

IN THE CIRCUIT COURT  
OF THE SECOND  
JUDICIAL CIRCUIT IN  
AND FOR LEON COUNTY,  
FLORIDA

PLANNED PARENTHOOD OF  
SOUTHWEST AND CENTRAL  
FLORIDA, INC.,

Plaintiff,

v.

Case No.

STATE OF FLORIDA, AGENCY  
FOR HEALTH CARE ADMINISTRATION,

Defendant.

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**VERIFIED COMPLAINT FOR DECLARATORY RELIEF AND  
FOR EMERGENCY TEMPORARY INJUNCTION**

COMES NOW, Planned Parenthood of Southwest and Central Florida, Inc. (“Plaintiff” or “Planned Parenthood”), by and through its undersigned counsel, and files this Complaint For Declaratory And Injunctive Relief And For Temporary Injunction pursuant to Chapter 86, Florida Statutes, against the State of Florida, Agency for Health Care Administration (“Defendant” or “AHCA”) and, in support thereof states the following:

**GENERAL ALLEGATIONS**

1. This action concerns correspondence sent by Defendant to three of Plaintiff’s affiliate facilities licensed to perform only first trimester pregnancy terminations, in which Defendant informed Plaintiff it was operating in violation of an unspecified law by performing second trimester abortion procedures. In making this determination, Defendant imposed a new and unpublished definition of first trimester

procedures upon Plaintiff, despite having agreed to, and adopted by rule, the definition used and followed by Plaintiff (in accordance with the agency's rule) for nearly ten years with Defendant's explicit approval.

2. This Court has jurisdiction over this matter pursuant to Chapter 86, Florida Statutes.

3. Venue is appropriate in Leon County because Defendant is headquartered there.

### **THE PARTIES**

4. Plaintiff is Planned Parenthood of Southwest and Central Florida, Inc., a non-profit Florida corporation with headquarters in Sarasota, Florida. Plaintiff provides broad reproductive health care services to women and men, including family planning counseling and services, gynecological examinations and treatment for minor gynecological disorders; testing and treatment for sexually transmitted infections; pregnancy testing and counseling; male services, including vasectomies; and pregnancy terminations. Petitioner owns and operates twelve affiliate facilities, or health care centers, nine of which are licensed to perform pregnancy terminations. Of these, three facilities are located in St. Petersburg, Ft. Myers and Naples, Florida and they are the subject of this action. All of the facilities licensed to perform pregnancy terminations are licensed by Defendant pursuant to Chapters 390 and 408, Florida Statutes. All pregnancy terminations performed in the facilities are performed by licensed Florida physicians.

The three subject facilities are authorized to perform first trimester abortions in accordance with the laws and rules governing licensed abortion clinics.<sup>1</sup>

5. Defendant is the Agency for Health Care Administration. AHCA is the licensing and regulatory authority responsible for oversight of various health care facilities in Florida, including abortion clinics. Applicable statutes and rules governing the licensing and regulation of abortion clinics include Chapters 390 and 408, Part II, Florida Statutes and Chapters 59A-9 and 59A-35, Fla. Admin. Code.

### **BACKGROUND**

6. Prior to July 1, 2005, §390.012, F.S., did not differentiate between rules for clinics providing abortions during the first trimester of pregnancy only and those providing abortions after the first trimester of pregnancy. A 2005 amendment to the law provided new authority for the adoption of rules for clinics providing abortions after the first trimester of pregnancy. The 2005 amendment did not change the previously existing authority to adopt rules regarding clinics that provide abortions during the first trimester only. Neither Chapter 390, nor the 2005 amendment to it, contained a definition of “trimester” or “first trimester”; likewise, neither term had been defined by rule.

7. AHCA undertook rulemaking and, in May 2006, published its proposed Rule 59A-9.019, Fla. Admin. Code, which contained the following definitions of trimester:

(25) *“Trimester” means a 12-week period of pregnancy*

(a) *First Trimester. The first 12 weeks of pregnancy.*

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<sup>1</sup> There are a total of sixteen (16) facilities in Florida owned and operated by Plaintiff or another affiliated entity. Only the three clinics listed herein are licensed to perform only first trimester non-medical pregnancy terminations.

*(b) Second Trimester. That portion of a pregnancy following the 12<sup>th</sup> week and extending through the 24<sup>th</sup> week of gestation.*

*(c) Third Trimester. That portion of pregnancy beginning with the 25<sup>th</sup> week of gestation.*

8. Planned Parenthood challenged the validity of the proposed rule and, specifically, the definition of the term “first trimester”. In Planned Parenthood of Southwest and Central Florida, Inc. v. State of Florida, Agency for Health Care Administration, DOAH Case No. 06-2342RP, Planned Parenthood alleged the proposed definition of “first trimester” as simply as “the first 12 weeks of pregnancy” failed to provide a meaningful and unambiguous definition. Planned Parenthood cited medical community standards that routinely defined the first trimester of pregnancy as extending through the completion of 14 weeks of pregnancy as measured from the first day of the woman’s last menstrual period (“LMP” or “menstrual weeks”). Because clinicians typically date a pregnancy from the last menstrual period, which in a normal menstrual cycle occurs approximately two weeks before fertilization, a pregnancy dated in menstrual weeks is generally two weeks longer than a pregnancy dated in weeks from likely fertilization. Thus, the medical community commonly defines the first trimester of pregnancy as extending through the completion of 14 menstrual weeks or, put another way, the passage of the first 14 weeks from the date of the last normal menstrual period.

9. Planned Parenthood alleged further in the rule challenge that AHCA’s proposed definition of “first trimester” was contrary to—and ignored-- current medical standards and conventions regarding the term and, as such, was vague and confusing by

not referring to weeks from LMP in the definition. **See Exhibit A, Petition Challenging the Validity of Proposed Rule.**

10. AHCA responded to these concerns and revised its proposed rule to include language regarding the LMP. “First trimester” was defined in the revised proposed rule as:

*(15)(a) First Trimester. The first 12 weeks of pregnancy (the first 14 completed weeks from the last menstrual period).*

Thus, AHCA revised its rule to include the language and clarification sought by Planned Parenthood, to wit: that the first 12 weeks of pregnancy—the first trimester-- is equivalent to the first 14 completed weeks from the last menstrual period.

11. Indeed, when responding to questions from the Joint Administrative Procedures Committee (JAPC) about the proposed rule revision, AHCA stated through its counsel:

*“It was clear from the medical professionals that the term ‘first twelve weeks of pregnancy’ and ‘first 14 completed weeks from the last normal menstrual period’ are used interchangeably by physicians, and in fact describe the same time period with the same ending point.” See*

**Exhibit B, Letter from AHCA counsel to JAPC.**

12. The final rule was adopted in September, 2006. The definition of “first trimester” contained in the rule has not changed. **See Exhibit C, Rule 59A-9.019, Fla. Admin. Code.**

13. Since promulgation of the rule, Planned Parenthood and other facilities licensed to perform first trimester termination procedures have recorded gestational age

in accordance with LMP and recorded first trimester abortions as weeks from LMP. This means patient records for first trimester abortions may reflect a gestational age of less than 14 weeks LMP. These patients are still within the “first trimester” of pregnancy because they are within the “first 12 weeks of pregnancy”, which is the first 14 completed weeks since LMP.

14. For nearly ten years, since promulgation of the rule, AHCA has reviewed patient records at the subject clinics during regular inspections and found no unlawful procedures performed under the clinics’ “first trimester only” licenses. AHCA officials consistently recognized that a notation in a patient record of a number less than 14 weeks LMP fell squarely within the definition of first trimester under AHCA’s rule.

15. Additionally, pursuant to §390.0112, F.S., Plaintiff is required to report monthly to AHCA the number of procedures it performs at each clinic and the number within three categories of gestational age. The three subject clinics have always reported the procedures by gestational age measured by LMP, in accordance with the rule. AHCA, knowing this and understanding its own rule, never deemed any procedure reported as between 12 and 14 weeks to be a second trimester procedure.

### **RECENT EVENTS**

16. On July 31, 2015, AHCA performed an unannounced “monitoring visit” of the three subject clinics.<sup>2</sup> Subsequently, on August 5<sup>th</sup>, AHCA advised Planned Parenthood that the type of procedure previously deemed to be a lawful first trimester procedure was, in retrospect, an unlawful second trimester procedure. AHCA reached this conclusion by deeming procedures in seven sampled patient records, performed with

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<sup>2</sup> All sixteen facilities licensed to perform pregnancy terminations affiliated with a Planned Parenthood entity were visited by AHCA inspectors in a coordinated effort. Only the three clinics named herein were cited for performing procedures beyond the scope of their licenses.

gestational ages documented as greater than 12 weeks LMP but less than 14 LMP, and 25 procedures similarly reported on AHCA's specified reporting form between June 2014 and June 2015, to have been second trimester procedures.<sup>3</sup> AHCA advised Plaintiff in a "Notice Of Activity Without Proper Licensure" that it was operating without appropriate licensure and would be subject to "penalties under Florida law.

