



Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

STATE OF INDIANA)
) SS: BEFORE AN ADMINISTRATIVE LAW JUDGE FOR
COUNTY OF MARION) THE INDIANA STATE DEPARTMENT OF HEALTH
 CAUSE NO. ACL- 000041 -15

DIVISION OF ACUTE CARE,)
INDIANA STATE DEPARTMENT OF HEALTH,)

Petitioner,)

v.)

MGK INC. a/k/a MGK INC d/b/a WOMEN'S PAVILION,)
2010 Ironwood Circle,)
South Bend, Indiana 46635,)

Respondent.)

Indiana State Department of Health
Office of Legal Affairs

JUN 26 2015

FILED

COMPLAINT AND REQUEST FOR HEARING

Notice is hereby given to MGK Inc. a/k/a MGK INC d/b/a Women's Pavilion, Facility No. 011127 ("Women's Pavilion" or "Respondent") that a complaint to revoke its abortion clinic license has been filed by the Indiana State Department of Health, Division of Acute Care ("ISDH" or "Petitioner") pursuant to Ind. Code § 16-21-3-1, Ind. Code § 16-21-3-2 and Ind. Code § 4-21.5-3-8. Petitioner is the state agency with the authority to regulate abortion clinics in the State of Indiana.

STATEMENT OF CHARGES

Women's Pavilion is charged with violating Ind. Code § 16-21 and multiple rules adopted thereunder. In support, the Petitioner avers:

1. Women's Pavilion is a licensed abortion clinic in the state of Indiana, and was so operating on or about June 3, 2015.

2. Notice is sent via certified and regular mail addressed to the following:

Dr. Ulrich Klopfer, D.O.
President and Registered Agent
MGK, Inc. a/k/a MGK INC d/b/a Women's Pavilion
2010 Ironwood Circle
South Bend, Indiana 46635



3. On or about October 29, 2014, the ISDH conducted a survey of Women's Pavilion and cited Women's Pavilion for twenty-seven (27) deficiencies.

4. As a result of the survey, on or about December 9, 2014, the ISDH sent the survey to Women's Pavilion and requested that Women's Pavilion submit a Plan of Correction addressing each of the twenty-seven (27) deficiencies cited (the "First Notice").

5. Women's Pavilion did not respond to the ISDH's First Notice, and on or about January 6, 2015, the ISDH issued a second notice of non-compliance ("Second Notice") to Women's Pavilion.

6. On or about January 28, 2015, having still not received a response, the ISDH filed a Complaint and Request for Hearing (Cause No. ACL-000031-15) seeking to revoke Women's Pavilion's abortion clinic license (hereinafter referred to as "First Complaint").

7. The above-referenced revocation action is currently pending before an Administrative Law Judge for the ISDH.

8. On or about June 3, 2015, the ISDH conducted a licensure complaint investigation of Women's Pavilion. A true and correct copy of the report for that investigation (the "Survey Report") is attached hereto and incorporated as Exhibit A.

9. During the course of the survey, the ISDH substantiated the complaint and cited deficiencies related to the initial allegation, as outlined in paragraphs ten (10) through fifteen (15) below.

10. Women's Pavilion failed to have a governing body in place to ensure that medical abortion services provided at the clinic are in compliance with Ind. Code § 16-34-2-1.1 (see Survey Report, pp. 3-9). Those acts and/or omissions constitute a critical breach by Women's Pavilion of 410 IAC 26-4-1(c)(2), which states in pertinent part:

(c) The governing body shall do the following:

(2) Ensure that:

(A) clinic policies are followed so as to provide quality health care in a safe environment; and

(B) the clinic complies with:

(i) this article;

(ii) IC 16-21; and

(iii) IC 16-34.

11. Ind. Code § 16-34-2-1.1 requires that at least eighteen (18) hours before the abortion, the woman must give her voluntary and informed consent, view the fetal ultrasound, and hear auscultation of the fetal heart tone.

12. Oral statements made by the facility physician indicated that patients seeking medical abortions are given the abortion medication during the consultation and not eighteen (18) hours after the consultation, as required by Ind. Code § 16-34-2-1.1 (see Survey Report, p. 9).

13. To knowingly or intentionally perform an abortion in violation of Ind. Code § 16-34-2-1.1 is a Class A infraction. See Ind. Code § 16-34-2-7.

14. Women's Pavilion failed to have a governing body in place 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 clinic (see Survey Report, pp. 1-2). Those acts and/or omissions constitute a breach by Women's Pavilion of 410 IAC 26-4-1(c)(1), which states in pertinent part:

- (c) The governing body shall do the following:
 - (1) Assume responsibility for:
 - (A) determining;
 - (B) implementing; and
 - (C) monitoring
- policies governing the clinic's operation.

