY: Wanda Wilson, RN | |
| A 033 | [redacted] | A 033 | | |

SOD - State Form

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE [redacted] TITLE Director of Clinical Services (X6) DATE 12/13/2016

STATE FORM 6899 WVQF11 If continuation sheet 1 of 5

PRINTED: 11/21/2016
FORM APPROVED

Texas Department of State Health Services

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 140007 | A. BUILDING: _____ B. WING _____ | 11/08/2016 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| WHOLE WOMANS HEALTH OF SAN ANTONIO | 4025 E SOUTHCROSS BLVED BLDG 5 SUITE 30 SAN ANTONIO, TX 78222 |

| (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 |
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| A 143 | Continued From page 2 | A 143 | | |
| A 143 | TAC 139.43(2)(3)(4)(5) Personnel Policies<br><br>(2) a requirement for orientation of all employees, volunteers, students and contractors to the policies and objectives of the facility and participation by all personnel in employee training specific to their job;<br>(3) job-related training for each position; | A 143 | A143<br><br>The Clinic Manager will be responsible for ensuring staff members received an annual evaluation of employee's performance.<br><br>The Clinic Manager has created a detailed schedule to complete all staff's annual | |

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| | (4) a requirement for an annual evaluation of employee performance;<br>(5) in-service and continuing education requirements;<br><br>This Requirement is not met as evidenced by:<br>Based on review of documentation and interview, the facility failed to ensure that an annual evaluation of employee performance was completed.<br><br>Findings included:<br><br>Review of the facility personnel files revealed that 6 out 10 employees did not have a current annual evaluation completed.<br>* Staff member # 1's last annual evaluation was completed on 10/15/15.<br>* Staff member # 5's last annual evaluation was completed on 07/14/14.<br>* Staff member # 7 had no annual evaluation completed with a hire date of 08/17/15.<br>* Staff member # 8's last annual evaluation was completed in March 2015.<br>* Staff member # 9 last had a 90 day review completed on 04/10/14.<br>* Staff member # 10's last annual evaluation | evaluations. this process was started on November 15, 2016, and all evaluation reports will be submitted to the DCS by January 15, 2017.<br><br>The Director of Clinical Services will ensure that new Clinic Manager is trained to adhere to the current written employee policy.<br><br>In order to ensure continued compliance with the Employee Policies, the Clinic Manager will ensure that all staff files are reviewed and evaluations are scheduled as part of the QA committee meeting. | 01/15/2017 | |

Texas Department of State Health Services

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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| | 140007 | A. BUILDING: _____ B. WING _____ | 11/08/2016 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| WHOLE WOMANS HEALTH OF SAN ANTONIO | 4025 E SOUTHCROSS BLVED BLDG 5 SUITE 30 SAN ANTONIO, TX 78222 |

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| A 143 | Continued From page 3<br>was completed on 07/17/15.<br><br>In an interview on 11/08/16, staff members #10 and 11 confirmed the facility was unable to locate current annual evaluations for the above staff members. | A 143 | | |
| A 197 | TAC 139.48(1)(A) Physical & Environmental Requirements<br><br>The physical and environmental requirements for a licensed abortion facility are as follows.<br>(1) A facility shall:<br>(A) have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients and staff at all times;<br><br>This Requirement is not met as evidenced by: | A 197 | | |
| A 201 | TAC 139.48(1)(E)(F) Physical & Environmental | A 201 | | |

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| | | Requirements<br><br>The physical and environmental requirements for a licensed abortion facility are as follows.<br>(1) A facility shall:<br>(E) store hazardous cleaning solutions and compounds in a secure manner and label substances;<br>(F) have the capacity to provide patients with liquids. The facility may provide commercially packaged food to patients in individual servings. If other food is provided by the facility, it shall be subject to the requirements of §§229.161 - 229.171 of this title (relating to Texas Food | | | | |





| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 140007 | A. BUILDING: _____ B. WING _____ | 11/08/2016 |

| NAME OF PROVIDER OR SUPPLIER: | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| WHOLE WOMANS HEALTH OF SAN ANTONIO | 4025 E SOUTHCROSS BLVED BLDG 5 SUITE 30 SAN ANTONIO, TX 78222 |

| (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 |
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| A 201 | Continued From page 4<br>Establishments);<br><br>This Requirement is not met as evidenced by:<br>Based on observation, the facility failed to store hazardous cleaning solutions and compounds in a secure manner.<br><br>Findings were:<br><br>During a tour of the facility on 11-8-16, the laundry area (closed off only by a curtain) contained a shelving unit where various cleaners and chemicals such as germicide, enzymatic cleaner and bleach were stored.<br><br>The above was confirmed in an interview with the co-owner and Director of Clinical Services on the afternoon of 11-8-16. | A 201 | A201<br><br>The Clinic Manager will be responsible for ensuring that hazardous cleaning solutions and compounds are stored in a secure manner.<br><br>Cleaners and solutions stored in laundry room area will be moved to a designated storage area. A lock will be installed on the storage closet door.<br><br>The Clinic Manager will conduct an in-service with all staff to advise what materials will be stored in the closet and also to advise staff that the storage room door must remain locked during clinic hours.<br><br>To ensure continued compliance, the QA committee will inspect the storage closet during the QA committee meeting. | 12/23/2016<br><br>01/17/2017 |