17. The correspondence provided by AHCA did not state which law was violated or the specific penalties to be imposed. The correspondence did not provide any due process rights, point of entry to initiate due process, or other avenue to challenge the findings. The correspondence did state that any "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." This suggests AHCA has now ordered Plaintiff to cease providing what AHCA now considers illegal second trimester procedures. **See Exhibit D, Correspondence and Statements of Deficiencies from AHCA.**

#### NATURE OF THE CONTROVERSY

18. AHCA's rule clearly defines first trimester abortions to include the first 14 completed weeks from the last menstrual period. The definition was specifically included in the rule as a result of litigation between the parties in 2006. For nearly ten years, both AHCA and Planned Parenthood have agreed that procedures noted by gestational age of greater than 12 weeks LMP but less than the 14 weeks LMP constituted first trimester abortions performed within the first 12 weeks of pregnancy, which is the first 14 completed weeks since LMP. AHCA has never before alleged or complained that any procedure with a gestational age recorded or reported as greater than

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<sup>3</sup> The sampled patient records documented 13 weeks, 13.2 weeks, and 13.3 weeks, 13.4 weeks, and 13.5 weeks gestation.

12 weeks LMP and less than 14 weeks LMP was anything other than a first trimester procedure.

19. Now, in an unprecedented change of position, AHCA has deemed these procedures to be second trimester abortions performed beyond the scope of the license for each of the subject clinics. There is no legal basis for this change of position and it is completely contrary to the language of the rule, AHCA's previous stated position, and AHCA's own course of conduct during the past nearly ten years.

20. As a result of AHCA's abrupt change of position, Plaintiff is in doubt as to its legal rights and responsibilities under its license to perform first trimester abortions. Plaintiff has conducted itself in accordance with all applicable state laws and rules and in accordance with sound medical practice. However, AHCA has now said Plaintiff is operating illegally. Plaintiff needs clarification that the procedures it has performed and documented with a gestational age of up to 14 weeks from the last menstrual period were, in fact, first trimester procedures as defined by Rule 59A-9.019, Fla. Admin. Code.

**DEMAND FOR RELIEF, INCLUDING EMERGENCY  
TEMPORARY INJUNCTIVE RELIEF**

21. Since being advised it was operating without appropriate licensure, Plaintiff's services to clients have been significantly disrupted. Rather than turn away patients in need of services it is licensed to provide, Plaintiff has paid to transport some women seeking first trimester termination services to other clinics licensed to perform first and second trimester abortions. This has caused disruption in care, delayed care, extended the time for care, and expanded Plaintiff's costs to provide care. (The additional transportation cost has not been passed on to the patients.) In addition,



Plaintiff and its physicians and staff are under a cloud of suspicion as a result of the very public accusations of allegedly performing illegal abortion procedures.<sup>4</sup>

22. Accordingly, Plaintiff requests a declaratory judgment that the procedures documented or reported as having been performed on patients at a gestational age of up to the first 14 completed weeks from the last menstrual period were first trimester procedures as defined by AHCA's rule and that, going forward, such procedures will continue to constitute first trimester termination procedures so long as the rule remains in place and in its current form,

23. Plaintiff requests immediate temporary injunctive relief to prevent AHCA from relying on its new and unpublished definition of "first trimester" as a basis for action against Plaintiff or other similarly situated providers or as a basis for initiating or causing the initiation of against such providers' physicians or other licensed staff by other regulatory agencies<sup>5</sup>.

24. Pursuant to Rule 1.610, Fla. R. Civ. P., Plaintiff is entitled to immediate injunctive relief because (a) Plaintiff's claims have a substantial likelihood of success on the merits; (b) Plaintiff has no adequate remedy at law; (c) irreparable harm will occur unless immediate injunctive relief is granted; and (d) injunctive relief serves the public interest.

25. Plaintiff has a substantial likelihood of success on the merits based on the specific language of the definition of first trimester contained in the rule, AHCA's own

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<sup>4</sup> In an unusual turn of events, state officials released the results of the July 31 inspections to the press before providing those same results to Planned Parenthood, the licensed provider which was the subject of the inspections.

<sup>5</sup> AHCA has requested the names of the physicians "who performed second trimester procedures" so it can refer them to the Department of Health for a disciplinary investigation against their licenses based on an accusation of having performed illegal abortion procedures. There is no basis for any such accusation.

explicit statement of the meaning and purpose of the language used in the definition, and AHCA's own reliance and affirmation of the meaning of the language in the definition during the past nearly 10 years since the rule was promulgated.

26. Plaintiff has no adequate remedy at law that can promptly return it to full and normal operations and allow it immediately to resume providing uninterrupted and readily accessible services to the women who seek such services. As noted, since being advised it was operating illegally, Plaintiff has been forced to inconvenience its patients by redirecting them to other providers and been forced to pay the transportation costs for such patients. Other patients have likely been intimidated by the very public claims of state officials that Plaintiff is operating illegally and is an "unscrupulous provider", and may have foregone or postponed health care services (not just pregnancy terminations) at risk to their personal health and well being. Physicians working for Plaintiff feel a heightened threat to their security and safety due to the very public allegations that the clinics are operating illegally. No adequate remedy at law exists to promptly address the ramifications of AHCA's illegal actions. **See Exhibit E, Statement from AHCA official.**

27. Plaintiff will suffer irreparable harm if immediate injunctive relief is not provided. Plaintiff has been maligned in the press by state officials and irreparable suffered harm to its reputation as a provider of competent and comprehensive care in Southwest and Central Florida for nearly 50 years. AHCA's misrepresentation of Plaintiff to the public as having performed illegal abortions has had a deleterious effect on the delivery of health care services by the clinics, intimidated patients from coming to the clinics for care, and forced other patients to endure significant inconvenience, delay

and hardship in order to exercise their rights to care and services. Such consequences cause irreparable damage to Plaintiff's ability to provide lawful healthcare services pursuant to its state issued licenses, its reputation, and its ability to serve the women who need its services.

28. A temporary injunction serves the public interest by permitting the subject facilities to return to their normal scope of lawful operations and fully serve the women of their communities in the manner they have been doing for decades. In so doing, women are permitted to fully exercise their right to accessible health care of their choice. The public interest is also served by halting an ongoing abuse of power by AHCA, which has used its regulatory authority to conduct "monitoring visits" —not provided for by statute or rule—rather than "inspections", which have procedures to be followed; and, in so doing, has concocted allegations against Plaintiff that have no basis in Florida law and, instead, serve only to defame and malign Plaintiff, disrupt and hinder the delivery of health care services to women by Plaintiff, and have forced Plaintiff to incur significant attorney's fees and other costs.

WHEREFORE, for the forgoing reasons Plaintiff requests this court:

- a) Grant Plaintiff's request for temporary injunction and enjoin AHCA from relying on its new definition of "first trimester" or current legal position as a basis for action against Plaintiff, or other similarly situated licensed providers<sup>6</sup>, or for initiating or causing to be initiated, any action by other state regulatory agencies against such providers' physicians and other licensed staff;

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<sup>6</sup>Plaintiff is aware of at least one other facility licensed to perform first trimester procedures only that has been similarly cited by AHCA. There may be others.

- b) Issue a declaratory judgment that finds the “Notice of Operating Without Appropriate Licensure” letters issued by AHCA were based on an illegal interpretation or application of Rule 59A-9.019, Fla. Admin. Code and, accordingly, have no legal force or effect;
- c) Reserve jurisdiction and award a reasonable attorney’s fee and costs to Plaintiff; and
- d) Grant any other relief deemed appropriate and just.

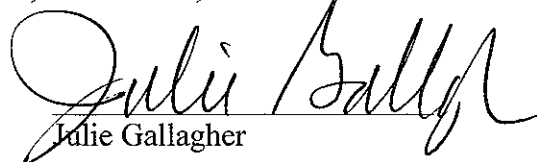
Respectfully submitted this 17<sup>th</sup> day of August, 2015.



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**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY, that a true and correct copy of the foregoing was provided to Ms. Elizabeth Dudek, Secretary, Agency for Health Care Administration, by email: [Elizabeth.Dudek@ahca.myflorida.com](mailto:Elizabeth.Dudek@ahca.myflorida.com); Stuart Williams, General Counsel, Agency for Health Care Administration by email: [Stuart.Williams@ahca.myflorida.com](mailto:Stuart.Williams@ahca.myflorida.com); Thomas Hoeler, Assistant General Counsel, Agency for Health Care Administration by email: [Thomas.Hoeler@ahca.myflorida.com](mailto:Thomas.Hoeler@ahca.myflorida.com) this 17<sup>th</sup> day of August, 2015 and that a copy of the foregoing will be served by a duly authorized process server on the same individuals at AHCA headquarters located at 2727 Mahan Drive, Tallahassee, FL 32301 as soon as can be accomplished.

