

STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

AGENCY FOR HEALTH CARE)
ADMINISTRATION,)
)
Petitioner,)
)
vs.) Case No. 12-1140
)
A MEDICAL OFFICE FOR WOMEN,)
INC., d/b/a MEDICAL OFFICE FOR)
WOMEN,)
)
Respondent.)
_____)

RECOMMENDED ORDER

On June 8, 2012, Robert E. Meale, Administrative Law Judge,
conducted the final hearing by video teleconference in
Tallahassee and Miami, Florida.

APPEARANCES

For Petitioner: Nelson E. Rodney, Esquire
Senior Attorney
Agency for Health Care Administration
Suite 300
8333 Northwest 53rd Street
Doral, Florida 33166

For Respondent: Vlad Van Rosenthal, M.D.
Qualified Representative
Medical Office for Women
Suite 402
909 Northeast 163rd Street
Miami, Florida 33160

STATEMENT OF THE ISSUES

The issues are whether Respondent failed to maintain emergency medications, in violation of Florida Administrative Code Rule 59A-9.0225(1), and failed to ensure that a defibrillator was available for immediate use, in violation of Florida Administrative Code Rule 59A-9.0225(2). If so, another issue is the penalty that should be imposed.

PRELIMINARY STATEMENT

By Administrative Complaint dated February 7, 2012, Petitioner alleged that Respondent operates a licensed abortion clinic in North Miami Beach. The Administrative Complaint contains two counts.

Count I alleges that, during a relicensure survey conducted on June 8, 2010, Petitioner's surveyor determined that Respondent "failed to maintain sterile suturing equipment and supplies, and their crash cart, which includes emergency medications." During a followup survey conducted on April 21, 2011, Petitioner's surveyor determined that medications on the crash cart were out-of-date: one 500-ml bag of Lactated Ringer's Intravenous Solution bore an expiration date of April 2009, a one-mg vial of Atropine bore an expiration date of November 2010, and one 2% Lidocaine Hydrochloride injection bore an expiration date of November 2010. For this uncorrected

deficiency, which allegedly violates Florida Administrative Code Rule 59A-9.0225(1), the Administrative Complaint seeks an administrative fine of \$500.

Count II alleges that, during a relicensure survey on June 8, 2010, Petitioner's surveyor determined that Respondent failed to ensure that emergency equipment was provided for immediate use. In particular, the surveyor found that Respondent's facility lacked a defibrillator. During a followup survey conducted by the surveyor on April 21, 2011, the surveyor determined that Respondent's facility still did not have a defibrillator. For this uncorrected deficiency, which allegedly violates Florida Administrative Code Rule 59A-9.0225(2), the Administrative Complaint seeks an administrative fine of \$500.

At the hearing, the Administrative Law Judge determined that Dr. Rosenthal was a Qualified Representative of Respondent. Petitioner called four witnesses and offered into evidence the following pages from its exhibit binder: 1-12, 18, 21, 32, 39-42, and 47. Respondent called one witness and offered into evidence no exhibits. All exhibits were admitted into evidence.

The court reporter filed the transcript on June 27, 2012. Petitioner filed a proposed recommended order on July 9, 2012.

FINDINGS OF FACT

1. At all material times, Respondent has operated, under the jurisdiction of Petitioner, a licensed abortion clinic facility, bearing license number 899. The facility in question is located in North Miami Beach. At the time of the surveys described below, Respondent also operated another facility in south Miami, but that facility is not involved in this case. All references to "facility" will therefore refer to the North Miami Beach location.

2. On June 8, 2010, one of Petitioner's surveyors conducted a relicensure survey of Respondent's facility. As is typical of such surveys, this survey was unannounced.

3. During the survey, the surveyor discovered three expired medications in the facility: 0.2 mg Isuprel[®]--expired August 2009, 0.4 mg atropine--expired February 2010, and an unspecified dosage of nalbuphene--expired February 2010. These expired medications were on a shelf in the operating room. During the survey, the surveyor also discovered that the facility did not have a defibrillator.

4. At the conclusion of the survey, the surveyor conducted an exit conference with the sole employee present at the facility. During this conference, the surveyor explained these deficiencies and gave Respondent until July 8, 2010, to correct them. Subsequently, the surveyor prepared a report showing

these violations and confirming that the deadline for correcting both deficiencies was July 8, 2010.

5. On April 21, 2011, the surveyor returned, again unannounced, to the facility to conduct a followup survey and again found only one employee present at the facility. During this survey, the surveyor discovered three expired medications in the facility: one 500-ml IV bag of Lactated Ringer's--expired April 2009, 1 mg atropine--expired November 2010, and 2% lidocaine hydrochloride injection--expired November 2010. The surveyor found these expired medications in a locked storage box on the crash cart, which is the cart used for medical emergencies. During the followup survey, the surveyor also discovered that the facility did not have a defibrillator.

6. On the dates of both surveys, the facility did not have any surgical procedures scheduled. Also, no patients were present at anytime during either survey.