Texas Department of State Health Services

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 008036 | A. BUILDING: _____ B. WING _____ | 09/13/2016 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| WHOLE WOMANS HEALTH OF MCALLEN LP | 902 SOUTH MAIN STREET MC ALLEN, TX 78501 |

| (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 |
|---|---|---|---|---|
| A 000 | TAC 139 Initial Comments<br><br>Note: The State Form is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be referred to the Office of the Texas Attorney General (OAG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.<br>An unannounced visit was made on the morning of 9/13/2016 to conduct a Re-licensure Survey to determine compliance with 25 TAC Chapter 139 State Licensing Rules for Abortion Facility. | A 000 | Acceptable L 10/14/16 | |

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| | An entrance conference was conducted with the Clinic Manager. The purpose of the visit and procedure for the survey was discussed.<br><br>An exit conference was conducted on 9/13/16 with the Clinic Manager. Violations were cited. The preliminary findings of the survey and the next steps in the survey process were explained. An opportunity was provided for facility to provide evidence of compliance with those requirements for which non-compliance had been found. | | | |
| A 197 | TAC 139.48(1)(A) Physical & Environmental Requirements<br><br>The physical and environmental requirements for a licensed abortion facility are as follows.<br>(1) A facility shall:<br>(A) have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients and staff at all times; | A 197 | | |

SOD - State F
LABORATORY

[redacted]

TITLE

LVN, Clinic Manager

(X6) DATE

10/14/2016

STATE FORM

XFWV11

If continuation sheet 1 of 2

Texas Department of State Health Services

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 008036 | A. BUILDING: _____ B. WING _____ | 09/13/2016 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| WHOLE WOMANS HEALTH OF MCALLEN LP | 802 SOUTH MAIN STREET MC ALLEN, TX 78501 |

| (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 |
|---|---|---|---|---|
| A 197 | Continued From page 1<br><br>This Requirement is not met as evidenced by:<br>Based on observation and interview, the facility failed to provide a clean and sanitary environment to protect the health and safety of patients and minimize the transmission of infections.<br><br>The findings included:<br><br>Observations on 9/15/14 at 10:00 a.m. of the facility's pathology room, revealed the laminate counter top was warped and bowed away from the particle board based, exposing the particle board. The counter top was no longer a wipeable surface which could harbor bacteria and infectious matter. This room was also used to clean and pack surgical instruments.<br><br>Interview with the facility clinical coordinator confirmed the above finding. | A 197 | A 197<br><br>The Clinic Manager will be responsible for ensuring that our facility maintains a safe and sanitary environment, properly constructed and equipped to protect the health and safety of patients and staff at all times.<br><br>During the survey on 09/13/2016, the surveyor noted that the laminate countertop in the pathology room was warped and bowed away from the particle board exposing the particle board material.<br><br>The Clinic Manager will hire a contractor to remove and replace damaged countertop in Pathology Room.<br><br>In order to ensure that the facility maintains a healthy and safe environment for patients and staff, the Clinic Manager will complete a physical walk through of the facilities while | 10/30/2016 |

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|---|---|---|---|---|
| | | | completing the Quarterly Clinic Reports. Any needed repairs will be included in the above reports and repairs scheduled immediately. | |



Texas Department of State Health Services

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 008137 | A. BUILDING _____ B. WING _____ | 11/17/2011 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| WHOLE WOMANS HEALTH OF BEAUMONT | 440 18TH ST STE A BEAUMONT, TX 77703 |

| (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 |
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| A 000 | | | | |

A 000 TAC 139 Initial Comments

A 000

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An on-site unannounced survey was conducted on 11/15/2011 to determine the facility's compliance with the requirements of the Abortion Facility Reporting and licensing Rules. An entrance conference was conducted with the Administrator on 11/15/2011 at 2:00 PM in the Administrator's office. The purpose and process of the survey was explained and an opportunity was provided for questions and discussion.

An exit conference was held in the waiting area of the clinic on 11/17/2010 at 9:00 AM with the Administrator. The preliminary findings of the survey and the next steps in the survey process were explained. An opportunity was provided for questions and discussion.

A 12[redacted]

A 126

SOD - State Form

LABORATORY DIRE[redacted]