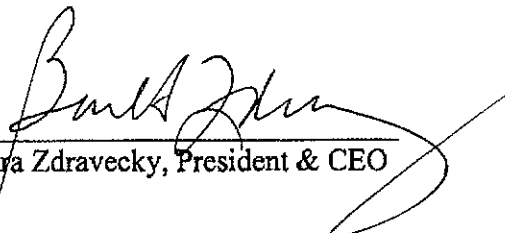


Julie Gallagher

**VERIFICATION**

I, Barbara Zdravecky, President & CEO OF Planned Parenthood of Southwest and Central Florida, Inc., under penalty of perjury under the laws of Florida, do declare that I have read the foregoing Complaint for Declaratory Relief and Emergency Temporary Injunction and the facts alleged therein are true and correct to the best of my knowledge and belief. I understand a false statement in this Verification could subject me to penalties for perjury.

Signed this 13<sup>th</sup> day of August, 2015.

  
Barbara Zdravecky, President & CEO

STATE OF FLORIDA  
COUNTY OF Sarasota

Being duly sworn, Ms. Barbara Zdravecky, who ~~is known to me or who presented~~ <sup>is personally</sup> known to me for identification, affirmed that the foregoing facts alleged are true and correct to the best of her knowledge and belief.

Signed before me on the 13<sup>th</sup> day of August, 2015.



Notary Public



STATE OF FLORIDA  
DIVISION OF ADMINISTRATIVE HEARINGS

FILED  
05 JUL -3 PM 4:09  
DIVISION OF  
ADMINISTRATIVE  
HEARINGS

PLANNED PARENTHOOD  
OF SOUTHWEST AND  
CENTRAL FLORIDA,

Petitioner,

vs.

Case No. *06-2342 RP*

STATE OF FLORIDA,  
AGENCY FOR HEALTH CARE  
ADMINISTRATION.

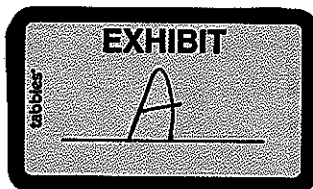
Respondent.  
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PETITION CHALLENGING  
THE VALIDITY OF PROPOSED RULE

Petitioner, Planned Parenthood of Southwest and Central Florida (hereinafter "Planned Parenthood"), by and through the undersigned attorney and pursuant to §120.56(2), F.S., and Chapter 59A-9, Florida Administrative Code, hereby petitions the State of Florida, Division of Administrative Hearings ("DOAH") for a formal administrative hearing to contest the validity of a proposed rule by the Respondent, Agency for Health Care Administration ("AHCA" or "Agency") and as grounds therefore states:

NATURE OF THE PETITION

1. This Petition is filed pursuant to §120.56(2), F.S., for the purpose of seeking an administrative determination that a proposed rule by AHCA, which would provide for adoption of rules for regulation of clinics providing abortions after the first trimester of pregnancy constitutes an "invalid exercise of delegated legislative authority"



as that term is defined in §120.52(8), F.S. (2005), and is otherwise invalid under the terms and provisions of Chapter 120, F.S.

### IDENTIFICATION OF THE PARTIES

2. The name and address of the agency affected by this Petition is the State of Florida, Agency for Health Care Administration, Fort Knox Executive Center, Building #3, 2727 Mahan Drive, Tallahassee, Florida 32308.

3. The name and address of the Petitioner is Planned Parenthood of Southwest and Central Florida. Petitioner is a Florida not-for-profit corporation with headquarters in Sarasota, Florida. Petitioner provides reproductive health care to women and men, including family planning counseling and services; gynecological examinations and treatment for minor gynecological disorders; testing and treatment for sexually transmitted infections; pregnancy testing and counseling; male services, including vasectomies; and first trimester abortions. All abortion procedures performed at Petitioner's clinics are provided by Florida licensed physicians. For purposes of this proceeding, the address of the Petitioner is that of undersigned counsel. Petitioner is a fully licensed provider of abortion services with clinics in Southwest and Central Florida. Pursuant to Chapter 390, F.S., Petitioner is authorized to terminate first trimester pregnancies in accordance with law.

### BACKGROUND FACTS

4. Prior to July 1, 2005, §390.012, F.S. did not differentiate between rules for clinics providing abortions only during the first trimester of pregnancy and those providing abortions after the first trimester of pregnancy. The 2005 amendment to the

law<sup>1</sup> provides new authority specifically for adoption of rules for the regulation of clinics providing abortions after the first semester of pregnancy. The 2005 amendment did not alter the previously existing authority to adopt rules regarding clinics that provide abortions during the first trimester only, except to emphasize that such rules shall be in accordance with §797.03, F.S.<sup>2</sup> and may not impose an unconstitutional burden on a woman's freedom to decide whether to terminate her pregnancy.

5 The terms "trimester" and "first trimester" are not defined in Chapter 390, F.S., 2005 and have not previously been defined in AHCA administrative rules.

6. The term "reasonable proximity" is not defined in Chapter 390, F.S., 2005 and has not previously been defined in AHCA administrative rules.

7. Chapter 390, F.S., 2005 does not specifically authorize unannounced inspections of licensed abortion clinics and AHCA has not previously interpreted existing agency administrative rules to require or permit unannounced inspections of licensed abortion clinics.

8. Traditionally, AHCA has scheduled inspections of abortion clinics in order to avoid disruption of activities at the clinics and to permit the clinic personnel an opportunity to redact and otherwise protect the confidentiality of medical records that may be reviewed in the inspection process.

9. Chapter 390, F.S., 2005 does not specifically authorize the review of personnel records maintained by the state's abortion clinics and AHCA has not previously required access to such records during routine pre-licensure or post-licensure inspections.

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<sup>1</sup> Ch. 2005-95 §2, Laws of Florida.

<sup>2</sup> Section 797.03, F.S. limits the performance of abortions, other than in emergency situations, to a validly licensed hospital or abortion clinic and physician offices; requires licensure of abortion clinics; and limits the performance of third trimester abortions to hospitals.



10. Chapter 59A-9, Florida Administrative Code, is entitled "Abortion Clinics" and establishes rules and standards governing the service and operations of abortion clinics to comply with the requirements of Chapter 390, F.S.

#### THE AGENCY'S PROPOSED RULE

11. In Volume 32, Number 21 of the Florida Administrative Weekly (May 26, 2006) AHCA gave notice of proposed revision to Chapter 59A-9, Florida Administrative Code, consistent with provisions of Chapter 2005-95, Laws of Florida, which revised §390.012, F.S. The purpose and effect statement in the published notice specifically states that the amendment to the law "provides for adoption of rules for regulation of clinics providing abortions after the first trimester of pregnancy." (emphasis added) A copy of the published notice of proposed rulemaking, including the text of the proposed rule, is attached as Exhibit "A" to this Petition.

12. Previously, §390.012, F.S. did not differentiate between rules for clinics providing abortions only during the first trimester of pregnancy and those providing abortions after the first trimester of pregnancy. The 2005 amendment to the law provides new authority specifically for adoption of rules for the regulation of clinics providing abortions after the first trimester of pregnancy<sup>3</sup>. The 2005 amendment did not alter the previously existing authority to adopt rules regarding clinics that provide abortions only during the first trimester, except to emphasize that such rules shall be in accordance with §797.03, F.S.,<sup>4</sup> and may not impose an unconstitutional burden on a woman's freedom to decide whether to terminate her pregnancy.

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<sup>3</sup> Section 390.012(3), F.S.

<sup>4</sup> Section 797.03, F.S. limits the performance of abortions, other than in emergency situations, to a validly licensed hospital or abortion clinic and physician offices; requires licensure of abortion clinics; and limits the performance of third trimester abortions to hospitals.

13. On June 22, 2006, as set forth in the published notice of proposed rulemaking, AHCA held the last public hearing on the proposed rule.

