



RICK SCOTT  
GOVERNOR

ELIZABETH DUDEK  
SECRETARY

## Notice of Activity without Proper Licensure

August 5, 2015

Planned Parenthood of SW & Central Florida  
8950 Martin Luther King St.  
St. Petersburg, FL 33702

The Agency for Health Care Administration (Agency) has determined that this facility is providing services beyond the scope of the license. This notice will serve as the official notification from the agency substantiating findings to support this facility is providing services beyond the scope of the license.

Under Florida law, it is unlawful for any person or entity to: own, operate, or maintain an unlicensed provider; or perform any services that require Agency licensure without proper licensure; or offer or advertise services that require Agency licensure to the public without first obtaining a valid license from the Agency. An existing license holder may not advertise or hold out to the public that he or she holds a license for other than that for which he or she actually holds the license.

Any person and entity that fails to immediately cease operation of an unlicensed provider is subject to the penalties set forth under Florida law. Each violation is a separate offense.

If you have any questions regarding this Notice of Activity without Proper Licensure, please contact Patricia Freed at 727-552-2000.

Sincerely,

A handwritten signature in black ink, appearing to read "Patricia Reid Kaufman".

Patricia Reid Kaufman  
Field Office Manager



Agency for Health Care Administration

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>AC13960082</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>08/05/2015</b>
NAME OF PROVIDER OR SUPPLIER  <b>PLANNED PARENTHOOD OF SW &amp; CENTRAL INC</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>8950 DR MLK JR STREET NORTH SAINT PETERSBURG, FL 33702</b>		
(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	INITIAL COMMENTS  An unannounced monitoring visit was completed on 7/31/2015 at the facility. Additional information was received on 8/5/2015. The following deficient practice was found.	A 000		
A 050	Licensure Procedures  All persons planning the operation of an abortion clinic under the provisions of Chapter 390, F.S., shall make application for a license to the Agency for Health Care Administration and must receive a license prior to the acceptance of patients for care and treatment.  Chapter 59A-9.020(1)  A current license shall be posted in a conspicuous place within the licensed premises where it can be viewed by patients.  Chapter 59A-9.020(4), F.A.C.          This Standard is not met as evidenced by: Based on observation, interview and record review, the provider failed to apply for and receive a license from the Agency prior to the acceptance of 2 out of 13 (#12, #13) sampled patients for care and treatment of second trimester procedures. Further review of reports revealed 25 out of 742 abortions performed between 7/1/14 and 6/30/15 were performed during the second trimester.	A 050		

AHCA Form 3020-0001

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Agency for Health Care Administration

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>AC13960082</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>08/05/2015</b>
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A 050	<p>Continued From Page 1</p> <p>Findings include:</p> <p>Observation conducted on July 31, 2015 at approximately 10:00 AM revealed the provider 's license was posted on the wall with an effective date of 03/28/2015 and an expiration date of 03/27/2017. Further observation revealed the provider was licensed for first trimester abortion only.</p> <p>On July 31, 2015 at 12:30 PM, the clinic manager stated that they provide 1st trimester abortion procedures only. They consider first trimester to be up to 13.6 weeks (13weeks 6 days).</p> <p>A review of sampled patient #12's file revealed an abortion procedure was conducted on 4/8/15 when sampled patient #12's ultrasound gestational age was 13.4 weeks. Sampled patient #13's file revealed an abortion procedure was conducted 4/1/15 when sampled patient #13's ultrasound gestational age was 13.3 weeks.</p> <p>Based upon the finding of second trimester abortions performed during onsite inspection, reports were reviewed and identified 25 second trimester abortions performed between 7/1/14 and 6/30/15. On 8/5/15 at 11:05 AM a telephone interview was conducted with the Director of Compliance Quality and Risk Management for Planned Parenthood in Florida. She confirmed that she submits the reports monthly in regards to the number of weeks at which the abortion was performed. The numbers of weeks are counted from the client ' s last reported menstrual period which is verified with ultra sound before the abortion takes place. When asked what gestational age is considered the end of the first trimester, she stated 13.6 weeks. She confirmed</p>	A 050			

