RICK SCOTT
GOVERNOR

ELIZABETH DUDEK
SECRETARY

April 7, 2015

Administrator
All Women's Health Center Of Gainesville, Inc.
1135 Northwest 23rd Avenue, # N
Gainesville, FL 32609

Dear Administrator:

This letter reports the findings of a state licensure survey that was conducted on April 3, 2015 by a representative of this office.

Attached is the provider's copy of the State (3020) Form, which indicates the deficiencies that were identified on the day of the visit.

Please provide a plan of correction to this Field Office, in accordance with enclosed instructions, for the identified deficiencies **within ten calendar days of receipt of this faxed report**. You will not receive a copy of this report in the mail; you will only receive this faxed report. **All deficiencies shall be corrected no later than May 3, 2015.**

The plan of correction must include the following:

1. Identify how corrective action will be accomplished for those residents found to have been affected by the deficient practice.
2. Describe how the facility will identify other residents having the potential to be affected by the same deficient practice.
3. Explain measures to be put into place or systemic changes made to ensure that the deficient practice will not recur.
4. Identify how the facility will monitor its corrective action to ensure the deficient practice is being corrected and will not recur; i.e., what program will be put into place to monitor the continued effectiveness of the systemic change.
5. Ensure that no protected or other confidential information (i.e., resident or staff names) are included in the plan.
6. State the completed date; the date that the facility identifies compliance can be achieved, which must be after the exit date.
7. You must sign the bottom of page 1 of the statement of deficiencies; include your title and date.

The Quality Assurance Questionnaire has long been employed to obtain your feedback following survey activity. This form has been placed on the Agency's website at http://ahca.myflorida.com/Publications/Forms.shtml as a first step in providing a web-based interactive consumer satisfaction survey system. You may access the questionnaire through

the link under Health Facilities and Providers on this page. Your feedback is encouraged and valued, as our goal is to ensure the professional and consistent application of the survey process.

Thank you for the assistance provided to the surveyor. Should you have any questions please call this office at (386) 462-6201.

Sincerely,

Kriste J. Mennella
Field Office Manager

KJM/bh
Enclosure

TBB2

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FORM APPROVED

Agency for Health Care Administration

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AC13910032	A. BUILDING: _____ B. WING _____	04/03/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ALL WOMEN'S HEALTH CENTER OF GAINESV	1135 NORTHWEST 23RD AVENUE, # N GAINESVILLE, FL 32609

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A 000	INITIAL COMMENTS An unannounced licensure survey was conducted on April 3, 2015, at All Women's Health Center of Gainesville. This facility was found not to be in compliance with the requirements of Chapter 390 F.S. and 59A-9 F.A.C.	A 000		
A 250	Clinic Policies/Procedures-2nd Trimester An abortion clinic providing second trimester abortions shall have written policies and procedures to implement policies and to assure that quality patient care shall relate specifically to the functional activities of clinic services. These written procedures shall apply to second trimester abortions and shall be available and accessible to clinic personnel and shall be reviewed and approved annually by the clinic's medical director. These clinic policies and procedures shall include but not be limited to the following: (1) Patient admission; (2) Pre- and post-operative care; (3) Physician ' s orders; (4) Standing orders with required signatures; (5) Medications, storage and administration; (6) Treatments; (7) Surgical asepsis; (8) Medial asepsis; (9) Sterilization and disinfection; (10) Documentation: Medical records and facility records; (11) Patient discharge; (12) Patient transfer; (13) Emergency measures; (14) Incident reports; (15) Personnel orientation; (16) Inservice education record; (17) Anesthesia; (18) Equipment and supplies: availability and maintenance;	A 250		

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A 250	Continued From page 1 (19) Volunteers; and (20) Visitors. Chapter 59A-9.024, F.A.C. This STANDARD is not met as evidenced by: Based on interview and record review the clinic failed to ensure the Medical Director had reviewed and approved the Clinic's policy and procedures. The clinic further failed to ensure there were policy and procedures related to volunteers and visitors. Findings: Record review of the Policy and Procedure Manual showed there was no documentation of the Medical Director having reviewed and approved the Clinic Policy and Procedures. An interview was conducted on 04/03/2015 at 1:07 PM with the Director and she verified there was no documentation of the Policy and Procedures having been reviewed and approved by the Medical Director. The Director further stated she was going to contact her corporate office. The Director returned and stated the corporate office would be contacting the Medical Director regarding the reviewing, and approval of the clinic ' s policy and procedures. Record review of the Policy and Procedure Manual showed there was no policy and procedure located in the manual for volunteers and visitors. An interview was conducted on 04/03/2015 at 2:02 PM with the Director and she stated there is	A 250	A 250 The medical director has reviewed and approved the clinic's policies and procedures. An updated signature page has been added to the policy and procedure manual. The Administrator will place a reminder on her calendar for the medical director to review policies and procedures annually and to sign an updated signature page. The Administrator will be responsible for monitoring this practice on an annual basis to ensure this deficient practice does not recur. 4-14-15 A policy and procedure for volunteers and visitors has been developed and will be added to the policy and procedure manual. 4-14-15	