ULTIMATE FACTS RELATING TO PROPOSED RULE  
AND BASIS FOR RULE INVALIDITY

14. The Agency's proposed rule constitutes an "invalid exercise of delegated legislative authority" as defined in §120.52 (8), F.S., 2005. The proposed definition of trimester, on which the Agency's intended adoption of rules for regulation of certain clinics is based is vague and fails to establish an adequate standard for agency decisions. As such it vests unbridled discretion with the Agency. The Agency's proposed rule defines a trimesters as follows:

- (25) *"Trimester" means a 12-week period of pregnancy*  
*(a) First Trimester. The first 12 weeks of pregnancy.*  
*(b) Second Trimester. That portion of a pregnancy following the 12<sup>th</sup> week and extending through the 24<sup>th</sup> week of gestation.*  
*(c) Third Trimester. That portion of pregnancy beginning with the 25<sup>th</sup> week of gestation.*

In defining a "Trimester" as "a 12-week period of pregnancy" and the "First Trimester" as "the first 12 weeks of pregnancy", the proposed rule fails to provide a meaningful and unambiguous definition. Medical community standards routinely and generally define the first trimester of pregnancy as extending through the completion of 14 weeks of pregnancy as measured from the first day of the woman's last menstrual period ("LMP" or "menstrual weeks"). *Williams Obstetrics*, F. Gary Cunningham, et al. eds., 22d ed. 2005, p. 208. Clinicians typically date pregnancy from the first day of the last menstrual period ("LMP") which in a normal menstrual cycle occurs approximately two weeks before fertilization. Therefore, a pregnancy dated in menstrual weeks is generally two

weeks longer than a pregnancy dated in weeks since fertilization. The medical community commonly defines the first trimester of pregnancy as extending through the completion of 14 menstrual weeks. The proposed rule definition of "First Trimester" is contrary to common understanding and practice and is vague and confusing and ignores the currently existing medical conventions regarding this term. In light of the common usage and understanding of this medical term, the Agency's proposed rule is confusing and may even be misleading in its failure to reference menstrual weeks or LMP. It is ambiguous and confusing not to define "First Trimester" consistently with current medical conventions including menstrual weeks or LMP. In defining these terms, AHCA should clearly and unambiguously adopt the standards commonly recognized in the medical community and define the first trimester as the completion of 14 menstrual weeks. To the extent that the proposed rule changes adopt inconsistent definitions or definitions not in keeping with the routine practice of medicine, the proposed rule contains a vague and inconsistent standard and constitutes an invalid exercise of delegated legislative authority by the Agency. The Agency's proposed rule is arbitrary and capricious because it is vague, fails to establish adequate standards for agency decisions and vests unbridled discretion in the Agency.

15. The Agency's proposed rule also constitutes an invalid exercise of delegated legislative authority for reasons that include, but are not limited to, the following:

a. The Agency's proposed rule<sup>5</sup> goes beyond the powers, functions and duties delegated by the Legislature to the Agency. The proposed rule amendments provide unfettered access by the Agency to confidential and private information that is otherwise protected under law. The language of §390.012, F.S., provides the Agency

with authority to develop rules which provide for the "making, protection, and preservation of patient records, which shall be treated as medical records under chapter 458." Chapter 458, however, clearly provides limitations and protections for such records that are not provided in the language of the proposed rules. Section 458.341 and 458.343, Florida Statutes specifically limit government access to situations where patient consent, subpoena, or search warrant has been obtained and also provides confidentiality protections for medical records obtained.<sup>6</sup> The proposed rule's allowance for unrestrained access to patient records would further violate the patient's constitutional right to informational privacy and the chilling affect of unfettered government access to private medical information would impose an unconstitutional burden on the patients' freedom to decide whether to terminate her pregnancy. Furthermore, unfettered access to medical records would not allow the clinics to avoid disclosure of any more than the information minimally necessary to accomplish the intended purpose. Redaction of readily identifiable personal health information in the records and documents retained by the clinics is required by Federal law<sup>7</sup> prior to any disclosure.

b. The Agency's proposed rule enlarges, modifies and contravenes §390.012, F.S., because it adopts regulatory rules which may govern first trimester abortion clinics as a result of its proposed definitions of "trimester" and "first trimester," in contravention of the legislative language that directs the Agency to adopt rules for clinics that perform or claim to perform abortions after the first trimester of pregnancy. Clinicians typically

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<sup>5</sup> Proposed rule 59A-9.021(1), F.A.C.

<sup>6</sup> Section 456.057(6), F.S., also applies to records maintained pursuant to Chapter 458, F.S. and provides additional limits to governmental access to such patient records by generally requiring patient consent or subpoena as a condition of access and imposing specific and strict confidentiality requirements on all medical records obtained by the government.

<sup>7</sup> Although AHCA may be permitted under Federal law to obtain personal health information (PHI), because of its health oversight activities, *see*, 45 C.F.R. §164.512(d)(1), the same law requires Petitioner, as a covered entity, to "make reasonable efforts to limit personal health information to the minimum necessary to accomplish the intended purpose of the use, disclosure or report." *See*, 45 C.F.R. §164.502(b)(1).

date pregnancy from the first day of the last menstrual period ("LMP") which in a normal menstrual cycle occurs approximately two weeks before fertilization. Therefore, a pregnancy dated in menstrual weeks is generally two weeks longer than a pregnancy dated in weeks since fertilization. The medical community commonly defines the first trimester of pregnancy as extending through the completion of 14 menstrual weeks. The proposed rule definition of "Trimester" as 12 weeks of pregnancy, together with the proposed definition of "First Trimester" as the first 12 weeks of pregnancy, are therefore, vague and confusing and ignore the currently existing medical conventions regarding these terms.

c. The Agency's proposed rule is without specific statutory authority for the adoption of rules regulating clinics that provide abortion services during the first trimester of pregnancy. As noted above, the problems associated with the proposed rule definition of "First Trimester" creates a situation where the rules statutorily authorized to be applicable to second trimester clinics might be applied equally to first trimester clinics in apparent contradiction to statute.

d. The Agency's proposed rule is without specific statutory authority to require unannounced inspections of the premises of first trimester clinics. The proposed change is a radical departure from current licensure requirements and would effectively diminish privacy and confidentiality protections. Unannounced inspections would create an unwarranted chilling effect upon the women who might be present in the clinic during an unannounced inspection by creating fear of being recognized by local inspectors and by compromising patient confidentiality. Unannounced inspections also risk possible disruption or delay of scheduled medical procedures while personnel respond to the inspection requirements and inspectors occupy areas required for continued service to

patients. This amendment is also counter to the longstanding provision of §390.012(2), F.S., which directs that regulations governing first trimester providers be equivalent to those regulations governing other providers of comparable services. The proposed rules requiring unannounced inspections are more burdensome than the rules applicable to similarly situated providers with fewer privacy and confidentiality concerns. Ambulatory surgical centers and hospitals, as examples, may be routinely inspected only upon scheduled appointment, and unannounced inspections are prohibited unless founded upon a reported complaint. See, Rule 59A-5.004, F.A.C. and Rule 59A-3.253, F.A.C.

e. In addition, the Agency's proposed rule is arbitrary and capricious. The proposed rule requires that the clinic "Medical Director" have admitting privileges or a transfer agreement with a licensed hospital within "reasonable proximity" of the abortion clinic. The proposed rule<sup>8</sup> further defines "reasonable proximity" as being a distance not to exceed thirty minutes transport time by emergency vehicle. Such a definition is arbitrary and capricious on its face and clearly fails to account for the geographic distribution of hospitals around the state, the distinctions between rural and urban settings, and such other variables as may impact travel time in various areas of the state.

f. The Agency has improperly noticed all materially affected parties of the nature of the proposed rule to be implemented. The language published in the Florida Administrative Weekly, Volume 32, Number 21, May 26, 2006 states as follows:

*PURPOSE AND EFFECT: The Agency proposes to revise Chapter 59A-9, Florida Administrative Code, consistent with provisions of Chapter 2005-95, Laws of Florida, which revised Section 390.012, F.S. The law provides for adoption of rules for regulation of clinics providing*

<sup>8</sup> Petitioner has been a provider of only first trimester abortions, however, as discussed above, if the currently proposed definitions become part of the rule, Petitioner's activities may be converted into second trimester abortions as well and they would then be required to comply with the medical director provisions of the rule.

abortions after the first trimester of pregnancy. (emphasis added).

The clinics affected by this proposed rule are purported to be those providing abortions after the first trimester of pregnancy, yet under the Agency's proposed definition of "First Trimester," such rules might equally apply to clinics performing abortions during what is generally recognized and accepted in the medical community as the first trimester of pregnancy. In addition, by amending the provisions of Rule 59A-9.021, F.A.C., to provide for AHCA's access to all medical records and personnel records during inspections and creating a requirement that all inspections be unannounced, even as to clinics that perform abortions only in the first trimester, the actual purpose and effect of the rule go significantly beyond the limitations set forth in the published notice of proposed rulemaking and the rulemaking authority set forth in §390.012(2), F.S.