TITLE

(X6) DATE

STATE FORM

[redacted] DIRECTOR OF MEDICAL SERVICES

OU7011

If continuation sheet 1 of 17

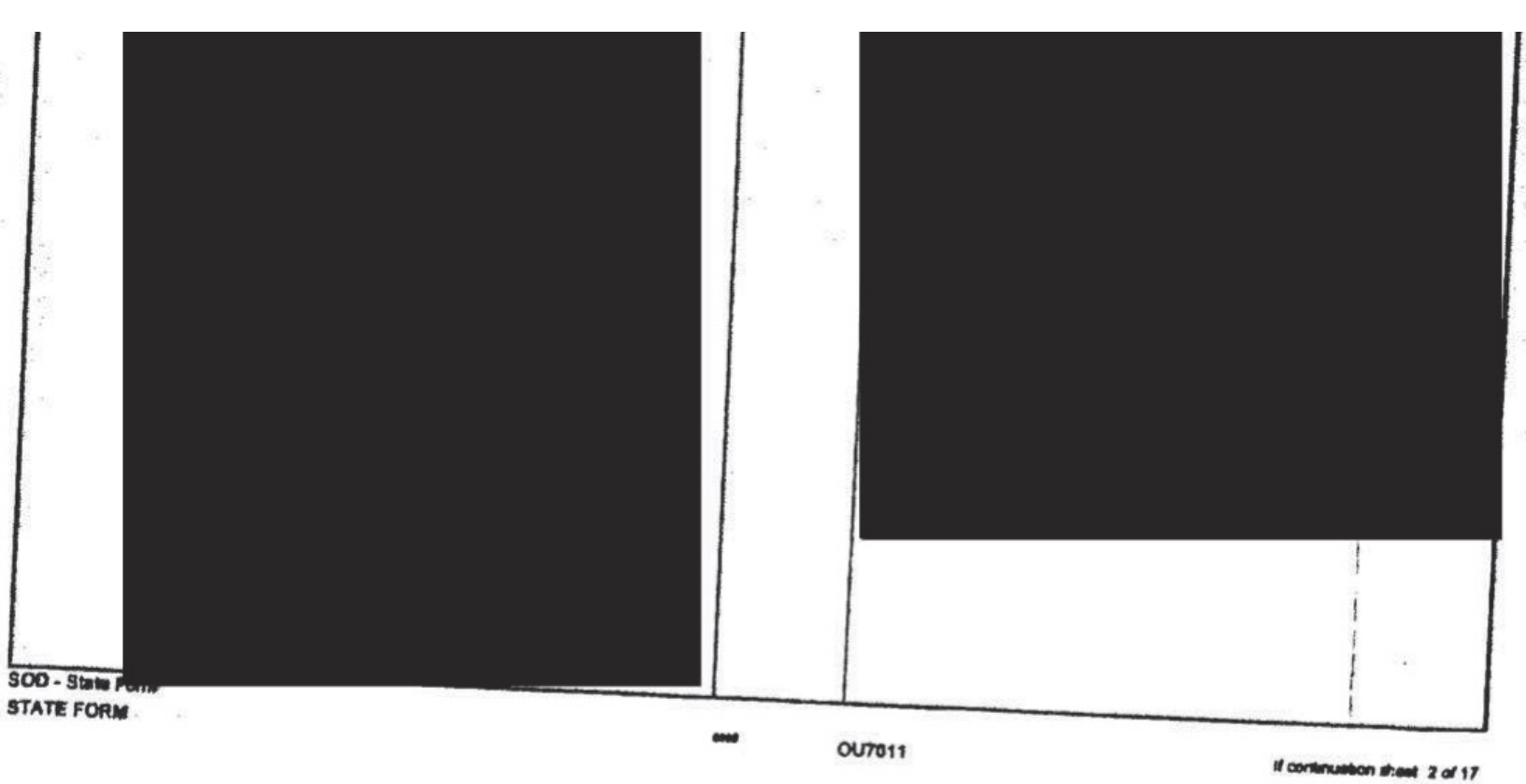
Texas Department of State Health Services

PRINTED: 12/07/2011
FORM APPROVED

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 008137 | A. BUILDING _____ B. WING _____ | 11/17/2011 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| WHOLE WOMANS HEALTH OF BEAUMONT | 440 18TH ST STE A BEAUMONT, TX 77703 |

| (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 |
|---|---|---|---|---|
| A 125 | Continued From page 1 [redacted] | A 125 | A125 [redacted] | |




§245.023

Texas Department of State Health Services

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 008137 | A. BUILDING _____ B. WING _____ | 11/17/2011 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| WHOLE WOMANS HEALTH OF BEAUMONT | 440 16TH ST STE A BEAUMONT, TX 77703 |

| (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 |
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| A 247 | 139.44(c) Orientation, Training, Competency<br><br>(c) The facility shall ensure that staff responsible for sterilization of critical surgical instruments are trained by the facility to meet the requirements of §139.49(d) of this title (relating to Infection Control Standards) and demonstrate competency in performing the sterilization procedures at the facility.<br><br>This Requirement is not met as evidenced by:<br>Based on demonstration and interview the facility failed to ensure the staff was trained in sterilization process of surgical instruments.<br><br>During the demonstration by staff #2 when using peel pouches (a type of package used for sterile instruments that is sealed with a peal away adhesive seal) revealed staff #2 did not know the proper technique for the use of the peel pouch. When staff #2 sealed the sterile package she left a open area in the package.<br><br>On touring the sterilization area where sterile instruments are kept, found eight (8) peel pouches sealed and sterilized with open areas still present in the sterile package. Opened a wrapped sterilized instrument and found no sterilization indicator in the package. Staff #2 did not know what a sterilization indicator was or what it is used for in the sterilization process.<br><br>An interview with staff # 2 on 11/16/2011 at 4:00 PM, asked the surveyor to demonstrate the proper technique on how to seal the packages.<br>An interview with the Administrator on 11/16/2011 at 4:30 PM, confirmed there were no sterilization | A 247 | The Clinic Administrator will be responsible for ensuring all personnel involved in Decontamination and Sterilization Processes will complete the Orientation and Training Checklists, as well as demonstrate accurate competency. (See procedure attached)<br>A staff Re-Training and Re-Orientation of all personnel involved in infection control practices will be facilitated by 02-10-12. This training will include a thorough review of WWH Sterilization and Decontamination practices, and explanation of the importance of sterilization indicators in all surgical pack and instruments. All instruments will be re-sterilized following the proper methods of Decontamination and sterilization.<br>The Clinic Administrator will be responsible for ensuring all Decontamination and Sterilization practices are being followed accurately by inspecting all surgical packs and pouches on a weekly basis for a period of 90 days if no deviations are found during this evaluation period. The Director of | 02-10-12 |

indicators in the facility.