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A 250	Continued From page 2 no Policy and Procedure in relation to volunteers and visitors. We do have students who come and work in the clinic to work off their required hours. We have them sign a confidentiality statement, but there is no Policy and Procedure for volunteers. We do have some patients that have someone come with them and stay with them before and after the procedure; I never really thought about them as a visitor. There is no Policy and Procedure in relation to visitors either.	A 250		
A 301	Medical Screening/eval.-2nd Trimester Laboratory Services. (a) Laboratory services shall be provided on-site or through arrangement with a laboratory that holds the appropriate federal Clinical Laboratory Improvement Amendments (CLIA) certificate and state of Florida clinical laboratory license issued pursuant to Chapter 483, Part I, F.S. (b) All laboratory services provided on-site shall be performed in compliance with state of Florida clinical laboratory licensure and federal CLIA provisions. Rh factor. Rh testing for Rh negative patients shall be conducted, unless reliable written documentation of blood type is available. All laboratory test reports shall be placed in the patient ' s medical record. All laboratory test and storage areas, records and reports shall be available for inspection by the agency. If a person who is not a physician performs an ultrasound examination, that person shall have	A 301		

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A 301	Continued From page 3 documented evidence that he or she has completed a course in the operation of ultrasound equipment. The physician, registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant shall, at the request of the patient and before the abortion procedure is performed, review the ultrasound evaluation results with the patient, including an estimate of the probable gestational age of the fetus. A test for anemia shall be performed. Chapter 59A-9.025(2), (4), (5), (6), (7), and (8) F.A.C. This STANDARD is not met as evidenced by: Based on interview and record review the clinic failed to ensure a person who was performing ultrasound examinations had documented evidence of having completed a course in the operation of the ultrasound equipment. Findings: An interview was conducted on 04/03/2015 at 12:05 PM with the Director and she stated I am the only one in the facility that conducts the ultrasounds and then the Physician reviews them. I do not have documented evidence that I have completed a course in the operation of the ultrasound equipment. I am in the process of completing the course training for NAF (National Abortion Federation) and I have not completed it as of this time. Record review was conducted of the Director's	A 301	A301 The Administrator completed a course in the operation of ultrasound equipment on 4/5/15. The physician reviews ultrasounds prior to any procedure. Documented evidence of completion of this course has been placed in the Administrator's personnel record.	

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A 301	Continued From page 4 personnel record and it showed the record did not contain documentation of the Director having been trained in the use of the ultrasound machine.	A 301		
A 302	Medical Screening/eval.-2nd Trimester Laboratory Equipment and Supplies. (a) All equipment and supplies for the collection, storage, and testing of specimens shall meet the provisions of Rule 59A-7 F.A.C., and shall be maintained according to manufacturer ' s instructions and in a manner that ensures accurate test results. (b) Temperature controlled spaces for the storage of specimens or testing supplies shall be monitored and recorded to ensure that the proper storage temperature is maintained. (c) All dated supplies and materials shall not be used beyond their expiration date. (d) Adequate facilities and supplies for the collection, storage and transportation of laboratory specimens shall be available on site. Chapter 59A-9.025(3), F.A.C. This STANDARD is not met as evidenced by: Based on interview, observation, and record review the clinic failed to ensure dated supplies and materials were not being used beyond their expiration date. Findings: An observation was conducted on 04/03/2015 at	A 302		