#### SUBSTANTIAL INTERESTS AFFECTED

16. Petitioner is substantially affected and its substantial interests are subject to a determination in this proceeding for reasons which include, but are not limited to the following:

a. Petitioner owns and operates abortion clinics in Southwest and Central Florida that offer and perform first trimester abortions. At all times relevant to this proceeding, Petitioner has operated under the definition of first trimester commonly used by the medical community which allows that the first trimester of a woman's pregnancy extends over 14 weeks as measured from the first day of the woman's last menstrual period. Petitioner was unaware that the proposed rule published by the Agency may have regulatory impact upon first trimester abortion clinics relying upon the Agency's published statement of purpose and effect that limited the scope and effect of the proposed rule amendments to "adoption of rules for regulation of clinics providing

abortions after the first trimester of pregnancy." Petitioner further relied upon the statutory provisions restricting Agency rulemaking as to clinics that provide abortions only during the first trimester and limiting the imposition of the terms set forth in §390.012(3), F.S. to those clinics that perform or claim to perform abortions after the first trimester.

b. Until such time as the Agency clarifies the proposed definition of "First Trimester" and specifies whether the amendments to Rule 59A-9.012, F.A.C. apply to all abortion clinics or just those providing abortions after the first trimester, Petitioner may be forced to comply with the proposed rule that is the subject of this challenge, the provisions of which were clearly intended by the Legislature to apply only to clinics providing abortions after the first trimester.

#### DISPUTED ISSUES OF LAW

17. Disputed issues of law include, but are not limited to:
  - a. Whether the Agency has exceeded its grant of rulemaking authority;
  - b. Whether the Agency's proposed rule enlarges, modifies or contravenes the specific provisions of Chapter 390.012, Florida Statutes.
  - c. Whether the Agency's proposed rule is without statutory authority.
  - d. Whether the Agency's proposed rule is unclear, vague, and sets forth inadequate standards by which a provider can have knowledge as to whether a certain act constitutes a violation under the rule.
  - e. Whether the Agency failed to publish proper notice of the proposed rule to all affected parties as required by law.



f. Whether the Agency's proposed rule imposes an unconstitutional burden on a woman's freedom to decide whether to terminate her pregnancy.

#### DISPUTED ISSUES OF MATERIAL FACT

18. Disputed issues of fact include, but are not limited to:
- a. Whether the Agency's proposed rule is vague, fails to establish adequate standards for agency decision, and vests unbridled authority in the Agency; and
  - b. Whether the Agency's proposed rule is arbitrary and capricious.
  - c. Whether the Agency's proposed rule imposes an unconstitutional burden on a woman's freedom to decide whether to terminate her pregnancy.

#### NOTICE

19. Petitioner received notice of the proposed rule from a review of Volume 32, Number 21 of the Florida Administrative Weekly (May 26, 2006). Although Petitioner did not participate in the workshop and public hearing on the proposed rule amendments held by AHCA, this petition is timely filed within 10 days following the last public hearing as required pursuant to §120.56(2)(a), F.S.

#### RELIEF REQUESTED

WHEREFORE, Petitioner respectfully requests as follows:

- a. That this matter be assigned to an Administrative Law Judge in accordance with the provisions of Chapter 120, F.S.;
- b. That the proposed rule be declared an invalid exercise of delegated legislative authority;

c. That Petitioner be granted reasonable costs and attorneys fees as set forth in §120.595, F.S.; and

d. That Petitioner be granted such other relief as is deemed just and proper.

Respectfully submitted this 3<sup>rd</sup> day of July, 2006.



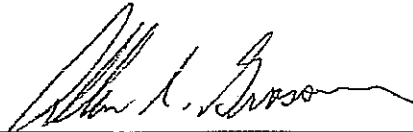
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Attorney for Petitioner

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 3<sup>rd</sup> day of July, 2006, the original and one copy of the foregoing have been filed with the Division of Administrative Hearings and a true and correct copy of the foregoing has been provided by Hand Delivery to Richard Shoop, Agency Clerk, Agency for Health Care Administration, 2727 Mahan Drive, Mail Stop #3, Tallahassee, FL 32308.



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ALLEN R. GROSSMAN

FILED

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DIVISION OF  
ADMINISTRATIVE  
HEARINGS

# Exhibit A

officer lieutenant or above, who will be responsible for hearing disciplinary reports. The correctional officer chief shall designate a correctional officer sergeant as a substitute team member only if neither a lieutenant nor captain is available and only when such substitution is absolutely necessary.

(9) Hearing Officer – An employee, ~~who is of the rank of lieutenant or higher,~~ who will be responsible for hearing disciplinary reports designated as minor.

(10) through (16) No change.

Specific Authority 944.09 FS. Law Implemented 20.315, 944.09 FS. History–New 3-12-84, Formerly 33-22.02, Amended 12-30-86, 10-01-95, Formerly 33-22.002, Amended 5-21-00, 2-11-01, 9-16-04,

NAME OF PERSON ORIGINATING PROPOSED RULE: Franchatta Barber, Deputy Assistant Secretary of Institutions – Programs

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: George Sapp, Assistant Secretary of Institutions

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: May 15, 2006

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: May 7, 2006

**AGENCY FOR HEALTH CARE ADMINISTRATION**

**Division of Health Quality Assurance**

RULE CHAPTER NO.: RULE CHAPTER TITLE:

59A-9	Abortion Clinics
RULE NOS.:	RULE TITLES:
59A-9.018	Purpose
59A-9.019	Definitions
59A-9.020	Licensure Procedures
59A-9.021	Investigations and License and Validation Inspections
59A-9.022	Physical Plant Requirements for Abortion Clinics When Providing Second Trimester Abortions
59A-9.0225	Clinic Supplies and Equipment Standards for Second Trimester Abortions
59A-9.023	Clinic Personnel
59A-9.024	Clinic Policies and Procedures for Second Trimester Abortions
59A-9.025	Medical Screening and Evaluation of Patients Receiving Second Trimester Abortions
59A-9.026	Second Trimester Abortion Procedure
59A-9.027	Recovery Room Standards for Second Trimester Abortions

59A-9.028	Post Procedure Follow-up Care for Patients Receiving Second Trimester Abortions
59A-9.029	Abortion Clinic Incident Reporting for Second Trimester Abortions
59A-9.030	Disposal of Fetal Remains
59A-9.031	Clinical Records
59A-9.034	Reports

PURPOSE AND EFFECT: The Agency proposes to revise Chapter 59A-9, Florida Administrative Code, consistent with provisions of Chapter 2005-95, Laws of Florida, which revised Section 390.012, F.S. The law provides for adoption of rules for regulation of clinics providing abortions after the first trimester of pregnancy.

SUMMARY: The proposed rule revisions establish criteria for abortion clinic's physical facilities, supplies and equipment, clinic personnel, medical screening and evaluation, abortion procedures, recovery room standards, follow up care and incident reporting.

SPECIFIC AUTHORITY: 390.012 FS.

LAW IMPLEMENTED: 390.012 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE HELD AT THE DATE, TIME AND PLACE SHOWN BELOW (IF NOT REQUESTED, THIS HEARING WILL NOT BE HELD):

DATE AND TIME: June 22, 2006, 1:00 p.m. – 5:00 p.m.

PLACE: Agency for Health Care Administration, 2727 Mahan Drive, Building #3, Conference Room A, Tallahassee, FL 32308

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULES IS: M. Riley Gibson, Bureau of Health Facility Regulation, 2727 Mahan Drive, Tallahassee, Florida, or call (850)922-7752

THE FULL TEXT OF THE PROPOSED RULES IS:

**59A-9.018 Purpose.**

The agency adopts the following minimum rules and standards governing services in the first and second trimesters provided in an abortion clinic to comply with the requirements of Chapters 381 and 390, F.S.

Specific Authority 390.012 FS. Law Implemented 381.0012, 382, 390.011, 390.012, 390.013 FS. History–New 6-13-90, Formerly 10D-72.018, Repromulgated

**59A-9.019 Definitions.**

The following definitions shall apply specifically to abortion clinics.

(1) "Abortion" means the termination of human pregnancy with the intention other than to produce a live birth or to remove a dead fetus.

(2) "Abortion Clinic" or "Clinic" means a facility, institution, or place in which abortions are performed other than a hospital or a physician's office that is not used primarily for the performance of abortions.

(3) "Anesthesiologist" means a person currently licensed to practice medicine or osteopathy pursuant to Chapter 458 or 459, F.S., and certified by the American Board of Anesthesiology. "Consultant" means an individual who provides professional services either upon request or on the basis of a prearranged schedule, usually on a contract basis, who is neither a member of the employed staff of the facility, nor whose services are provided within the terms of an affiliation agreement.

(4) "Advanced Registered Nurse Practitioner. (ARNP)" means a person currently licensed pursuant to Chapter 464, F.S.

(5)(4) "Agency" "AHCA" means the Agency for Health Care Administration.

(5) "F.A.C." means the Florida Administrative Code.

(6) "Certified Registered Nurse Anesthetist. (CRNA)" means a person currently licensed pursuant to Chapter 464, F.S., and certified by the Council on Certification of Nurse Anesthetists.

(7) "Clinical staff" means the individuals employed full or part time by an abortion clinic who are licensed or certified to provide care prior to, during, or after an abortion.

(8) "Department" means the Department of Health.

(9) "F.A.C." means the Florida Administrative Code.