15. Women's Pavilion failed to maintain a patient register of all patients receiving services at the clinic including medical abortion services (see Survey Report, pp. 10-11). Those acts and/or omissions constitute a breach by Women's Pavilion of 410 IAC 26-7-1(c), which states in pertinent part:

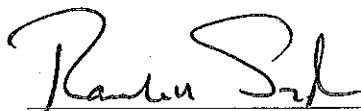
- (c) A written or electronic register must be kept of all patients treated that provides the following:
 - (1) Identification data.
 - (2) Treatment rendered.
 - (3) Attending physician.
 - (4) Condition on discharge.
 - (5) Transfers to hospital facility.
 - (6) Other data deemed necessary by the clinic.

16. The deficiencies recited in the Survey Report as detailed above show that Women's Pavilion is not in compliance with the laws governing the conduct of abortion clinics in this state, and that such noncompliance is willful, intentional, and detrimental to the welfare of clinic patients.

WHEREFORE, Petitioner respectfully prays for entry of an Order revoking Respondent's license pursuant to Ind. Code §§ 16-21-3-1, 16-21-3-2, and 4-21.5-3-8, and for all just and appropriate relief for Petitioner.

Respectfully submitted,

DIVISION OF ACUTE CARE, INDIANA STATE DEPARTMENT OF HEALTH



Randall Snyder, Director
Division of Acute Care

24 Jun 15

Date



Terry L. Whitson, Assistant Commissioner
Health Regulatory Services Commission

June 24, 2015

Date

Sent by regular and certified mail, return receipt requested, to:

Dr. Ulrich Klopfer, D.O.
President and Registered Agent
MGK, Inc. a/k/a MGK INC d/b/a Women's Pavilion
2010 Ironwood Circle
South Bend, Indiana 46635

Sent Certified Mail, Return Receipt Requested No.

**91 7190 0005 2730 0008 6437
Z900000669822**

MGK, Inc. a/k/a MGK INC d/b/a Women's Pavilion
c/o Timothy S. Shelly
121 West Franklin Street, Suite 400
Elkhart, Indiana 46516

Sent Certified Mail, Return Receipt Requested No.

**91 7190 0005 2730 0008 6444
Z900000669826**

Representing ISDH:

Adrienne Brune, Attorney
Indiana State Department of Health
Office of Legal Affairs
2 North Meridian Street
Indianapolis, IN 46204
317/233-7270

Matthew Foster, Attorney
Indiana State Department of Health
Office of Legal Affairs
2 North Meridian Street
Indianapolis, Indiana 46204
317/233-9827

cc: Mr. Terry L. Whitson, Mr. Randall Snyder, Ms. Adrienne Brune, Mr. Matthew Foster
Public File

Indiana State Department of Health

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

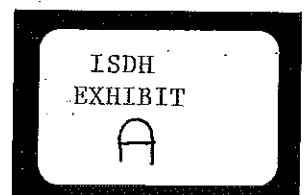
STREET ADDRESS, CITY, STATE, ZIP CODE
**2010 IRONWOOD CIR
SOUTH BEND, IN 46635**

(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 000	<p>INITIAL COMMENTS</p> <p>The visit was for a licensure complaint investigation.</p> <p>Complaint Number: IN 00170828</p> <p>Substantiated: deficiencies related to the allegations are cited</p> <p>Date: 6-03-15</p> <p>Facility Number: 011127</p> <p>QA: cjl 06/12/15</p>	T 000		
T 022	<p>410 IAC 26-4-1 GOVERNING BODY</p> <p>410 IAC 26-4-1(c)(1)</p> <p>(c) The governing body shall do the following: (1) Assume responsibility for: (A) determining; (B) implementing; and (C) monitoring; policies governing the clinic ' s operation.</p> <p>This RULE is not met as evidenced by: 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,</p>	T 022		

Indiana State Department of Health
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE



Indiana State Department of Health

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NAME OF PROVIDER OR SUPPLIER WOMEN'S PAVILION			STREET ADDRESS, CITY, STATE, ZIP CODE 2010 IRONWOOD CIR SOUTH BEND, IN 46635		
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T 022	Continued From page 1 29 and 30). Findings: 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. 2. Review of the following medical records indicated: a. Patient 21 received medical abortion services on 05/01/15. b. Patient 22 received medical abortion services on 04/29/15. c. Patient 23 received medical abortion services on 05/13/15. d. Patient 24 received medical abortion services on 05/29/15. e. Patient 25 received medical abortion services on 05/26/15. f. Patient 26 received medical abortion services on 04/21/15. g. Patient 27 received medical abortion services on 05/01/15. h. Patient 28 received medical abortion services on 05/15/15. i. Patient 29 received medical abortion services on 05/27/15. j. Patient 30 received medical abortion services on 05/27/15. 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 T 024	<p>Continued From page 2</p> <p>410 IAC 26-4-1 GOVERNING BODY</p> <p>410 IAC 26-4-1(c)(2)</p> <p>(c) The governing body shall do the following: (2) Ensure that: (A) clinic policies are followed so as to provide quality health care in a safe environment; and (B) the clinic complies with: (i) this article; (ii) IC 16-21; and (iii) IC 16-34.</p> <p>This RULE is not met as evidenced by: 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.</p> <p>Findings:</p> <p>1. Review of Indiana Code (IC) 16-34-2-1.1 indicates the following:</p>	T 024 T 024		