Medical Services will assess competency of the Administrator as well as all staff involved in Infection Control Practices during QA Visits.



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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 008137 | A. BUILDING _____ B. WING _____ | 11/17/2011 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| WHOLE WOMANS HEALTH OF BEAUMONT | 440 18TH ST STE A BEAUMONT, TX 77703 |

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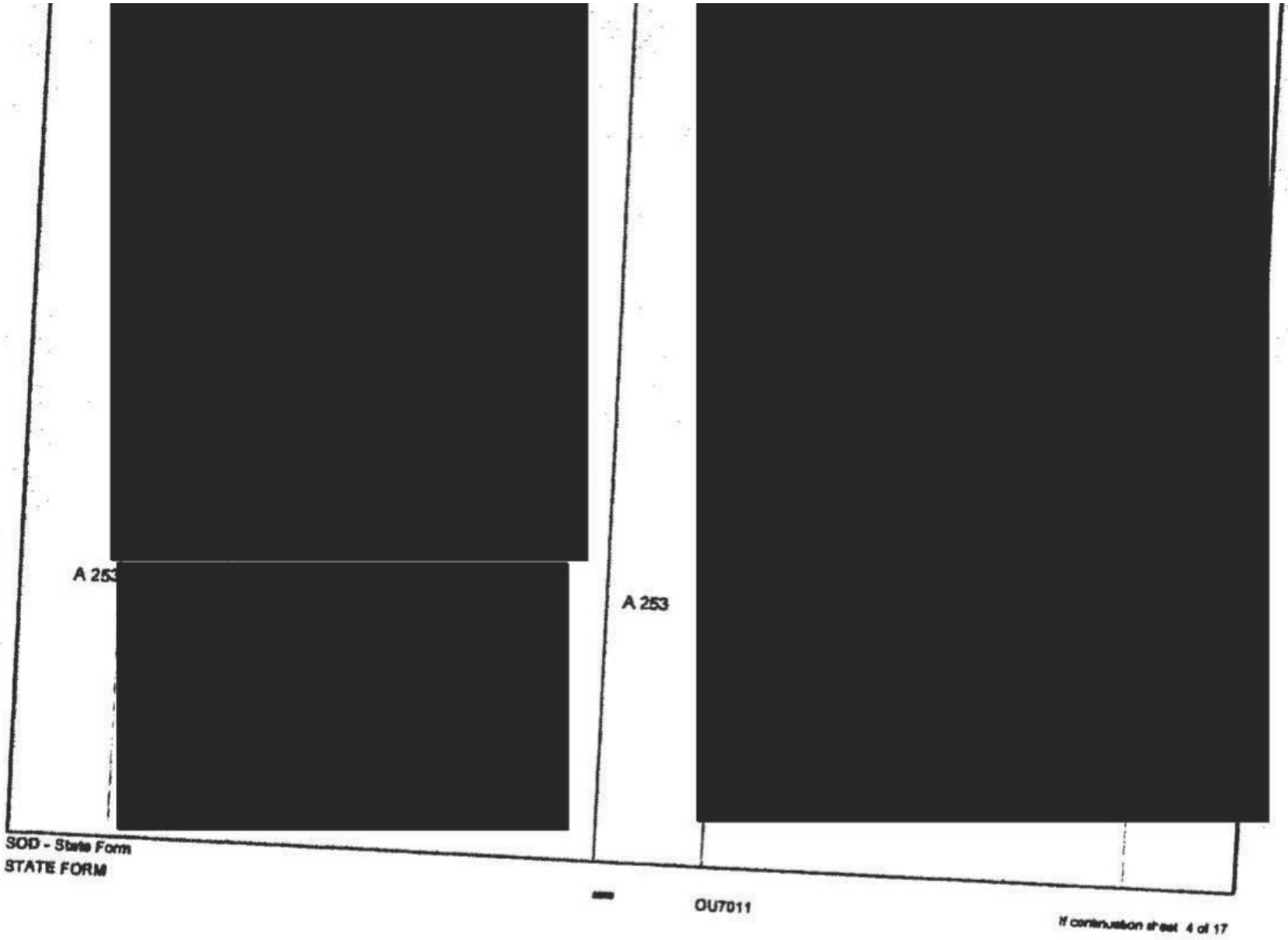
|---|---|---|---|---|
| A 252 | Continued From page 3 | A 252 | A252 | |
| | [redacted] | A 25 | [redacted] | |


A 253
A 253
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If continuation sheet 4 of 17

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Texas Department of State Health Services

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 006137 | A. BUILDING _____ B. WING _____ | 11/17/2011 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| WHOLE WOMANS HEALTH OF BEAUMONT | 440 15TH ST STE A BEAUMONT, TX 77703 |

| (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 |
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| | [redacted] | A 253 | A261<br><br>The Clinic Administrator will ensure all staffing requirements are met, including an LVN or RN as part of Direct Patient Care Staff.<br><br>As outlined in the Texas Administrative Code, Title 25, Chapter 139, Subchapter D, and Section 139.46 (3) Direct Patient Care (B) Nursing Staff. Whole Woman's Health has always been compliant with our staffing and nursing coverage. During the time in question WWH contracted the services of a nursing agency in order to satisfy the nursing requirements by having an LVN at the facility during direct | 02-10-12 |
| A 261 | 139.46(3)(B) Staffing Requirements<br><br>(3) Direct patient care staff | A 261 | patient care hrs. in addition to having a | |