(10)(6) "Facility" means those objects, including physical plant, equipment, and supplies necessary for providing required services.

(11)(7) "Hospital" means a facility licensed under Chapter 395, F.S.

(12)(8) "License" means the certificate issued by the agency for the operation of the facility. This document constitutes the authority to receive patients and to perform the services included within the scope of this rule and as specified on the license.

(13)(9) "Licensed" means that person or facility to which the term is applied has a current or valid license, certificate or registration issued by the State of Florida to follow his profession or vocation within the State of Florida, and when applied to a health care facility means that the facility has a current license issued by the agency AHCA.

(14)(10) "Licensee" means the person who has been granted a license to operate an abortion clinic and who has ultimate authority and responsibility for the operation, management, control, conduct, and functioning of the abortion clinic.

(15)(11) "Licensure" means the process of obtaining official or legal permission to operate an abortion clinic.

(12) "Clinical staff" means the individuals employed full or part-time by an abortion clinic who are licensed or certified to provide care prior to, during, or after an abortion.

(16) "Licensed Practical Nurse. (L.P.N. )" means a person currently licensed as an L.P.N. pursuant to Chapter 464, F.S.

(17) "Medical Director" means a physician licensed under Chapter 458 or Chapter 459, F.S., and who has admitting privileges at a licensed hospital in this state or has a transfer agreement with a licensed hospital within reasonable proximity of the abortion clinic.

(18)(12) "Patient" means any woman receiving services in an abortion clinic.

(19)(14) "Person" means any individual, firm, partnership, corporation, or association.

(20) "Physician Assistant. (P.A. )" means a person currently licensed as a P.A. pursuant to Chapter 458 or 459, F.S.

(21)(15) "Physician" means a person currently physician licensed to practice medicine or osteopathy pursuant to Chapter 458 or 459, F.S. under Chapter 458 or Chapter 459, F.S., or a physician practicing medicine or osteopathy in the employment of the United States or this state.

(22)(16) "Premises" means those buildings, beds, and facilities of the clinic and all other buildings, beds, and facilities for the performance of abortions located in such reasonable proximity to the main address of the licensee and appear to the public to be under the domain and the control of the licensee.

(23) "Reasonable proximity" means a distance not to exceed thirty (30) minutes transport time by emergency vehicle.

(24) "Registered Professional Nurse. (R.N. )" means a person currently licensed as a R.N. pursuant to Chapter 464, F.S.

(25) "Trimester" means a 12-week period of pregnancy.

(a) First Trimester. The first 12 weeks of pregnancy.

(b) Second Trimester. That portion of a pregnancy following the 12th week and extending through the 24th week of gestation.

(c) Third Trimester. That portion of pregnancy beginning with the 25th week of gestation.

(26) "Volunteer" means a person who is not employed by the facility who interacts with patients on behalf of the abortion clinic.

Specific Authority 390.012 FS. Law Implemented 390.011, 390.012, 390.013 FS. History—New 6-13-90, Amended 4-17-91, Formerly 10D-72.019, Amended 8-24-94.

59A-9.020 Licensure Procedures.

(1) All persons planning contemplating 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, Office of Health Facility Regulation,

Tallahassee, Florida, on Agency Form 3130-1000-revised July 2005 MAR-94, "Abortion Clinic Licensure Application", hereby incorporated by reference, which can be obtained from the Agency for Health Care Administration, Bureau Office of Health Facility Regulation, Tallahassee, Florida, or on the agency website, and must shall receive a license prior to the acceptance of patients for care and treatment. The application shall be made under oath and shall contain such information as the agency AHCA reasonably requires, which may include evidence of the applicant's ability to comply with applicable laws and rules.

(2) A license fee of \$250 shall accompany the application for a license or a license renewal. The license fee shall be made payable to the agency and is not refundable.

(3) Each license shall be valid only for the persons to whom it is issued and shall not be subject to sale, assignment, or other transfer, voluntary or involuntary, nor shall a license be valid for any premises other than for which it was originally issued.

(4) A current license shall be posted in a conspicuous place within on the licensed premises where it can be viewed by patients.

(5) A license, unless sooner suspended or revoked, shall automatically expire one year from the date of issuance, and shall be renewable annually upon application for renewal and payment of the fee prescribed by these rules, provided that the applicant and abortion clinic meet the requirements established under Chapter 390, F.S., and Chapter 59A-9, F.A.C. Application for renewal of a license shall be made not less than 60 days prior to expiration of a license on agency Form 3130-1000-revised July 2005 MAR-94, provided by the Agency for Health Care Administration AHCA, Office of Health Facility Regulation, Tallahassee, Florida. The application is also available on-line at the agency website.

(6) Where the agency finds that there has been a failure to comply with the requirements established under this part or in rules promulgated hereunder, the agency is authorized to deny, modify, suspend, or revoke a license.

Specific Authority 390.012 FS. Law Implemented 20.42(2)(a), 390.011, 390.012, 390.014, 390.015, 390.016, 390.017, 390.018, 390.019, 390.021 FS. History-New 6-13-90, Amended 4-17-91, 10-9-91, Formerly 10D-72.020, Amended 8-24-94, \_\_\_\_\_.

59A-9.021 Investigations and License and Validation Inspections.

(1) The agency AHCA has the right to enter an abortion clinic to make or cause to be made such inspections and investigations, including the review of all medical records, policies, procedures, personnel records and training records, as are necessary to:

- (a) Assure compliance with the licensure requirements; and standards as specified in statute and rule;
- (b) Respond to complaints; and

(c) Protect the public health and safety.

(2) The agency shall conduct an annual unannounced licensure inspection of all abortion clinics facilities.

(3) The fee for the renewal license shall be \$250.

(4) Representatives of the agency shall have the right to enter upon the premises of any facility licensed or applying for license, pursuant to this Chapter, at any reasonable time in order to determine the state of compliance with the provisions of Chapter 390, F.S., and these rules, providing that such entry and inspection shall be made with the least possible disruption to clinic activities and in a manner considerate of the privacy and confidentiality of any patient who is present therein. All inspections shall be unannounced.

Specific Authority 390.012 FS. Law Implemented 381.0012, 382, 390.011, 390.012, 390.014, 390.019 FS. History-New 6-13-90, Amended 4-17-91, 10-9-91, Formerly 10D-72.021, Amended \_\_\_\_\_.

59A-9.022 Physical Plant Requirements for Abortion Clinics When Providing Second Trimester Abortions.  
The following are minimum standards of construction and specified minimum essential physical plant requirements which must be met when providing second trimester abortions. These requirements shall apply to all new abortion clinic construction and shall apply to any abortion clinics receiving an initial license after the effective date of these rules when the abortion clinic provides second trimester abortions. Any abortion clinic which provides second trimester abortions and is in operation at the time of adoption of this rule shall be given one year within which to comply with the physical plant requirements.

(1) Consultation room(s) with adequate private space specifically designated for interviewing, counseling, and medical evaluations;

(2) Dressing rooms designated for staff and patients;

(3) Handwashing station(s) equipped with a mixing valve and wrist blades and located in each patient exam/procedure room or area;

(4) Private procedure room(s) with adequate light and ventilation for abortion procedures;

(5) Post procedure recovery room(s) equipped to meet the patient's needs;

(6) Emergency exits wide enough to accommodate a standard stretcher or gurney;

(7) Cleaning and sterilizing area(s) adequate for the cleaning and sterilizing of instruments;

(8) Adequate and secure storage area(s) for the storage of medical records and necessary equipment and supplies; and

(9) If not otherwise required by the Florida Building Code, at least one general use toilet room equipped with a hand washing station.

Specific Authority 390.012(1) FS. Law Implemented 390.012(3)(a), 390.013 FS. History-New \_\_\_\_\_.

59A-9.0225 Clinic Supplies and Equipment Standards for Second Trimester Abortions.

(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.

(3) Anesthesia.

(a) The clinic shall have anesthesia equipment maintained in proper working order for the appropriate administering of general and local anesthesia, analgesia, and sedation if ordered by the physician.

(b) All reusable anesthesia equipment in direct contact with the patient shall be cleaned or sterilized as appropriate after each use and such cleaning and sterilization shall be documented.

(4) Resuscitative Medications Required. The clinic shall have a crash cart at the location the anesthetizing is being carried out. The crash cart must include, at a minimum, those emergency medications to support the procedures performed as determined by the medical director.

(5) Sterilization Equipment. Sterilizing equipment of appropriate type shall be available and of adequate capacity to properly sterilize instruments and materials. The sterilizing equipment shall have approved control and safety features.

(6) Ultrasound equipment shall be located in the clinic.

(7) Equipment Maintenance.

(a) When patient monitoring equipment is utilized, a written preventive maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with manufacturer's specifications at periodic intervals, not less than annually, to insure proper operation, and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper calibration before returning it to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance.

