STATE OF FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION



STATE OF FLORIDA, AGENCY FOR HEALTH CARE ADMINISTRATION.

2012 AUG 31 A 9:37

Petitioner,

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| v | |

AHCA NO. 2011013924
RENDITION NO.: AHCA-12- OSGO-S-OLC

CANDACE M. DYE d/b/a A WOMAN'S WORLD MEDICAL CENTER,

| Respondent. |
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FINAL ORDER

Having reviewed the Administrative Complaint, and all other matters of record, the Agency for Health Care Administration finds and concludes as follows:

- 1. The Agency has jurisdiction over the above-named Respondent pursuant to Chapter 408, Part II, Florida Statutes, and the applicable authorizing statutes and administrative code provisions.
- 2. The Agency issued the attached Administrative Complaint and Election of Rights form to the Respondent. (Ex. 1) The Election of Rights form advised of the right to an administrative hearing.
 - 3. The parties have since entered into the attached Settlement Agreement. (Ex. 2)

Based upon the foregoing, it is **ORDERED**:

- 1. The Settlement Agreement is adopted and incorporated by reference into this Final Order. The parties shall comply with the terms of the Settlement Agreement.
- 2. The Respondent shall pay the Agency \$4,000.00. If full payment has been made, the cancelled check acts as receipt of payment and no further payment is required. If full payment has not been made, payment is due within four (4) months of the Final Order. Overdue amounts are subject to statutory interest and may be referred to collections. A check made payable to the "Agency for Health Care Administration" and containing the AHCA ten-digit case number should be sent to:

Office of Finance and Accounting Revenue Management Unit Agency for Health Care Administration 2727 Mahan Drive, MS 14 Tallahassee, Florida 32308

| ORDERED at Tallahassee, Florida, on this | 30 | _day of _ | August | , 2012. |
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Elizabeth Dudek, Secretary

Agency for Health Care Administration

NOTICE OF RIGHT TO JUDICIAL REVIEW

A party who is adversely affected by this Final Order is entitled to judicial review, which shall be instituted by filing one copy of a notice of appeal with the Agency Clerk of AHCA, and a second copy, along with filing fee as prescribed by law, with the District Court of Appeal in the appellate district where the Agency maintains its headquarters or where a party resides. Review of proceedings shall be conducted in accordance with the Florida appellate rules. The Notice of Appeal must be filed within 30 days of rendition of the order to be reviewed.

CERTIFICATE OF SERVICE

Richard Shoop, Agency Clerk

Agency for Health Care Administration 2727 Mahan Drive, Bldg. #3, Mail Stop #3 Tallahassee, Florida 32308-5403

Telephone: (850) 412-3630

| Jan Mills Facilities Intake Unit (Electronic Mail) | Finance & Accounting Revenue Management Unit (Electronic Mail) |
|--|--|
| Nelson E. Rodney Office of the General Counsel Agency for Health Care Administration (Electronic Mail) | Candace M. Dye A Woman's World Medical Center 503 South 12 th Street Fort Pierce, Florida 34950 (U.S. Mail) |
| | |

STATE OF FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION

STATE OF FLORIDA, AGENCY FOR HEALTH CARE ADMINISTRATION

Petitioner, v.

AHCA No.: 2011013924

Return Receipt Requested: 7009 0080 0000 0586 5310

CANDACE M. DYE, d/b/a A WOMAN'S WORLD MEDICAL CENTER, INC.,

Respondent.

ADMINISTRATIVE COMPLAINT

COMES NOW the Agency for Health Care Administration ("AHCA"), by and through the undersigned counsel, and files this administrative complaint against Candace M. Dye d/b/a A Woman's World Medical Center, Inc. (hereinafter "A Woman's World Medical Center, Inc."), pursuant to Chapter 390, and Section 120.60, Florida Statutes (2010), and alleges:

NATURE OF THE ACTION

1. This is an action to impose an administrative fine in the amount of \$4,000.00 pursuant to Section 390.018, Florida Statutes for the protection of the public health, safety and welfare pursuant to 408, Part II, Florida Statutes.

JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to Sections 120.569 and 120.57 Florida Statutes, Chapter 28-106, Florida Administrative Code.