Agency for Health Care Administration

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>AC13960082</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>08/05/2015</b>
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A 050	Continued From Page 2  that the reports she sends in monthly are the accurate number of weeks and most months will have numbers that fall into the second column range. She further explained that she uses Chapter 59A-9(14)(a) which states the first 12 weeks of pregnancy is the first 14 completed weeks from the last normal menstrual period.	A 050		
CZ828	408.813(3) FS Administrative Fines; Violations  (3) The agency may impose an administrative fine for a violation that is not designated as a class I, class II, class III, or class IV violation. Unless otherwise specified by law, the amount of the fine may not exceed \$500 for each violation. Unclassified violations include: (a) Violating any term or condition of a license. (b) Violating any provision of this part, authorizing statutes, or applicable rules. (c) Exceeding licensed capacity. (d) Providing services beyond the scope of the license. (e) Violating a moratorium imposed pursuant to s. 408.814.  This Statute or Rule is not met as evidenced by: Based upon the finding of second trimester abortions performed during an on-site inspection, reports were reviewed and identified 25 out of 742 abortions performed between 7/1/14 and 6/30/15 were performed during the second trimester. The clinic provided services beyond the scope of the license.  Findings included:  Observation conducted on July 31, 2015 at approximately 10:00 AM revealed the provider's license which indicated the provider was licensed	CZ828		

Agency for Health Care Administration

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>AC13960082</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>08/05/2015</b>
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CZ828	<p>Continued From Page 3</p> <p>for first trimester abortion only.</p> <p>On July 31, 2015 at 12:30 PM, the clinic manager stated that they provide 1st trimester abortion procedures only. They consider first trimester to be up to 13.6 weeks (13weeks 6 days).</p> <p>A review of sampled patient #12's file revealed an abortion procedure was conducted on 4/8/15 when sampled patient #12's ultrasound gestational age was 13.4 weeks. Sampled patient #13's file revealed an abortion procedure was conducted 4/1/15 when sampled patient #13's ultrasound gestational age was 13.3 weeks.</p> <p>Based upon the finding of second trimester abortions performed during onsite inspection, reports were reviewed and identified 25 second trimester abortions performed between 7/1/14 and 6/30/15. On 8/5/15 at 11:05 AM a telephone interview was conducted with the Director of Compliance Quality and Risk Management for Planned Parenthood in Florida. She confirmed that she submits the reports monthly in regards to the number of weeks at which the abortion was performed. The numbers of weeks are counted from the client's last reported menstrual period which is verified with ultra sound before the abortion takes place. When asked what gestational age is considered the end of the first trimester, she stated 13.6 weeks. She confirmed that the reports she sends in monthly are the accurate number of weeks and most months will have numbers that fall into the second column range. She further explained that she uses Chapter 59A-9(14)(a) which states the first 12 weeks of pregnancy is the first 14 completed weeks from the last normal menstrual period.</p>	CZ828			



RICK SCOTT  
GOVERNOR

ELIZABETH DUDEK  
SECRETARY

## NOTICE OF ACTIVITY WITHOUT PROPER LICENSURE

August 5, 2015

Administrator  
Planned Parenthood of Southwest and Central Florida, Inc.  
8595 College Parkway, Suite 250  
Fort Myers, Florida 33919

Dear Administrator:

The Agency for Health Care Administration (Agency) has determined that this facility is providing services beyond the scope of the license. This notice will serve as the official notification from the agency substantiating findings to support this facility is providing services beyond the scope of the license.

Under Florida law, it is unlawful for any person or entity to: own, operate, or maintain an unlicensed provider; or perform any services that require Agency licensure without proper licensure; or offer or advertise services that require Agency licensure to the public without first obtaining a valid license from the Agency. An existing license holder may not advertise or hold out to the public that he or she holds a license for other than that for which he or she actually holds the license.

Any person and entity that fails to immediately cease operation of an unlicensed provider is subject to the penalties set forth under Florida law. Each violation is a separate offense.

If you have any questions regarding this Notice of Activity without Proper Licensure you may contact me at (239) 335-1315.

Sincerely,

A handwritten signature in black ink, appearing to read "Jon Seehawer", is written over a horizontal line.