7. During each survey, the surveyor selected five dates at random to determine if the facility had performed any second-trimester abortions, and she found that no such procedures had been performed on any of these dates. For this reason, the surveyor did not cite the facility for any violations that are contingent on the actual performance of second-trimester abortions--such as, the failure to have a registered nurse in the recovery room. Similarly, because no patient was present

during the surveys, the surveyor testified that she did not cite the facility for a failure to maintain anaesthesia equipment in the operating room; the surveyor explained that the anaesthesiologist brings his or her own equipment when attending a surgical procedure.

8. The surveyor explained that she cited Respondent for the deficiencies alleged in this case because they are contingent upon licensure only, not licensure and the actual performance of second-trimester abortions. At the time of each survey, regardless of the level of patient activity, the facility was open and capable of supporting the procedures for which it is licensed.

9. Dr. Rosenthal offered an explanation for each of the deficiencies cited in this case. As he testified, the expired medications found during the followup survey were in a locked storage box maintained by a certified registered nurse anesthetist, who had not worked at the facility for several years, but had never returned to retrieve her storage box. However, Dr. Rosenthal's explanation does not account for why the surveyor missed the Lactated Ringer's IV fluid during the original relicensure survey, if, in fact, she did miss this item. (The other two items were not expired at the time of the earlier survey.)

10. Notwithstanding any shortcoming in Dr. Rosenthal's explanation, more importantly, the record fails to establish the absence of current emergency medications and IV fluids at the facility. As noted below, the cited rule requires that the facility contains these items; as long as it does, the cited rule is not violated by the presence of expired medications and fluids at the facility. The presence of such expired items is insufficient, especially when the standard of proof, as noted below, is clear and convincing evidence, to support an inference that adequate, current medications and IV fluids were not also available at the facility.

11. As Dr. Rosenthal testified, at the time of both surveys, Respondent maintained a single defibrillator, which he transferred from one facility to another, depending on which facility was to be the site of surgical procedures on a given day. This explanation is not responsive to the requirement of a defibrillator at each facility.

CONCLUSIONS OF LAW

12. The Division of Administrative Hearings has jurisdiction. §§ 120.569 and 120.57, Fla. Stat.

13. Florida Administrative Code Rule 59A-9.0225(1) and (2) provides:

- (1) Each abortion clinic providing second trimester abortions shall provide essential clinic supplies and equipment as required in

subsections (1) through (7) when performing second trimester abortions. Any such abortion clinic which is in operation at the time of adoption of this rule and providing second trimester abortions shall be given one year within which to meet these standards as follows:

- (a) A surgical or gynecological examination table(s);
- (b) A bed or recliner(s) suitable for recovery;
- (c) Oxygen with flow meters and masks or equivalent;
- (d) Mechanical suction;
- (e) Resuscitation equipment to include, at a minimum, resuscitation bags and oral airways;
- (f) Emergency medications, intravenous fluids, and related supplies and equipment;
- (g) Sterile suturing equipment and supplies;
- (h) Adjustable examination light;
- (i) Containers for soiled linen and waste materials with covers; and
- (j) Appropriate equipment for the administering of general anesthesia, if applicable.

(2) Emergency equipment shall be provided for immediate use, maintained in functional condition, and capable of providing at least the following services:

- (a) Inhalation therapy;
- (b) Defibrillation;
- (c) Cardiac monitoring;
- (d) Suctioning; and
- (e) Maintenance of patient airway.

14. The burden of proof is on Petitioner to prove the material allegations by clear and convincing evidence. Dep't of Banking & Fin. v. Osborne Stern & Co., Inc., 670 So. 2d 932 (Fla. 1996).

15. As explained above, Petitioner has failed to prove that the facility lacked adequate emergency medications and IV fluids at the time of either survey. However, Petitioner has provided that the facility lacked the required defibrillator at the time of both surveys.

16. Section 390.018, Florida Statutes, authorizes an administrative fine of up to \$1000 for any violation of, among other things, the rules governing an abortion clinic. Petitioner has proved one of the two counts that it asserted in the Administrative Complaint, which seeks a fine of \$500 for each count. Thus, a fine of \$500 is reasonable for the offense of failing to maintain a defibrillator at the facility.

RECOMMENDATION

It is RECOMMENDED that the Agency for Health Care Administration enter a final order finding Respondent guilty of failing to maintain a defibrillator and imposing an administrative fine of \$500 for this violation and dismissing the charge pertaining to expired medications and IV fluids.

DONE AND ENTERED this 10th day of July, 2012, in
Tallahassee, Leon County, Florida.



ROBERT E. MEALE
Administrative Law Judge
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Filed with the Clerk of the
Division of Administrative Hearings
this 10th day of July, 2012.

COPIES FURNISHED:

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NOTICE OF RIGHT TO SUBMIT EXCEPTIONS

All parties have the right to submit written exceptions within 15 days from the date of this Recommended Order. Any exceptions to this Recommended Order should be filed with the agency that will issue the Final Order in this case.