| | | | |
|---|---|---|---|
| | (B) Nursing staff. The nursing staff shall include a registered nurse(s) or a licensed vocational nurse(s).<br><br>This Requirement is not met as evidenced by:<br>Based on record review and interview the facility failed to staff the clinic with a registered nurse(s) or a licensed vocational nurse(s).<br><br>Review of staffing record and personnel records revealed no full time licensed nurse in the facility. Record review revealed a contract agency nurse | contract with a nursing agency, An LVN was hired on 11-18-11, her Orientation documents, Trainings, Competencies, and Vaccinations have been initiated and are been kept in her personnel file.<br><br>The Administrator will monitor the completion of nursing staff hiring and training process. Including orientation and training of agency nurses. | |



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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 008137 | A. BUILDING _____ B. WING _____ | 11/17/2011 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| WHOLE WOMANS HEALTH OF BEAUMONT | 440 18TH ST STE A BEAUMONT, TX |

| (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 |
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| A 261 | Continued From page 5<br><br>was being staffed part time in the facility. In reviewing agency nurse's personnel file it was revealed the facility failed to orientate the agency nurse to the abortion facility.<br><br>An interview with the agency nurse on 11/16/2011 at 5:00 PM, confirmed she worked there part time. She stated "I work for a hospital in Houston thru the agency".<br><br>An interview with staff #1 (Administrator) on 11/16/2011 at 5:30 PM, confirmed the full time nurse last day worked in the facility was November 3, 2011. | A 261 | | |
| A 274 | 139.47(b)(6) Facility Administration<br><br>(b) The administrator shall:<br>(6) ensure that staff receive training, education, and orientation to their specific job description, facility personnel policies, philosophy, and emergency procedures in accordance with this section;<br><br>This Requirement is not met as evidenced by:<br>Based on record review and interview the facility administration failed to ensure staff received training, education, and orientation to their specific job description.<br><br>A review of the agency nurse's personnel file revealed no documentation the facility administration had orientated the agency nurse to the abortion facility.<br><br>An interview with staff #1 (Administrator) on 11/16/2011 at 5:30 PM, confirmed the personnel file of the agency nurse contained no documentation the facility had oriented the | A 274 | A274<br><br>The Administrator will be responsible for ensuring all staff receives training, education, and orientation to their specific job description, facility personnel policies, philosophy, and emergency procedures.<br>The Director of Medical Services has reviewed Administrative responsibilities with the Clinic Administrator to ensure proper follow through of Company Policies. All personnel records, orientation, and proof of follow through of company policies regarding Personnel Records will be completed by 02-10-12, this procedure will also be followed for per diem, agency, and temporary staff.<br><br>The Administrator will monitor all personnel records in a monthly basis in order to ensure proper maintenance. | 02-10-12 |

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 008137 | A. BUILDING _____ B. WING _____ | 11/17/2011 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| WHOLE WOMANS HEALTH OF BEAUMONT | 440 18TH ST STE A BEAUMONT, TX 77703 |

| (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 |
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| A 274 | Continued From page 8<br>agency nurse to the Abortion facility. | A 274 | A283 | |
| A 283 | 139.48(1)(A) Physical & Environmental Requirements<br><br>The physical and environmental requirements for a licensed abortion facility are as follows.<br>(1) A facility shall:<br>(A) have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients and staff at all times; | A 283 | The Clinic Administrator will ensure the facility's physical and environmental requirements are followed.<br><br>It is not unusual for office and medical equipment to suffer damage due to the wear and tear of regular use and repairs | |

This Requirement is not met as evidenced by:
Based on observation and interview the facility failed to provide a safe and sanitary environment.

Findings included:

During the tour of the facility on 11/15/2011 at 3:00 PM observed in exam room #1 there was a sign on the bed written it was broken. The bed remained broken during the survey. When questioned the Administrator, she stated someone was to suppose to come fix the bed.

During the tour of the facility on 11/15/2011 at 3:20 PM observed in the procedure room #2 there was a drain in the middle of the room, but the cover was loose and caused a hole to be in the floor right in front of the patient's bed.

During the tour of the facility on 11/15/2011 at 3:20 PM observed in the procedure room #2 there was numerous rusty spots on the suction machine used on the patient for evacuation of the products of conception.

During the tour of the facility on 11/15/2011 at

are undertaken promptly at WWH. The broken exam table found on exam room #1 was not available for patents until completely repaired and did not affect patient safety in the clinic. The clinic had 2 other exam rooms available for patient care, without hindering the patient's safety at any point. At this point, the exam table has been completely repaired and it is now available for patient care.