EXHIBIT 1

3. Venue lays pursuant Rule 28-106.207, Florida Administrative Code.

PARTIES

- 4. AHCA is the regulatory authority responsible for licensure and enforcement of all applicable statutes and rules governing birth centers pursuant to Chapter 390, Florida Statutes (2010), and Chapter 59A-9, Florida Administrative Code.
- 5. A Woman's World Medical Center, Inc. operates an abortion clinic located at 503 South 12th Street, Fort Pierce, Florida 34950. A Woman's World Medical Center, Inc. is licensed as an abortion clinic facility license number 820, with an expiration date of September 18, 2012. A Woman's World Medical Center, Inc. was at all times material hereto a licensed facility under the licensing authority of AHCA and was required to comply with all applicable rules and statutes.

COUNT I

A WOMAN'S WORLD MEDICAL CENTER, INC. DID NOT MEET THE MINIMUM REQUIREMENTS WHEN PROVIDING SECOND TRIMESTER ABORTIONS Rule 59A-9.022, Florida Administrative Code (PHYSICAL PLANT REQUIREMENTS-2nd TRIMESTER)

- 6. AHCA re-alleges and incorporates paragraphs (1) through (5) as if fully set forth herein.
- 7. During the re-licensure survey conducted on 11/16/2011 And based on observation and interview it was determined that this abortion clinic did not meet the minimum

requirements when providing second trimester abortions, specifically related to providing adequate privacy in the consultation room.

- The staff member at the reception desk (identified self as an LPN), was interviewed on 11/16/2011 at approximately 10:15 AM, and was asked where the consultation room is located. She pointed to the desk behind the reception desk. She stated that the following procedures are performed in this area: vitals are obtained; weight is obtained; Rh test is conducted; and procedures are discussed. This room has the sliding glass reception window; a door that is locked providing access to and from lobby; a closet door (containing patient records); and a door leading to the hallway that accesses all areas of the clinic. The 2 desks are separated by 2 six foot tall shelves. During interview and observation with the Administrator, conducted on 11/16/2011 at approximately 11:15 AM, she was asked how this area provided confidentiality to each patient. She stated that nobody can hear anything. She stated the door can be closed if necessary. This concern had been previously cited during the August 2010 re-licensure survey. The clinic's plan of correction indicated that this area would not be The Administrator the consultation room. utilized as acknowledged that was the plan of correction.
- 9. A review of the clinic's policy and procedure, related to pre-op appointment and counseling sections,

indicates patient counseling includes discussion of the following confidential topics:

- Demographics
- Previous pregnancies
- Drug addiction status
- Medical conditions or problems
- What they should expect the day of procedure
- Counselor will discuss any questions related to feelings or fears of the patient.
- Counselor will also note why procedure is being conducted: financial; age; finish education first; and future birth control options (if requested)
- 11. Based on the foregoing, A Woman's World Medical Center, Inc. violated Rule 59A-9.022, Florida Administrative Code, a deficiency, which warrants an assessed fine of \$1,000.00.

COUNT II

A WOMAN'S WORLD MEDICAL CENTER, INC. DID NOT ENSURE WRITTEN PREVENTIVE MAINTENANCE PROGRAMS RELATED TO PATIENT MONITORING EQUIPMENT

Rule 59A-0225(7), Florida Administrative Code (CLINIC SUPPLIES/EQUIPMENT STANDARDS-2nd TRIMESTER)

- 12. AHCA re-alleges and incorporates paragraphs (1) through (5) as if fully set forth herein.
- 13. During the re-licensure survey conducted on 11/16/2011 and based on observation, interview, and record review it was determined that this clinic did not ensure that written preventative maintenance programs were developed and/or

implemented, specifically related to patient monitoring equipment; anesthesia and surgical equipment; and all surgical instruments.