Indiana State Department of Health

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T 024	<p>Continued From page 3</p> <p>Voluntary and informed consent required; viewing of fetal ultrasound and hearing auscultation of fetal heart tone</p> <p>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:</p> <p>(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:</p> <p>(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.</p> <p>(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.</p> <p>(C) The nature of the proposed procedure or information concerning the abortion inducing drug.</p> <p>(D) Objective scientific information of the risks of and alternatives to the procedure or the use of an abortion inducing drug, including:</p> <p>(i) the risk of infection and hemorrhage;</p>	T 024		

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T 024	<p>Continued From page 4</p> <p>(ii) the potential danger to a subsequent pregnancy; and</p> <p>(iii) the potential danger of infertility.</p> <p>(E) That human physical life begins when a human ovum is fertilized by a human sperm.</p> <p>(F) The probable gestational age of the fetus at the time the abortion is to be performed, including:</p> <p>(i) a picture of a fetus;</p> <p>(ii) the dimensions of a fetus; and</p> <p>(iii) relevant information on the potential survival of an unborn fetus; at this stage of development.</p> <p>(G) That objective scientific information shows that a fetus can feel pain at or before twenty (20) weeks of postfertilization age.</p> <p>(H) The medical risks associated with carrying the fetus to term.</p> <p>(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.</p> <p>(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.</p> <p>(2) At least eighteen (18) hours before the abortion, the pregnant woman will be informed orally and in writing of the following:</p> <p>(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.</p> <p>(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.</p>	T 024		

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NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE

WOMEN'S PAVILION **2010 IRONWOOD CIR**
SOUTH BEND, IN 46635

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T 024	Continued From page 5 (C) That adoption alternatives are available and that adoptive parents may legally pay the costs of prenatal care, childbirth, and neonatal care. (D) That there are physical risks to the pregnant woman in having an abortion, both during the abortion procedure and after. (E) That Indiana has enacted the safe haven law under IC 31-34-2.5. (F) The: (i) Internet web site address of the state department of health's web site; and (ii) description of the information that will be provided on the web site and that are; described in section 1.5 of this chapter. (3) The pregnant woman certifies in writing, on a form developed by the state department, before the abortion is performed, that: (A) the information required by subdivisions (1) and (2) has been provided to the pregnant woman; (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: (i) viewed or refused to view the offered fetal ultrasound imaging; and (ii) listened to or refused to listen to the offered auscultation of the fetal heart tone if the fetal heart tone is audible; and (C) the pregnant woman has been given a written copy of the printed materials described in section 1.5 of this chapter. (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		

Indiana State Department of Health

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T 024	<p>Continued From page 6</p> <p>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:</p> <p>(A) The name of the physician performing the abortion and the physician's medical license number.</p> <p>(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.</p> <p>(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.</p> <p>(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:</p> <p>(1) does not want to view the fetal ultrasound imaging; and</p> <p>(2) does not want to listen to the auscultation of the fetal heart tone if the fetal heart tone is audible.</p> <p>2. On 6/3/15 at 4:45 PM, the medical director and clinic physician #50 was requested to provide</p>	T 024		

Indiana State Department of Health

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T 024	<p>Continued From page 7</p> <p>a copy of a policy/procedure for medical abortion services provided at the clinic and none was provided prior to exit.</p> <p>3. Review of the following medical records (MR) indicated:</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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</p>	T 024		

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T 024	<p>Continued From page 8</p> <p>before the abortion.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>4. At 3:55 PM, 4:05 PM and 4:45 PM, during the interview with the facility physician, #50, physician #50 reported:</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>d. There is no written policy/procedure related to the medical abortion process at the facility.</p>	T 024		

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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 128	Continued From page 9	T 128		
T 128	<p>410 IAC 26-7-1 MEDICAL RECORDS</p> <p>410 IAC 26-7-1(c)</p> <p>(c) A written or electronic register must be kept of all patients treated that provides the following:</p> <ol style="list-style-type: none"> (1) Identification data. (2) Treatment rendered. (3) Attending physician. (4) Condition on discharge. (5) Transfers to hospital facility. (6) Other data deemed necessary by the clinic. <p>This RULE is not met as evidenced by: 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.</p> <p>Findings:</p> <ol style="list-style-type: none"> 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. 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		

Indiana State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 011127	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED 06/03/2015
NAME OF PROVIDER OR SUPPLIER WOMEN'S PAVILION		STREET ADDRESS, CITY, STATE, ZIP CODE 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 128	Continued From page 10 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		