The loose cover on the drain on Procedure room #2 will be repaired, as well as the rusted spots on the suction machines. These repairs will be completed by 02-10-12. The Administrator will contract with a medical cleaning company to clean, and buff the floors to address the rust stains that are a natural result of metal equipment seating

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECT ON | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 008137 | A. BUILDING _____ B. WING _____ | 11/17/2011 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| WHOLE WOMANS HEALTH OF BEAUMONT | 440 18TH ST STE A BEAUMONT, TX 77703 |

| (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 |
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| A 283 | Continued From page 7<br>3:00 PM observed the facility's floor were stained and discolored which gives the appearance of being dirty.<br><br>During the tour of the facility on 11/15/2011 at 3:00 PM observed the three facility's fire extinguishes were last inspection on March of 2010.<br><br>During the tour of the facility on 11/15/2011 at 3:00 PM observed no postings of a plan to evacuate the building in case of a disaster.<br><br>An interview with the administrator on 11/15/2011 at 4:00 PM confirmed the bed was broken in room #1, there was a hole in the in procedure room #2, the floors were stained, and the evacuation plan of the building was not posted for the safety of the patients and employees. | A 283 | on vinyl floors throughout the clinic. A fire extinguisher company will be contacted in order to inspect all fire extinguishers for proper functioning.<br><br>The Administrator will post the emergency evacuation plan throughout the clinic, and will offer a staff training to ensure all personnel is aware of proper emergency evacuation procedure.<br><br>The Administrator will ensure all equipment it's in optimal functioning and complaint with physical and environmental requirements in order to provide a safe environment for patients. | 02-10-12 |
| A 284 | 139.48(1)(B) Physical & Environmental Requirements<br><br>The physical and environmental requirements for a licensed abortion facility are as follows.<br>(1) A facility shall:<br>(B) equip each procedure room so that procedures can be performed in a manner that assures the physical safety of all individuals in the area; | A 284 | A284<br><br>See correction for A283 | |

This Requirement is not met as evidenced by:
Based on observation and interview the facility failed to provide safe equipment in the patient's procedure rooms.

Findings Included:

During the tour of the facility on 11/15/2011 at





| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 008137 | A. BUILDING _____ B. WING _____ | 11/17/2011 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| WHOLE WOMANS HEALTH OF BEAUMONT | 440 18TH ST STE A BEAUMONT, TX 77703 |

| (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 |
|---|---|---|---|---|
| A 284 | Continued From page 8<br>3:00 PM observed in exam | A 284 | | |

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| | sign on the bed written it was broken. The bed remained broken during the survey. When questioned the Administrator, she stated "someone was to suppose to come fix the bed".<br><br>During the tour of the facility on 11/15/2011 at 3:20 PM observed in the procedure room #2 there was numerous rusty spots on the suction machine used on the patient for evacuation of the products of conception.<br><br>An Interview with the administrator on 11/15/2011 at 4:00 PM confirmed the bed was broken in room #1, and there were numerous rusty spots on the suction machine used on patients for evacuation of the products of conception. | | | |
| A 286 | 139.48(1)(D) Physical & Environmental Requirements<br><br>The physical and environmental requirements for a licensed abortion facility are as follows.<br>(1) A facility shall:<br>(D) have a written protocol for emergency evacuation for fire and other disasters tailored to the facility's geographic location. Each staff member employed by or under contract with the facility shall be able to demonstrate their role or responsibility to implement the facility ' s emergency evacuation protocol required by this subparagraph;<br><br>This Requirement is not met as evidenced by:<br>Based on record review and Interview the facility failed to conduct and follow the facility's policy on fire and/or disaster drills for evacuation of patients and staff in the facility. | A 286 | A286<br><br>The Clinic Administrator will be responsible for ensuring all staff is properly trained on the facilities emergency evacuation plan (See Attached)<br><br>A staff in service will be facilitated by 02-10-12 in order to train the staff on the Facility's Emergency evacuation plan (Fire, and Natural Disasters)<br><br>The Clinic Administrator will ensure an annual Emergency Evacuation Drill has been completed, and documented. | 02-10-12 |

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| A 286 | Continued From page 9<br><br>Review of record titled "Fire Safety" revealed "It is the policy of this facility to conduct a fire drill or handle a fire in such a manners to preserve lives, prevent undue panic, and control the spread of fire. Each employee will be aware of fire exits, fire extinguishes, the proper procedure for ensuring fire safety, and the steps to be taken in case of fire. It is not the intent of this policy that any staff member endangers him/herself; rather, the intent is to ensure the safety both staff and patients."<br><br>Review of facility records found no evidence of that fire and/or disaster drills had been conducted.<br><br>An interview with staff #1 (Administrator) on 11/16/2011 at 5:00 PM, confirmed no drills had been conducted in the facility in the last year. | A 286 | A306<br><br>The Clinic Administrator will be responsible for the accurate follow | |
| A 306 | 139.49(d) Infection Control | | | |

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| | 748.48(d) Infection Control Standards<br><br>(d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies. A licensed abortion facility shall have written policies covering its procedures for the decontamination and sterilization activities performed. Policies shall include, but not be limited to, the receiving, cleaning, decontaminating, disinfecting, preparing and sterilization of critical items (reusable items), as well as those for the assembly, wrapping, storage, distribution, and the monitoring and control of sterile items and equipment.<br><br>This Requirement is not met as evidenced by:<br>Based on observation and interview the facility's staff failed to monitor the expiration dates on sterile supplies. | A 306 | through of the company's Infection control policies (Cleaning, Decontamination, and Sterilization)<br><br>All expired supplies were removed from the facility. The Clinic Administrator will inspect supplies inventory to check for expiration dates on a monthly basis, to ensure patient safety. The findings will be submitted to the Director of Medical Services to address any deviations and training needs. Competency of the Administrator and all staff involved in Infection Control Practices will be addresses during QA visits. | 02-10-12 |