- During tour and interview with the administrator, conducted on 11/16/2011 beginning at approximately 11:15 AM the facility monitoring equipment, located in the procedure room, the anesthesia and surgical equipment and the room identified the lab were observed. Observation of the calibration/inspection (related to preventative maintenance) stickers on equipment revealed that the last inspection was on 08/08/1010. The Administrator was asked if this clinic has a written preventative maintenance program. She stated that she was under the impression that the provider of the calibration services tracks when the inspection is due.
- 15. During review of the clinic's policies and procedures and interview with the Administrator, conducted on 11/16/2011 at approximately 5:30 PM, this surveyor was unable to locate any specific written preventative maintenance programs. The Administrator was provided the opportunity to locate present for review specific written preventative maintenance had been developed and/or implemented, programs that specifically related to patient monitoring equipment; anesthesia and surgical equipment; and all instruments. The Administrator provided the clinic's Equipment Maintenance Policy and acknowledged that it does not contain

policies for specific types of equipment and/or instruments. This 1/4 page document reflects the following:

- "Equipment will be maintained according to manufacturer's instructions. Preventative maintenance and calibration will be recorded on appropriate control logs. All equipment malfunction or breakdown should be reported to the Medical Director and/or Administrator in a timely fashion. In cases of equipment failure, the contingency plan will depend on the availability of immediate placement or loaner apparatus."
- 17. Based on the foregoing, A Woman's World Medical Center, Inc. violated Rule 59A-9.0225(7), Florida Administrative Code, a deficiency, which warrants an assessed fine of \$1,000.00.

COUNT III

A WOMAN'S WORLD MEDICAL CENTER, INC. DID NOT ENSURE WHEN A PERSON OTHER THAN A PHYSICIAN PERFORMS AN UNLTRASOUND EXAMINATION

Rule 59A-9.025(2)(4)(6)(7) and (8), Florida Administrative Code (MEDICAL SCREENING-2ND TRIMESTER)

- 18. AHCA re-alleges and incorporates paragraphs (1) through (5) as if fully set forth herein.
- 19. During the biennial licensure survey conducted on 11/16/2011 and based on record review and interview it was determined that this clinic (that conducts 2nd trimester abortions) did not ensure when a person other than a physician performs an ultrasound (US) examination, that staff have

documentation of course completion in the operation of ultrasound equipment.

- 20. During an interview and personnel record review with the Administrator on 11/16/2011, beginning at approximately 2:30 PM, she confirmed that all staff conducts the US (ultrasound) screening. She stated that this screening is only utilized to determine gestational age, so the clinic can determine the appropriate service charge. She was asked where this US screening picture is placed. She replied that it is taped to the back of the procedure form.
- 21. This clinic had previously been cited for staff conducting US without appropriate training. The clinic's approved correction reflected the physician would be the only staff member to conduct the before and after ultrasounds.
- 22. The Administrator stated that the physician is the only employee that does conduct the US (other than the screening used to determine charges). The Administrator was asked how many US pictures should be located in each clinical record. She explained that there should be 3 (1st is clinic screening by employees; 2nd is US prior to procedure by physician; and the 3rd is the US after the procedure by physician. She was asked what days the physicians work at the clinic to which she stated Wednesdays and Saturdays.
- 23. During subsequent interview and clinical record review with the Administrator, conducted on 11/16/2011 at

approximately 3:30 PM, she was asked why all sampled clinical records (#1, #2, #3, #4, and #5) only contained 2 US pictures and each had been dated 1 day apart. This surveyor asked if the US "screening" is utilized by the clinic's physicians, in lieu of the physician's conducting the initial US. The Administrator confirmed the US "screening" that is conducted by clinic staff is the one that the physicians will use for reference prior to the procedure.

- 24. During interview and review of policy and procedure entitled "Pre-Counsel/Pre-Op Visit", specifically the ultrasound section with the Administrator, conducted on 11/16/2011 at approximately 5:30 PM, she acknowledged that this policy reflects the following: Each patient will have an ultrasound done to verify age of pregnancy prior to the procedure. Each ultrasound done will have a picture printed and placed in the patient's chart for the physician's viewing.
- 25. All 3 staff members conduct ultrasounds on patients without documentation of completion of a Sonography course that has been accredited (Rule 6A-14.030), as meeting the requirements, by the State of Florida.
- 26. Based on the foregoing, A Woman's World Medical Center, Inc. violated Rule 59A-9.025(2)(4)(5)(6)(7), and (8), Florida Administrative Code, a deficiency, which warrants an assessed fine of \$1,000.00.