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A 302	Continued From page 5 9:28 AM in procedure room two and it showed there was a container of Urispec 11 - Way Reagent test strips for blood, urobilinogen, bilirubin, protein, nitrite, ketones, ascorbic acid, glucose, pH, specific gravity and Leucocytes in Urine by Dip and Read Technique that had expired on 10/2014. There was a 10 cc syringe observed with 6 cc of clear liquid that was unlabeled and did not have a cap covering the end of the syringe located in a bin with packaged and label heparin syringes. An interview was conducted on 04/03/2015 at 9:38 AM with the Director and she stated the syringe contained normal saline that it is used for flushes. " I don't know why there is no cap at the end of the syringe. We have multi dose vials and we draw up the saline in syringes for use, and we don't label them. The Director also verified the Urispec 11 - Way Reagent Test Strips had expired 10/2014. An observation conducted on 04/03/2015 at 11:02 AM of the lab and it showed there were two bottles of 70% Isopropyl Rubbing Alcohol First Aid Antiseptic with an expiration date of 07/2014. There was one bottle of Hydrogen Peroxide Solution with an expiration date of 02/2014. An interview was conducted on 04/03/2015 at 11:04 AM with the Director and she stated verification that the two bottles of 70% Isopropyl Rubbing Alcohol First Aid Antiseptic had expired on 07/2014, and the Hydrogen Peroxide Solution had expired on 02/2014. An observation was conducted on 04/03/2015 at 12:16 PM of the sterile suturing equipment and supplies and it showed two 2 - 0 Polysorb packages with one having an expiration date of	A 302	A302 The expired reagent test strips, Isopropyl rubbing alcohol, Hydrogen Peroxide and suturing supplies were discarded the same day the inspector was present. The lab and procedure rooms will be thoroughly checked at the end of every month for any items due to expire. Any item needing replacement will be done prior to the expiration date. Labels have been made for syringes containing normal saline. Staff members have been instructed by the Administrator to label any syringe containing normal saline and to be certain there is a cap covering the end of the syringe. The Administrator is responsible for monitoring that these deficiency do not recur. 4-3-15	

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A 302	Continued From page 6 09/2009, and the second with an expiration date of 10/2005. One package of Maxon 2 - 0 with an expiration date of 08/2010, and one package of Prolene 2 -0 with an expiration date of 01/2012. Two packages of Sofilk 3 - 0 with an expiration date of 01/2009. Five packages of Sofsilk 4 - 0 which showed an expiration date of 03/2002 on two of the packages, an expiration date of 03/2007 on one of the packages, and an expiration date of 11/2007 on two of the packages. An interview was conducted on 04/03/2015 at 12:18 PM with the Director and she verified the suture material as listed had expired. Record review of the Policy and Procedure titled, " Section IX Laboratory, General Standards and Guidelines, Laboratory Safety Policy " showed 3. All laboratory equipment and supplies are stored in a safe manner as suggested by the manufacturer, assuring protection of the device(s)and protection of sterility and quality. 4. All sterile and dated supplies and solutions are monitored for quality, sterility and expiration dated on an on-going basis.	A 302		
A 600	Clinical Records A permanent individual clinical record shall be kept on each clinic patient. Clinical records shall be complete, accurately documented, and systematically organized to facilitate storage and retrieval. (a) Clinical records shall be complete, accurately documented, and systematically organized to facilitate storage and retrieval.	A 600		

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A 600	Continued From page 7 (b) Clinical records involving second trimester abortion procedures shall be kept confidential and secure. (c) Operative reports signed by the physician performing the second trimester abortion shall be recorded in the clinical record immediately following the procedure or that an operative progress note is entered in the clinical record to provide pertinent information. Chapter 59A-9.031(1), F.A.C. This STANDARD is not met as evidenced by: Based on observation and interview the clinic failed to ensure clinical records involving second trimester abortion procedures were kept confidential and secure. Findings: An observation was conducted on 04/03/2015 at 10:14 AM of the sonogram room, also used for exams and counseling, and it showed there were bio fold doors over a large closet area with one of the doors opened. Observed were multiple patients' records. Both doors were unsecured and were easily opened for assess to the records. An interview was conducted on 04/03/2015 at 10:18 AM with the Director and she stated I have nowhere else to put these records. When this surveyor asked about access to the records by a patient in the exam room the Director stated a patient may be in the room a minute or two alone. When this surveyor asked about patients being able to view the records, the Director stated that would be possible since they were not locked. The Director further stated the records consisted	A 600	A600 The charts in the closet have been secured. Locks were installed on the bi-fold doors on 4/8/15. The closet doors will remain locked.	

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A 600	Continued From page 8 of a combination of first and second trimester abortion patients.	A 600		