| STATEMENT OF CORRECTION | IDENTIFICATION NUMBER: 008137 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 11/17/2011 |
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| A 308 | Continued From page 10<br><br>During a tour of the facility on 11/15/2011 at 4:00 PM found in the procedure room #1 and #2, and the supply closet were expired sterile supplies.<br><br>Size #6 Straight curettes, expired 2011-04 X 46<br>Size #7 Straight curettes, expired 2011-02 X 1<br>Size #7 Straight curettes, expired 2011-03 X 8<br>Size #7 Straight curettes, expired 2011-03 X 8<br>Size #11 Straight curettes, expired 2011-08 X 15<br>Size #11 Straight curettes, expired 2011-09 X 6<br>Size #14 Straight curettes, expired 2011-07 X 26<br><br>An interview with staff #1 (Administrator) on 11/15/2011 at 4:00 PM confirmed the sterile supplies from the list above were expired. | A 308 | | |
| A 334 | 138.49(d)(5)(F)(iv) Infection Control Standards<br><br>(d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies.<br>(5) Equipment and sterilization procedures.<br>(F) Biological indicators.<br>(iv) If a test is positive, the sterilizer shall immediately be taken out of service. A malfunctioning sterilizer shall not be put back into use until it has been serviced and successfully tested according to the manufacturer ' s recommendations.<br><br>This Requirement is not met as evidenced by:<br>Based on record review and interview the facility failed to read the biological indicators within the 24 hour incubation period on 14 of 54 readings over period of 3 months 8/4/2011-11/15/2011. | A 334 | | |

Manufacturer's recommendations revealed "ProSpore2 is ideal for in-office validation and



Texas Department of State Health Services

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| A 334 | Continued From page 11<br>monitoring of steam sterilizers and has the same ease of use and indications as the ProSpore. It consists of a paper disc carrier containing Geobacillus stearothermophilus spores. The disc is enclosed in a plastic tube along with a glass vial containing media for growing the bacterial spores. Bromocresol purple has been added to assist in detecting | A 334 | A334<br><br>The Clinic Administrator will be responsible for ensuring all Infection Control Standards are being | |

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| | sporas decreases pH, causing a color change from purple to yellow. A shorter incubation period allows a validated 24 hour result."<br><br>Review of record titled "Biological Monitoring log for Prospora2 revealed 14 of 54 readings had been read either before the 24 hour period or over the 24 hour period.<br>Biological Test Run Date—Biological Test Read Date<br>8/5/2011 — 8/8/2011<br>8/13/2011 — 8/13/2011<br>8/13/2011 — 8/15/2011<br>8/15/2011 — 8/15/2011<br>8/20/2011 — 8/20/2011<br>8/22/2011 — 8/22/2011<br>8/27/2011 — 8/29/2011<br>9/1/2011 — 9/1/2011<br>9/10/2011 — 9/10/2011<br>9/10/2011 — 9/12/2011<br>9/24/2011 — 9/26/2011<br>10/8/2011 — 10/10/2011<br>10/22/2011 — 10/24/2011<br>11/12/2011 — 11/15/2011<br><br>Interview with staff #1 (Administrator) on 11/16/2011 4:00 PM, confirmed the readings were not read according to the manufacturer's recommendations. | | standards are being followed<br><br>A staff in Service will be facilitated by 02-10-12 to train the staff on Decontamination and Sterilization Procedures. The Clinic Administrator will ensure all instruments have been sterilized, and the Manufacturer's instructions regarding proper reading of bio indicators has been followed, as well as ensuring all sterilization packs and pouches are properly sealed including a Sterilization Indicator Strip on the inside of the packs.<br><br>The Clinical Administrator will ensure proper follow through of Decontamination and Sterilization practices as well as all Infection Control Practices. The findings will be submitted to the Director of Medical Services for a period of 90 days in order to address competency, and further training needs. | 02-10-12 |
| A 340 | 139.49(d)(5)(H)(iii) Infection Control Standards | A 340 | | |

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| A 340 | Continued From page 12<br>(d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies.<br>(5) Equipment and sterilization procedures.<br>(H) Maintenance of sterility.<br>(III) All packages shall be inspected before use. If a package is torn, wet, discolored, has a broken seal, or is damaged, the item may not be used. The item shall be returned to sterile processing for reprocessing.<br><br>This Requirement is not met as evidenced by:<br>Based on observation and interview the facility failed to maintain the sterility of the surgical instruments.<br><br>On touring the sterilization area where sterile instruments are kept, found eight (8) peel pouches sealed and sterilized with open areas still present in the sterile package. Opened a wrapped sterilized instrument and found no sterilization indicator in the package, continued to open all wrapped instruments and none of the wrapped instruments contained sterilization indicator for steam autoclaves. | A 340 | A340<br><br>See Correction A334 | |

An interview with staff #2 confirmed she did not know what a sterilization indicator was or what it is used for in the sterilization process nor did she know how to properly seal the peel pouch. Staff # 2 on 11/16/2011 at 4:00 PM, asked the surveyor to demonstrate the proper technique on how to seal the packages.

An interview with the Administrator on 11/16/2011 at 4:30 PM confirmed there were no sterilization indicators in the facility and observed that staff #2 did not know the proper technique for sealing peel pouches.