COUNT IV

A WOMAN'S WORLD MEDICAL CENTER, INC. DID NOT FOLLOW THE APPROPRIATE PRECAUTIONS FOR THE ESTABLISHMENT OF INTRAVENOUS ACCESS OF PATIENTS THAT RECEIVED 2ND TRIMESTER ABORTION Section 59A-9.026, Florida Administrative Code (ABORTION PROCEDURE-2ND TRIMESTER)

- 27. AHCA re-alleges and incorporates paragraphs (1) through (5) as if fully set forth herein.
- 28. During the re-licensure survey conducted on 11/16/2011 and based on interview and record review, it was determined that this clinic, that provides 2nd trimester abortions, did not follow the appropriate precautions for the establishment of intravenous access (at least for the patients undergoing post-first trimester abortions) for 5 of 5 clinical records of patients that received 2nd trimester abortions (#1, #2, #3, #4, and #5).
- 29. In addition, based on interview and record review it was determined that this clinic, that provides 2nd trimester abortions, did not have documentation to reflect appropriate monitoring of patient's vital signs by professionals licensed and qualified to assess the patient's condition throughout the abortion procedure and during the recovery room period until the patient's condition as specified by the type of abortion procedure performed, is deemed to be stable for 5 of 5 patients that received 2nd trimester abortions (#1, #2, #3, #4, and #5).
- 30. Based on observation and interview it was determined the clinic failed to provide any monitoring of vital signs, by

- a qualified individual, for the 6 patients identified as receiving 1st trimester abortions.
- 31. During review of this clinic's policies and procedures with the Administrator, conducted on 11/16/2011 at approximately 5:30 PM, she was asked to locate and provide the policy related to the establishment of intravenous access at least for patients undergoing the 2nd trimester abortion procedure. She replied that this clinic does not establish an intravenous access port for any of their patients because they do not provide general anesthesia. The regulation (noted above) was reviewed with her and she stated that she was not aware they were required to establish intravenous access. When asked what they would do if there was an emergency during a procedure, she replied that the patient would be transferred to the hospital.
- 32. During interview and clinical record review (of 5 patients that had received 2nd trimester abortion procedures) with the Administrator, conducted on 11/16/2011 beginning at approximately 2:30 PM she was asked to locate documentation of the monitoring of vital signs during the procedure and in the recovery room (in order to determine if the patient has become stable). She was unable to locate any documentation to reflect this had occurred related to patients #1, #2, #3, #4, and #5 that had received 2nd trimester abortion procedures.

- revealed that the unlicensed LPN (Licensed Practical Nurse) was the staff member that was present. There were 6 patients that the Administrator had reported, on 11/16/2011 at approximately 1:00 PM as being present to receive 1st trimester abortions. This surveyor was present on 11/16/2011 prior to patient arrivals beginning at 1:00 PM through recovery room discharges at 6:30 PM. Neither this unlicensed nurse, nor any other staff member was observed to monitor vitals at any time for any of the 6 patients present. This unlicensed nurse was observed to provide 2 pills and a cup of water to one of the patients in the recovery room.
- 34. Based on the foregoing, A Woman's World Medical Center, Inc. violated Rule 59A-9.026, Florida Administrative Code, a deficiency, which warrants an assessed fine of \$1,000.00.

CLAIM FOR RELIEF

WHEREFORE, the Agency requests the Court to order the following relief:

1. Enter a judgment in favor of the Agency for Health Care Administration against A Woman's World Medical Center, Inc. on Counts I, II, III and IV.

- 2. Assess an administrative fine of \$4,000.00 against A Woman's World Medical Center, Inc. on Counts I, II, III and IV for the violation cited above.
- 3. Grant such other relief as this Court deems is just and proper.

Respondent is notified that it has a right to request an administrative hearing pursuant to Sections 120.569 and 120.57, Florida Statutes (2010). Specific options for administrative action are set out in the attached Election of Rights form. All requests for hearing shall be made to the Agency for Health Care Administration, and delivered to the Agency Clerk, Agency for Health Care Administration, 2727 Mahan Drive, MS #3, Tallahassee, Florida 32308.