Jon Seehawer, RN  
Field Office Manager  
Division of Health Quality Assurance  
Area 8 Field Operations

JS/cs



NAME OF PROVIDER OR SUPPLIER

STREET ADDRESS, CITY, STATE, ZIP CODE

**PLANNED PARENTHOOD OF SW & CENTRAL FL-FT 1**

8595 COLLEGE PARKWAY SUITE 250  
FORT MYERS, FL 33919

AHCA Form 3020-0001

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Agency for Health Care Administration

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>AC13960081</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING: _____	(X3) DATE SURVEY COMPLETED  <b>08/05/2015</b>
NAME OF PROVIDER OR SUPPLIER  <b>PLANNED PARENTHOOD OF SW &amp; CENTRAL FL-FT #</b>		STREET ADDRESS, CITY, STATE, ZIP CODE <b>8595 COLLEGE PARKWAY SUITE 250 FORT MYERS, FL 33919</b>		
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A 050	Continued From page 1  the 12th week and extending through the 24th week of gestation ..."  Findings include:  Observation conducted on 7/31/15 at 12:20 p.m. revealed the clinic's license was posted on the bulletin board. Further observation revealed the clinic was licensed for first trimester abortions.  On 7/31/15 at 12:50 p.m., the clinic manager stated that they provide first trimester surgical procedures up to 13.6 weeks.  A review of sampled patient #4's file revealed an abortion procedure was conducted when sampled patient #4's gestational age was 13.2 weeks. Sampled patient #5's file revealed an abortion procedure was conducted when sampled patient #5's gestational age was 13 weeks.  On 8/5/15 at 1:04 p.m. a telephone interview was conducted with the Director of Compliance Quality and Risk Management for Planned Parenthood in Florida. She confirmed that she submits the reports monthly in regards to the number of weeks at which the abortion was performed and that the numbers of weeks are counted from the client's last reported menstrual period. When asked what gestational age is considered the end of the first trimester, she said 13 weeks, 6 days. She confirmed the reports she sends in monthly are accurate to the number of weeks and most months will have numbers that fall into the second column range.	A 050		
CZ828	408.813(3) FS Administrative Fines; Violations  (3) The agency may impose an administrative	CZ828		



Agency for Health Care Administration

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CZ828	<p>Continued From page 2</p> <p>fine for a violation that is not designated as a class I, class II, class III, or class IV violation. Unless otherwise specified by law, the amount of the fine may not exceed \$500 for each violation. Unclassified violations include:</p> <p>(a) Violating any term or condition of a license.</p> <p>(b) Violating any provision of this part, authorizing statutes, or applicable rules.</p> <p>(c) Exceeding licensed capacity.</p> <p>(d) Providing services beyond the scope of the license.</p> <p>(e) Violating a moratorium imposed pursuant to s. 408.814.</p> <p>This Statute or Rule is not met as evidenced by: Based upon the finding of second trimester abortions performed during an on-site inspection, reports were reviewed and identified 21 second trimester abortions performed between 7/1/14 and 6/30/15. The clinic provided services beyond the scope of the license.</p> <p>Findings included:</p> <p>Observation conducted on 7/31/15 at 12:20 p.m. revealed the clinic's license was posted on the bulletin board. Further observation revealed the clinic was licensed for first trimester abortions.</p> <p>On 7/31/15 at 12:50 p.m., the clinic manager stated that they provide first trimester surgical procedures up to 13.6 weeks.</p> <p>A review of sampled patient #4's file revealed an abortion procedure was conducted when sampled patient #4's gestational age was 13.2 weeks. Sampled patient #5's file revealed an abortion procedure was conducted when sampled patient #5's gestational age was 13 weeks.</p>	CZ828		

Agency for Health Care Administration

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CZ828	<p>Continued From page 3</p> <p>Review of abortions reported to the state July 2014 through June 2015 revealed 21 second trimester abortions.</p> <p>On 8/5/15 at 1:04 p.m. a telephone interview was conducted with the Director of Compliance Quality and Risk Management for Planned Parenthood in Florida. She confirmed that she submits the reports monthly in regards to the number of weeks at which the abortion was performed, and that the number of weeks are counted from the client's last reported menstrual period. When asked what gestational age is considered the end of the first trimester, she said 13 weeks, 6 days. She confirmed the reports she sends in monthly are accurate to the number of weeks and most months will have numbers that fall into the second column range.</p>	CZ828		



RICK SCOTT  
GOVERNOR

ELIZABETH DUDEK  
SECRETARY

## NOTICE OF ACTIVITY WITHOUT PROPER LICENSURE

August 5, 2015

Administrator  
Planned Parenthood of Collier County, Inc.  
1425 Creech Road  
Naples, Florida 34103

Dear Administrator:

The Agency for Health Care Administration (Agency) has determined that this facility is providing services beyond the scope of the license. This notice will serve as the official notification from the agency substantiating findings to support this facility is providing services beyond the scope of the license.