(b) All anesthesia and surgical equipment shall have a written preventive maintenance program developed and implemented. Equipment shall be checked and tested in accordance with the manufacturer's specifications at designated intervals, not less than annually, to ensure proper operation and a state of good repair.

(c) All surgical instruments shall have a written preventive maintenance program developed and implemented. Surgical instruments shall be cleaned and checked for function after use to ensure proper operation and a state of good repair.

Specific Authority 390.012(1) FS, Law Implemented 390.012(3)(a), 390.013 FS, History-New

59A-9.023 Clinic Personnel Clinic Staff and Consultants. Abortions shall be performed only by a licensed physician. Each abortion clinic providing second trimester abortions shall have a staff that is adequately trained and capable of providing appropriate service and supervision to the patients. The clinic will have a position description for each position delineating duties and responsibilities and maintain personnel records for all employees performing or monitoring patients receiving a second trimester abortion. Any abortion clinic which is in operation at the time of adoption of this rule and performing second trimester abortions shall be given six months within which to comply with these clinical staff requirements as follows:

(1) Physicians. The clinic shall designate a licensed physician to serve as a medical director.

(2) Nursing Personnel. Nursing personnel in the clinic shall be governed by written policies and procedures relating to patient care, establishment of standards for nursing care and mechanisms for evaluating such care, and nursing services.

(3) Allied health professionals, working under appropriate direction and supervision, may be employed to work only within areas where their competency has been established.

(4) Orientation. Each facility shall have and execute a written orientation program to familiarize each new staff member, including volunteers, with the facility and its policies and procedures, to include, as a minimum, fire safety and other safety measures, medical emergencies, and infection control.

(5) In-service Training. In-service training programs shall be planned and provided for all employees including full time, part time and contract employees, at the beginning of

employment and at least annually thereafter and will also apply to all volunteers to insure and maintain their understanding of their duties and responsibilities. Records shall be maintained to reflect program content and individual attendance. The following training shall be provided at least annually, and for surgical assistants and volunteers must include training in counseling, patient advocacy and specific responsibilities associated with the services they provide:

(a) Infection control, to include as a minimum, universal precautions against blood-borne diseases, general sanitation, personal hygiene such as hand washing, use of masks and gloves, and instruction to staff if there is a likelihood of transmitting a disease to patients or other staff members.

(b) Fire protection, to include evacuating patients, proper use of fire extinguishers, and procedures for reporting fires;

(c) Confidentiality of patient information and records, and protecting patient rights;

(d) Licensing regulations; and

(e) Incident reporting.

Specific Authority 390.012 FS. Law Implemented 381.0012, 382, 390.011, 390.012, 390.013 FS. History—New 6-13-90, Amended 4-17-91, Formerly 10D-72.023, Amended \_\_\_\_\_.

#### 59A-9.024 Clinic Policies and Procedures for Second Trimester Abortions.

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. Any abortion clinic which is in operation at the time of adoption of this rule and providing second trimester abortions shall be given six months within which to comply with these clinic policies and procedure requirements which 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;

(19) Volunteers; and

(20) Visitors.

Specific Authority 390.012(1) FS. Law Implemented 390.012(3)(c), 390.013 FS. History—New \_\_\_\_\_.

#### 59A-9.025 Medical Screening and Evaluation of Patients Receiving Second Trimester Abortions.

(1) Each abortion clinic that provides second trimester abortions shall formulate and adhere to written patient care policies and procedures designed to ensure professional and safe care for patients undergoing second trimester abortions and shall maintain a medical record for each such patient that records history, care and services. Any abortion clinic that performs second trimester abortions which is in operation at the time of adoption of this rule shall be given six months within which to comply with these patient care policies and procedures for patients undergoing second trimester abortions, to include but not limited to the following:

(a) Admission criteria and procedures;

(b) Identification in the medical record of physician(s) and nurse(s) involved in providing the services offered for patients undergoing second trimester abortions;

(c) Specific details regarding the pre-operative procedures performed, to include:

1. History and physical examination, to include verification of pregnancy, estimation of gestational age, identification of any preexisting conditions or complications, including allergies to medications, antiseptic solutions, or latex; and a complete obstetric and gynecological history.

2. Special examinations, lab procedures, and/or consultations required, to include ultrasonography to confirm gestational age and a physical examination including a bimanual examination estimating uterine size and palpation of the adnexa. The physician shall keep original prints of each ultrasound examination of a patient in the patient's medical history file. For an abortion in which an ultrasound examination is not performed before the abortion procedure, urine or blood tests for pregnancy shall be performed before the abortion procedure.

(2) 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, Florida Statutes.

(b) All laboratory services provided on-site shall be performed in compliance with state of Florida clinical laboratory licensure and federal CLIA provisions.



(3) Laboratory Equipment and Supplies.

(a) All equipment and supplies for the collection, storage, and testing of specimens shall meet the provisions of Chapter 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.

(4) Rh factor. Rh testing for Rh negative patients shall be conducted, unless reliable written documentation of blood type is available.

(5) All laboratory test reports shall be placed in the patient's medical record.

(6) All laboratory test and storage areas, records and reports shall be available for inspection by the agency.

(7) If a person who is not a physician performs an ultrasound examination, that person shall have 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.

(8) A test for anemia shall be performed.

Specific Authority 390.012(1) FS. Law Implemented 390.012(3)(d), 390.013 FS. History--New \_\_\_\_\_.

59A-9.026 Second Trimester Abortion Procedure.

Any abortion clinic which is providing second trimester abortions must be in compliance with the following standards relative to second trimester abortion procedures. Any abortion clinic in operation at the time of adoption of this rule, when performing second trimester abortions, shall be given six months within which to comply.

(1) A physician, registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant shall be available to all patients throughout the abortion procedure.

(2) The abortion procedure will be performed in accordance with obstetric standards and in keeping with established standards of care regarding the estimation of gestational age of the fetus.

(3) Anesthesia service shall be organized under written policies and procedures relating to anesthesia staff privileges, the administration of anesthesia, and the maintenance of strict safety controls.

(4) Prior to the administration of anesthesia, patients shall have a history and physical examination by the individual administering anesthesia, including laboratory analysis when indicated.

(5) Appropriate precautions, such as the establishment of intravenous access at least for patients undergoing post-first trimester abortions.

(6) Appropriate monitoring of the patient's vital signs by professionals licensed and qualified to assess the patient's condition will occur throughout the abortion procedure and during the recovery period until the patient's condition as specified by the type of abortion procedure performed, is deemed to be stable in the recovery room.

Specific Authority 390.012(1) FS. Law Implemented 390.012(3)(e), 390.013 FS. History--New \_\_\_\_\_.

59A-9.027 Recovery Room Standards for Second Trimester Abortions.

Each abortion clinic which is providing second trimester abortions shall comply with the following recovery room standards when providing second trimester abortions. Any abortion clinic providing second trimester abortions and in operation at the time of adoption of this rule shall be given one year within which to comply with these standards.

(1) Following the procedure, post procedure recovery rooms will be supervised and staffed to meet the patient's needs. A physician or physician assistant, a licensed registered nurse, a licensed practical nurse or an advanced registered nurse practitioner who is trained in the management of the recovery area shall be available to monitor the patient in the recovery room until the patient is discharged. The individual must be certified in basic cardiopulmonary resuscitation. A patient in the post-operative or recovery room shall be observed for as long as the patient's condition warrants.

(2) The clinic shall arrange hospitalization if any complication beyond the medical capability of the staff occurs or is suspected. The clinic shall ensure that all appropriate equipment and services are readily accessible to provide appropriate emergency resuscitative and life support procedures pending the transfer of the patient or a viable fetus to the hospital. A physician shall sign the discharge order and be readily accessible and available until the last patient is discharged to facilitate the transfer of emergency cases if hospitalization of the patient or viable fetus is necessary. The clinic medical records documenting care provided shall accompany the patient. These records will include the contact information for the physician who performed the procedure at the clinic.

(3) A physician shall discuss Rho (D) immune globulin with each patient for whom it is indicated and will ensure that it is offered to the patient in the immediate postoperative period or that it will be available to the patient within 72 hours following completion of the abortion procedure. If the patient

refuses the Rho (D) immune globulin, refusal Form 3130-1002, herein incorporated by reference, shall be signed by the patient and a witness, and shall be included in the patient's medical record.

(4) Written instructions with regard to post abortion coitus, signs of possible medical complications, and general aftercare shall be given to each patient. Each patient shall have specific written instructions regarding access to medical care for complications, including a telephone number to call for medical emergencies. The physician will ensure that either a registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant from the abortion clinic makes a good faith effort to contact the patient by telephone, with the patient's consent, within 24 hours after surgery to assess the patient's recovery. A contact for post-operative care from the facility shall be available to the patient on a 24-hour basis.

(5) Facility procedures must specify the minimum length of time for recovery as warranted by the procedure type and gestation period.