RESPONDENT IS FURTHER NOTIFIED THAT THE FAILURE TO RECEIVE A REQUEST FOR A HEARING WITHIN TWENTY-ONE (21) DAYS OF RECEIPT OF THIS COMPLAINT WILL RESULT IN AN ADMISSION OF THE FACTS ALLEGED IN THE COMPLAINT AND THE ENTRY OF A FINAL ORDER BY THE AGENCY.

IF YOU WANT TO HIRE AN ATTORNEY, YOU HAVE THE RIGHT TO BE REPRESENTED BY AN ATTORNEY IN THE MATTER

Nelson E. Rodney, Esq. Assistant General Counsel Agency for Health Care

Administration

8333 NW 53RD Street,

Suite 300

Miami, Florida 33166

Copies furnished to:

Field Office Manager Agency for Health Care Administration 5150 Linton Boulevard, Suite 500 Delray Beach, Florida 33484 (U.S. Mail

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by U.S. Certified Mail, Return Receipt Requested to Candace M. Dye, Administrator, A Woman's World Medical Center, Inc. 503 South 12th Street, Fort Pierce, Florida 34950, on this Aday of Aday of

Nelson E. Rodney

STATE OF FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION

STATE OF FLORIDA, AGENCY FOR HEALTH CARE ADMINISTRATION,

Petitioner,

| VS. | Case No: 2011013924 |
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| | |

CANDACE M. DYE d/b/a A WOMAN'S WORLD MEDICAL CENTER,

| Responde | ent. | |
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SETTLEMENT AGREEMENT

Petitioner, State of Florida, Agency for Health Care Administration (hereinafter the "Agency"), through its undersigned representatives, and Respondent, Candace M. Dye d/b/a A Woman's World Medical Center (hereinafter "Respondent"), pursuant to Section 120.57(4), Florida Statutes, each individually, a "party," collectively as "parties," hereby enter into this Settlement Agreement ("Agreement") and agree as follows:

WHEREAS, Respondent is an abortion clinic licensed pursuant to Chapters 390 and 408, Part II, Florida Statutes, Section 20.42, Florida Statutes, and Chapter 59A-9, Florida Administrative Code; and

WHEREAS, the Agency has jurisdiction by virtue of being the regulatory and licensing authority over Respondent, pursuant to Chapter 390, Florida Statutes; and

WHEREAS, the Agency served Respondent with an administrative complaint on or about June 21, 2912, notifying the Respondent of its intent to impose administrative fines in the amount of \$4,000.00; and

WHEREAS, Respondent requested a formal administrative proceeding by selecting Option 2 on the Election of Rights form; and

WHEREAS, the parties have negotiated and agreed that the best interest of all the parties will be served by a settlement of this proceeding; and

NOW THEREFORE, in consideration of the mutual promises and recitals herein, the parties intending to be legally bound, agree as follows:

- 1. All recitals herein are true and correct and are expressly incorporated herein.
- 2. Both parties agree that the "whereas" clauses incorporated herein are binding findings of the parties.
- 3. Upon full execution of this Agreement, Respondent agrees to waive any and all appeals and proceedings to which it may be entitled including, but not limited to, an informal proceeding under Subsection 120.57(2), Florida Statutes, a formal proceeding under Subsection 120.57(1), Florida Statutes, appeals under Section 120.68, Florida Statutes; and declaratory and all writs of relief in any court or quasi-court of competent jurisdiction; and agrees to waive compliance with the form of the Final Order (findings of fact and conclusions of law) to which it may be entitled, provided, however, that no agreement herein shall be deemed a waiver by either party of its right to judicial enforcement of this Agreement.
- 4. Upon full execution of this Agreement, Respondent agrees to pay \$4,000.00 in administrative fines, to be paid within four (4) months of the entry of the Final Order.
- 5. Venue for any action brought to enforce the terms of this Agreement or the Final Order entered pursuant hereto shall lie in Circuit Court in Leon County, Florida.
- 6. By executing this Agreement, Respondent admits, and the Agency asserts the validity of the allegations raised in the administrative complaint referenced herein. However, no

agreement made herein shall preclude the Agency from imposing a penalty against Respondent for any deficiency/violation of statute or rule identified in a future survey of Respondent, which constitutes an "uncorrected" deficiency from surveys identified in the administrative complaint.