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| A 446 | 139.56(c) Emergency Services<br><br>(c) Personnel providing direct patient care shall be currently certified in basic life support by the American Heart Association, the American Red Cross, or the American Safety and Health Institute, or in accordance with their individual professional licensure requirements, and if required in their job description or job responsibilities.<br><br>This Requirement is not met as evidenced by:<br>Based on record review and interview the facility failed to ensure staff was trained in CPR (cardiopulmonary resuscitation) and follow the facility's policy on 1 (#3) of 4 staff members in the facility.<br><br>Review of record titled "Job Description Patient Advocate" revealed "Required Continuing Education /Training: 1.) Basic Life Support Certification biannually 2.) Annual OSHA and PPE inservice training" per the facility's policy.<br><br>A review of staff #3's personnel record revealed no documentation staff #3 had been trained in CPR.<br><br>An interview with the Administrator on 11/16/2011 at approximately 11:00 AM, confirmed staff #3 does not have CPR training. | A 446 | A446<br><br>See Correction A254 | |
| A 476 | 139.59(j)(1)(E) Anesthesia Services<br><br>(j) Emergency equipment and supplies appropriate for the type of anesthesia services provided shall be maintained and accessible to staff at all times.<br>(1) Functioning equipment and supplies which | A 476 | | |

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| A 476 | Continued From page 14<br>are required for all facilities include:<br>(E) emergency medications specified by the medical staff and appropriate to the type of surgical procedures and anesthesia services provided by the facility.<br><br>This Requirement is not met as evidenced by:<br>Based on record review, observation, and interview the facility failed to have current emergency medication in the emergency crash cart and follow the facility's policy. | A 476 | A476<br><br>The Clinic Administrator will be responsible for ensuring all Anesthesia Services requirements are been properly followed.<br><br>All expired medications have been properly disposed, and the crash cart has been re stocked with | |

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| | An inventory of the crash cart revealed expired medication of 50% Dextrose 50 ml vial with expiration date of (September 2011).<br><br>Review of policy titled "Medication Therapy Practices" revealed:<br>"Medications Inventory and Audit<br>1. Each month the Clinical Coordinator, Nurse or the Administrator will perform a detailed inventory of all medicines and medical supplies in the facility using WWH inventory and tracking tools. (see medicines and medical supplies ordering inventory)<br>2. Each week the Clinical Coordinator, Nurse or Administrator will perform a detailed review and inventory of the crash cart in order to ensure all required medications are current and available. This will include all injectable, tablets and IV solutions, as well as supplies such as syringes, needles, bandages and airways.<br>All expired medications and supplies will be disposed according to WWH wasting medications procedure. (See page 2) the crash cart inventory list will be updated | | [illegible] stocked with current required medications.<br><br>The Clinic Administrator will be responsible for monitoring the inventory and expiration dates of all crash cart medications. A review of the inventory will be performed on a monthly basis; the findings will be submitted to the Director of Medical Services in order to ensure accuracy. The Director of Medical Services will facilitate a retraining on this policy to the Clinic Administrator by 02-10-12 | 02-10-12 |

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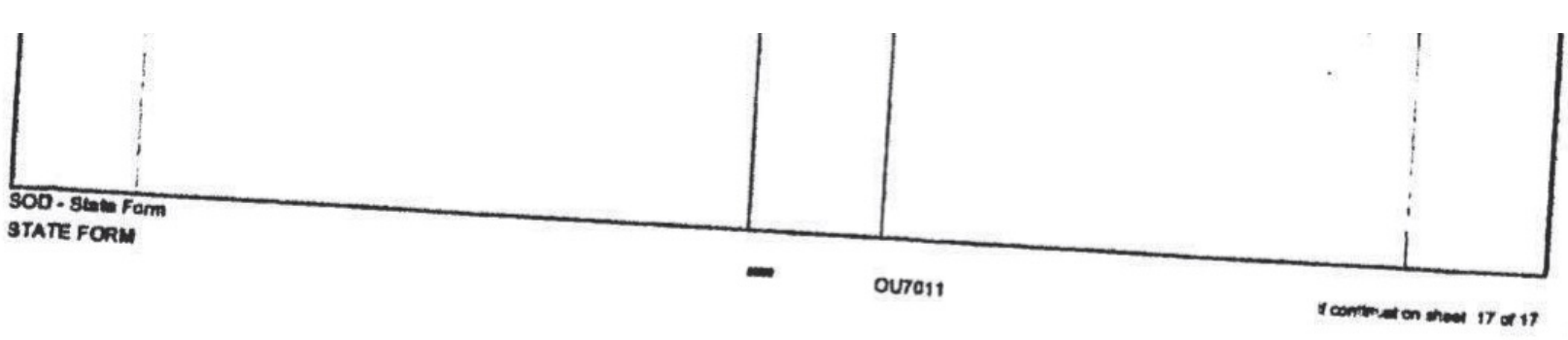
| A 478 | Continued From page 16<br>complete emergency airway equipment. | A 478 | | |
| A 495 | 139.60(h)(6) State and Federal Requirements<br><br>(h) A licensed abortion facility shall comply with the following federal Occupation Safety and Health Administration requirements:<br>(6) 29 Code of Federal Regulations, Subpart L, §1910.157, concerning portable fire extinguishers;;<br><br>This Requirement is not met as evidenced by:<br>Based on observation and interview the facility failed to follow the 29 Code of Federal Regulations, Subpart L, 1910.157 concerning portable fire extinguishers.<br><br>During the tour of the facility on 11/15/2011 at 3:00 PM observed the three facility's fire extinguishes were last inspection on March of 2010.<br><br>An interview with the administrator on 11/15/2011 at 4:00 PM confirmed the fire extinguishes were last inspection on March of 2010. | A 495 | A495<br><br>See Correction A283 | |



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