Under Florida law, it is unlawful for any person or entity to: own, operate, or maintain an unlicensed provider; or perform any services that require Agency licensure without proper licensure; or offer or advertise services that require Agency licensure to the public without first obtaining a valid license from the Agency. An existing license holder may not advertise or hold out to the public that he or she holds a license for other than that for which he or she actually holds the license.

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If you have any questions regarding this Notice of Activity without Proper Licensure you may contact me at (239) 335-1315.

Sincerely,

A handwritten signature in black ink, appearing to read "Jon Seehawer".

Jon Seehawer, RN  
Field Office Manager  
Division of Health Quality Assurance  
Area 8 Field Operations

JS/cs



AHCA Form 3020-0001

TITLE

(X6) DATE

Agency for Health Care Administration

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>AC13960120</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>08/05/2015</b>
NAME OF PROVIDER OR SUPPLIER  <b>PLANNED PARENTHOOD OF COLLIER COUNTY, INC.</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>1425 CREECH RD NAPLES, FL 34103</b>		
(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 050	<p>Continued From Page 1</p> <p>week of gestation ..."</p> <p>Findings included:</p> <p>Observation conducted on 7/31/15 at 2:11 p.m. revealed the clinic's license was posted on the wall. Further observation revealed the clinic was licensed for first trimester abortions.</p> <p>On 7/31/15 at 2:11 p.m., the clinic manager stated that they provide first trimester procedures up to 13.6 weeks.</p> <p>A review of sampled patient #1's file revealed an abortion procedure was conducted when sampled patient #1's gestational age was 13.2 weeks. Sampled patient #2's file revealed an abortion procedure was conducted when sampled patient #2's gestational age was 13.3 weeks. Sampled patient #3's file revealed an abortion procedure was conducted when sampled patient #3's gestational age was 13.5 weeks.</p> <p>On 8/5/15 at 1:04 p.m. a telephone interview was conducted with the Director of Compliance Quality and Risk Management for Planned Parenthood in Florida. She confirmed that she submits the reports monthly in regards to the number of weeks at which the abortion was performed and that the numbers of weeks are counted from the client's last reported menstrual period. When asked what gestational age is considered the end of the first trimester, she said 13 weeks, 6 days. She confirmed the reports she sends in monthly are accurate to the number of weeks and most months will have numbers that fall into the second column range.</p>	A 050			

Agency for Health Care Administration

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CZ828	Continued From Page 2	CZ828		
CZ828	<p>408.813(3) FS Administrative Fines; Violations</p> <p>(3) The agency may impose an administrative fine for a violation that is not designated as a class I, class II, class III, or class IV violation. Unless otherwise specified by law, the amount of the fine may not exceed \$500 for each violation. Unclassified violations include:</p> <p>(a) Violating any term or condition of a license.</p> <p>(b) Violating any provision of this part, authorizing statutes, or applicable rules.</p> <p>(c) Exceeding licensed capacity.</p> <p>(d) Providing services beyond the scope of the license.</p> <p>(e) Violating a moratorium imposed pursuant to s. 408.814.</p> <p>This Statute or Rule is not met as evidenced by: Based upon the finding of second trimester abortions performed during an on-site inspection, reports were reviewed and identified 19 second trimester abortions performed between 7/1/14 and 6/30/15. The clinic provided services beyond the scope of the license.</p> <p>Findings included:</p> <p>Observation conducted on 7/31/15 at 2:11 p.m. revealed the clinic's license was posted on the wall. Further observation revealed the clinic was licensed for first trimester abortions.</p> <p>On 7/31/15 at 2:11 p.m., the clinic manager stated that they provide first trimester procedures up to 13.6 weeks.</p> <p>A review of sampled patient #1's file revealed an abortion procedure was conducted when sampled patient #1's gestational age was 13.2 weeks. Sampled patient #2's file revealed an abortion</p>	CZ828		