The parties agree that in such an "uncorrected" case, the deficiencies from the surveys identified in the administrative complaint shall be deemed found without further proof.

- 7. No agreement made herein shall preclude the Agency from using the deficiencies from the surveys identified in the administrative complaint in any decision regarding licensure of Respondent, including, but not limited to, a demonstrated pattern of deficient performance. The Agency is not precluded from using the subject events for any purpose within the jurisdiction of the Agency. Further, Respondent acknowledges and agrees that this Agreement shall not preclude or estop any other federal, state, or local agency or office from pursuing any cause of action or taking any action, even if based on or arising from, in whole or in part, the facts raised in the administrative complaint. This agreement does not prohibit the Agency from taking action regarding Respondent's Medicaid provider status, conditions, requirements or contract.
- 8. Upon full execution of this Agreement, the Agency shall enter a Final Order adopting and incorporating the terms of this Agreement and closing the above-styled case.
 - 9. Each party shall bear its own costs and attorney's fees.
- 10. This Agreement shall become effective on the date upon which it is fully executed by all the parties.
- 11. Respondent for itself and for its related or resulting organizations, its successors or transferees, attorneys, heirs, and executors or administrators, does hereby discharge the State of Florida, Agency for Health Care Administration, and its agents, representatives, and attorneys of and from all claims, demands, actions, causes of action, suits, damages, losses, and expenses,

of any and every nature whatsoever, arising out of or in any way related to this matter and the Agency's actions, including, but not limited to, any claims that were or may be asserted in any federal or state court or administrative forum, including any claims arising out of this agreement, by or on behalf of Respondent or related facilities.

- 12. This Agreement is binding upon all parties herein and those identified in paragraph eleven (11) of this Agreement.
- 13. In the event that Respondent was a Medicaid provider at the subject time of the occurrences alleged in the complaint herein, this settlement does not prevent the Agency from seeking Medicaid overpayments related to the subject issues or from imposing any sanctions pursuant to Rule 59G-9.070, Florida Administrative Code.
- 14. Respondent agrees that if any funds to be paid under this agreement to the Agency are not paid within four (4) months of entry of the Final Order in this matter, the Agency may deduct the amounts assessed against Respondent in the Final Order, or any portion thereof, owed by Respondent to the Agency from any present or future funds owed to Respondent by the Agency, and that the Agency shall hold a lien against present and future funds owed to Respondent by the Agency for said amounts until paid.
- 15. The undersigned have read and understand this Agreement and have the authority to bind their respective principals to it. Respondent has the capacity to execute this Agreement. Respondent understands that it has the right to consult with counsel and has knowingly and freely entered into this Agreement without exercising its right to consult with counsel. Respondent affirms that Respondent understands counsel for the Agency represents solely the Agency and Agency counsel has not provided legal advice to or influenced Respondent in its decision to enter into this Agreement.

- 16. This Agreement contains and incorporates the entire understandings and agreements of the parties.
- 17. This Agreement supersedes any prior oral or written agreements between the parties.
- This Agreement may not be amended except in writing. Any attempted 18. assignment of this Agreement shall be void.
 - All parties agree that a facsimile signature suffices for an original signature. 19.

The following representatives hereby acknowledge that they are duly authorized to enter

into this Agreement.

Molly McKinstry

Deputy Secretary

Agency for Health Care Administration

2727 Mahan Drive, Bldg #1 Tallahassee, Florida 32308

William H. Roberts

Deputy General Counsel

Agency for Health Care Administration

2727 Mahan Drive, Mail Stop #3

Tallahassee, Florida 32308

DATED: \$/27//2

Candace M. Dye, Owner

A Woman's World Medical Center 503 South 12th Street

Fort Pierce, Florida 34950

Nelson E. Rodney

Assistant General Counsel

Agency for Health Care Administration

8333 N.W. 53rd Street, Suite 300

Miami, Florida 33166