Agency for Health Care Administration

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>AC13960120</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>08/05/2015</b>
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CZ828	<p>Continued From Page 3</p> <p>procedure was conducted when sampled patient #2's gestational age was 13.3 weeks. Sampled patient #3's file revealed an abortion procedure was conducted when sampled patient #3's gestational age was 13.5 weeks.</p> <p>Review of abortions reported to the state July 2014 through June 2015 revealed 19 second trimester abortions.</p> <p>On 8/5/15 at 1:04 p.m. a telephone interview was conducted with the Director of Compliance Quality and Risk Management for Planned Parenthood in Florida. She confirmed that she submits the reports monthly in regards to the number of weeks at which the abortion was performed and that the numbers of weeks are counted from the client's last reported menstrual period. When asked what gestational age is considered the end of the first trimester, she said 13 weeks, 6 days. She confirmed the reports she sends in monthly are accurate to the number of weeks and most months will have numbers that fall into the second column range.</p>	CZ828			



RICK SCOTT  
GOVERNOR

ELIZABETH DUDEK  
SECRETARY

August 5, 2015

Administrator  
Planned Parenthood of S. FL & Treasure Coast Pembroke Pines  
263 N. University Drive  
Pembroke Pines, FL 33024

**RE: Monitoring Visit**

Dear Administrator:

This letter reports the findings of a state licensure monitoring visit that was conducted on July 29, 2015 by representative(s) 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 August 29, 2015.**

**The plan of correction must include the following:**

1. Identify how corrective action will be accomplished for those clients found to have been affected by the deficient practice.
2. Describe how the facility will identify other clients 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., client 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

AHCA.MyFlorida.com  
5150 Linton Blvd., Suite 500  
Delray Beach, FL 33484  
T - (561) 381-5840  
F - (561) 496-5925



Facebook.com/ACHAFlorida  
Youtube.com/AHCAFlorida  
Twitter.com/AHCA\_FL  
SlideShare.net/AHCAFlorida

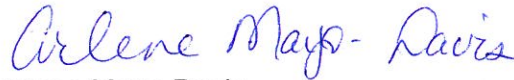


Planned Parenthood of S. FL & Treasure Coast Pembroke Pines  
August 5, 2015  
Page 2

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(s). Should you have any questions please call Arlene Mayo-Davis, Field Office Manager.

Sincerely,



Arlene Mayo-Davis  
Field Office Manager

TBB2

and  
Enclosure-State Form 3020

Agency for Health Care Administration

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>AC13960122</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>07/29/2015</b>
NAME OF PROVIDER OR SUPPLIER  <b>PLANNED PARENTHOOD OF S FL &amp; TREAS COAST PEMB</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>263 N UNIVERSITY DRIVE PEMBROKE PINES, FL 33024</b>		
(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	INITIAL COMMENTS  An unannounced monitoring visit was completed on 7/29/2015 at the facility. The following deficient practice was found.	A 000			
A 550	Disposal of Fetal Remains  Fetal remains shall be disposed of in a sanitary and appropriate manner and in accordance with standard health practices and Chapters 381 and 390, F.S., and 64E-16, F.A.C.  Chapter 59A-9.030, F.A.C.  This Standard is not met as evidenced by: Based on interview, observations and record review, the facility failed to follow its policy regarding proper labeling and dating of the disposal of fetal remains. This affected at least the disposal of fetal remains from 25 surgical abortions, including for Patient #1, #2, and #3, performed from 7/10/15 to 7/29/15.  The findings include:  In an interview conducted with the Health Center Manager (Manager) on 7/29/15 at 3:18 PM, the Manager stated was asked about the process for disposal of fetal remains at the facility. She stated "they are kept in a biohazard freezer until a biohazard disposal company picks them up; pickups are every 30 days." She reported that "All of the fetal remains are handled in the same way." The Manager reported that the clinic performed surgical abortions only on Saturdays.  Observations conducted on 7/29/15 starting at 3:22 PM with the Manager revealed a freezer that contained 3 red biohazard bags, wrapped in off-white tape in several locations, each forming a	A 550			

AHCA Form 3020-0001

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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A 550	<p>Continued From Page 1</p> <p>bundle. Further observations revealed that the shapes of the bundles were irregular, but they were about 12 inches in diameter; there were no apparent labels or facility-made markings on the biohazard bags. There was also a note on the freezer "Please check the freezer and doc in lab and poc logs daily." The Manager reviewed the note and was asked to explain the word "poc". She stated it stood for "products of conception". She was asked about the "poc logs" and she stated that there were no such logs, but the note referred to the refrigerator/freezer temperature logs that the facility staff completed. She repeated this when asked again about the "poc logs" several seconds later and stated that there were no such logs and the note was referring to thermometer logs.</p> <p>The Manager showed on 7/29/15 at 3:31 PM the biohazard log and supporting documents, which included biohazard pickups each month, with the most recent pickups occurring on 7/10/15. The receipts were not specific to what kind of material (e.g. fetal remains) was picked up.</p> <p>In an interview conducted on 7/29/15 at 3:36 PM with the Manager, she stated that a note on the bottom of the receipts, "incinerate only" indicated that biohazard Disposal Company had picked up fetal remains. She further stated that the current process for the disposal of fetal remains had been in process at the facility since the beginning of the center; she was not sure of the exact date, but stated that it coincided with the initial license date. She stated that she had been employed at the facility for the past 3 years and the process had been in place thru her employment. The Manager was asked at that time if any of the staff members who worked on Saturdays and assisted/performed abortions were at the clinic at this time; she stated that one staff member, Staff A was present.</p>	A 550		

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A 550	<p>Continued From Page 2</p> <p>In an interview conducted on 7/29/15 at 3:40 PM with Staff A, a Family Planning Assistant, she confirmed that she worked on Saturdays. She reported that the POC (Products of Conception) person, Staff B handled the fetal remains as "she will dispose it in a sock and red bag, seal and place it in the top freezer". She stated that every month the biohazard disposal company picked up the regular biohazard and embryotic products. According to staff A, "all fetal remains are handled the same way". She confirmed that staff B was not on site on 7/29/15. She stated "We have more than one, two persons"; stated she did not know their names, "I don't, I'm sorry".</p> <p>In a subsequent interview conducted with the Manager on 7/29/15 at 3:51 PM, she stated that the clinic performed 25 surgical abortions from 7/10/15, the date of the last documented biohazard pick up, to date; this was confirmed with a calendar as 3 Saturdays. She stated that "each of the packaged bags is for each day (each Saturday)" about the three red biohazard bags observed in the freezer and confirmed that the remains were not individually packaged in its own red bag.</p> <p>A side by side review was conducted on 7/29/15 starting at 3:54 PM with the Manager of the clinical records for 3 patients, Patient #1, #2, and #3 who had surgical abortions in July 2015. Patient #1 had a surgical abortion on 7/11/15. Patient #2 had a surgical abortion on 7/18/15. Patient #3 had a surgical abortion on 7/25/15. The review revealed that staff B indicated in each of the 3 records that the facility handled "POC Tissue" with "Routine Disposal".</p> <p>In an interview conducted with the Manager on 7/29/15 at 4:01 PM, she explained that the</p>	A 550			

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A 550	<p>Continued From Page 3</p> <p>"routine disposal" was the process that she explained during the previous interviews on 7/29/15.</p> <p>Review of the facility's undated policy and procedure titled "Policy and Procedure for Retention of POC's" revealed that it called for "Procedure for storage of POC's: after the POCs have been examined, they are to be placed in a zip lock bag. At the end of the shift all will be placed in a red biohazard bag, and ties, the red bag is to then be placed in a larger zip lock, dated and initialed, and placed in a freezer."</p> <p>In an interview conducted on 7/29/15 at 4:33 PM with the Manager, the Manager reviewed the "Policy and Procedure for Retention of POC's" and acknowledged that the policies and procedures indicated that staff was to place the red biohazard bag in a zip lock bag with indications of the date and initials of the person who was preparing the bag. She acknowledged that the facility did not follow the policy for the 3 fetal remains bags that were observed in the freezer.</p> <p>A second observation was conducted with the Manager of the 3 fetal remains bags in the freezer on 7/29/15 at 4:34 PM. The Manager donned gloves and handled the 3 bags, looking at all sides; she confirmed that none had the zip lock bag and none had any markings for initials and dates. She stated that she maybe they were noted "within" the red bags.</p> <p>Further observations revealed the Manager making a telephone call to Employee B, at the surveyor's request on 7/29/15 at 4:36 PM, but the employee did not respond and did not return the telephone call by the end of the survey.</p> <p>In an interview conducted on 7/29/15 at 4:45 PM</p>	A 550		

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A 550	Continued From Page 4  with the Manager, she stated that there are no logs in place for monitoring or tracking of POC's and no Quality Assurance logs or performance tracking for the disposal of fetal remains.	A 550			