Specific Authority 390.012(1) FS. Law Implemented 390.012(3)(f), 390.013 FS. History-New \_\_\_\_\_.

59A-9.028 Post Procedure Follow-up Care for Patients Receiving Second Trimester Abortions.

Each abortion clinic which is providing second trimester abortions shall comply with the following post procedure follow-up care requirements when providing a second trimester abortion. Any abortion clinic operating at the time of adoption of this rule shall be given six months within which to comply.

(1) The clinic shall offer a post abortion medical visit that includes a medical examination and a review of the results of all laboratory tests.

(2) A urine pregnancy test will be obtained at the time of the follow-up visit to rule out continuing pregnancy. If a continuing pregnancy is suspected, the patient shall be evaluated and a physician who performs abortions shall be consulted.

(3) The clinic shall provide for the education of the patient in post-procedure care, including specific instructions in case of emergency.

Specific Authority 390.012(1) FS. Law Implemented 390.012(3)(g), 390.013 FS. History-New \_\_\_\_\_.

59A-9.029 Abortion Clinic Incident Reporting for Second Trimester Abortions.

This section shall apply to incidents involving patients receiving second trimester abortions in any abortion clinic providing second trimester abortions. Those abortion clinics providing second trimester abortions which are in operation at

the time of adoption of this rule shall be given six months within which to comply with the following clinic incident reporting requirements.

(1) At a minimum an abortion clinic shall record each incident that results in serious injury to a patient as defined in Section 390.012(3)(h)1., F.S., or a viable fetus at an abortion clinic and shall report an incident in writing to the agency within 10 days after the incident occurs.

(2) If a patient death occurs the abortion clinic shall report the death to the department and the appropriate regulatory board not later than the next workday. The report to the department shall be filed as required by Rule 64V-1.0061, F.A.C.

Specific Authority 390.012(1) FS. Law Implemented 390.012(3)(h), 390.013 FS. History-New \_\_\_\_\_.

59A-9.030 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 Chapter 64E-16 10D-104, F.A.C.

Specific Authority 390.012 FS. Law Implemented 381.0012, 382, 390.011, 390.012, 390.013 FS. History-New 6-13-90, Amended 4-17-91, Formerly 10D-72.030, Amended \_\_\_\_\_.

59A-9.031 Clinical Records.

(1) A permanent individual clinical record shall be kept on each clinic patient.

(a) Clinical records shall be complete, accurately documented, and systematically organized to facilitate storage and retrieval.

(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.

(2) Clinical records shall be kept on file for a minimum of five years from the date of the last entry.

Specific Authority 390.012 FS. Law Implemented 381.0012, 382, 390.011, 390.012, 390.013 FS. History-New 6-13-90, Amended 4-17-91, Formerly 10D-72.031, Amended \_\_\_\_\_.

59A-9.034 Reports.

Pursuant to Chapters 382 and 390, F.S., an abortion clinic must submit a report each month to the Office of Vital Statistics of the Department of Health and Rehabilitative Services, regardless of the number of terminations of pregnancy. Monthly reports must be received by the department within 30 days following the preceding month using DOH HRS Form 1578, November 1999 May-94, "Report of Induced Terminations of Pregnancy", hereby incorporated by reference,

and which can be obtained from the Department of Health and Rehabilitative Services, Office of Vital Statistics, Jacksonville, Florida.

Specific Authority 390.012 FS. Law Implemented 20.42(2)(a), 382.002, 390.002, 390.011, 390.012 FS. History-New 6-13-90, Formerly 10D-72.034, Amended 8-24-94, \_\_\_\_\_.

NAME OF PERSON ORIGINATING PROPOSED RULE: M. Riley Gibson, Bureau of Health Facility Regulation, Division of Health Quality Assurance

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Elizabeth Dudek, Deputy Secretary, Health Quality Assurance, Agency for Health Care Administration

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: May 15, 2006

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: October 21, 2005

**DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION**

Division of Hotels and Restaurants

RULE CHAPTER NO.: RULE CHAPTER TITLE:

61C-5 Florida Elevator Safety Code

RULE NO.: RULE TITLE:

61C-5.007 Fees; Certificates of Competency, Renewal

PURPOSE AND EFFECT: The purpose of this rule amendment is to implement the statutory requirements of Section 399.01(14)-(15), Florida Statutes, through the adoption of the insurance requirements for independent certified elevator inspectors and certified elevator technicians.

SUMMARY: This proposed rule amendment provides insurance requirements to be carried by certified elevator inspectors and certified elevator technicians working independent of a registered elevator company.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COST: No Statement of Estimated Regulatory Costs has been prepared.

Any person who wishes to provide information regarding the statement of estimated regulatory costs, or to provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 399.001, 399.01(14), (15), 399.10 FS.

LAW IMPLEMENTED: 399.01(14), (15) FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW:

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: John Calpini, Bureau Chief, Department of Business and Professional Regulation, Division of Hotels and Restaurants, 1940 North Monroe Street, Tallahassee, FL 32399-1012; telephone: (850)488-1133

THE FULL TEXT OF THE PROPOSED RULE IS:

61C-5.007 Fees; Certificates of Competency, Renewal.

(1) through (5) No change.

(6) Each elevator company employing a person or persons to construct, install, inspect, maintain, or repair any vertical conveyance regulated by the bureau, must register and have on file with the division a valid Certificate of Comprehensive General Liability Insurance evidencing coverage limits in the minimum amounts of \$100,000 per person and \$300,000 per occurrence and the name of at least one employee who holds a current Certificate of Competency issued pursuant to Section 399.01(17) 399.045, F.S.

(7) No change.

(8) Each certified elevator inspector and each certified elevator technician who, independent of a registered elevator company as defined in Section 399.01(13), F.S., performs any services on any vertical conveyance regulated by the bureau must have on file with the division a valid Certificate of Comprehensive General Liability Insurance evidencing coverage limits in the minimum amounts of \$100,000 per person and \$300,000 per occurrence prior to performing any services independent of a registered elevator company.

Specific Authority 399.001, 399.049, 399.02(s)(d), 399.10, 399.105(2) FS. Law Implemented 399.01(13), 399.01(14), 399.01(15), 399.01(17) 399.01(s)(d) FS. History-New 10-8-81, Amended 11-27-83, 2-19-84, Formerly 7C-5.07, Amended 4-11-91, Formerly 7C-5.007, Amended 2-2-94, \_\_\_\_\_.

NAME OF PERSON ORIGINATING PROPOSED RULE: John Calpini, Bureau Chief, Division of Hotels and Restaurants, Department of Business and Professional Regulation

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Simone Marstiller, Secretary, Department of Business and Professional Regulation

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: May 3, 2006

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: February 24, 2006

**DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION**

Board of Cosmetology

RULE NO.: RULE TITLE:

61G5-24.020 Special Assessment Fee

PURPOSE AND EFFECT: The rule will impose a one-time fee assessment on all license and registration holders.

FILED

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DIVISION OF  
ADMINISTRATIVE  
HEARINGS

# Exhibit A

officer lieutenant or above, who will be responsible for hearing disciplinary reports. The correctional officer chief shall designate a correctional officer sergeant as a substitute team member only if neither a lieutenant nor captain is available and only when such substitution is absolutely necessary.

(9) Hearing Officer – An employee, who is of the rank of lieutenant or higher, who will be responsible for hearing disciplinary reports designated as minor.

(10) through (16) No change.

Specific Authority 944.09 FS. Law Implemented 20.315, 944.09 FS. History–New 3-12-84, Formerly 33-22.02, Amended 12-30-86, 10-01-95, Formerly 33-22.002, Amended 5-21-00, 2-11-01, 9-16-04,

NAME OF PERSON ORIGINATING PROPOSED RULE:  
Franchatta Barber, Deputy Assistant Secretary of Institutions – Programs

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: George Sapp, Assistant Secretary of Institutions

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: May 15, 2006

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: May 7, 2006

**AGENCY FOR HEALTH CARE ADMINISTRATION**

**Division of Health Quality Assurance**

RULE CHAPTER NO.: RULE CHAPTER TITLE:

59A-9	Abortion Clinics
RULE NOS.:	RULE TITLES:
59A-9.018	Purpose
59A-9.019	Definitions
59A-9.020	Licensure Procedures
59A-9.021	Investigations and License and Validation Inspections
59A-9.022	Physical Plant Requirements for Abortion Clinics When Providing Second Trimester Abortions
59A-9.0225	Clinic Supplies and Equipment Standards for Second Trimester Abortions
59A-9.023	Clinic Personnel
59A-9.024	Clinic Policies and Procedures for Second Trimester Abortions
59A-9.025	Medical Screening and Evaluation of Patients Receiving Second Trimester Abortions
59A-9.026	Second Trimester Abortion Procedure
59A-9.027	Recovery Room Standards for Second Trimester Abortions

59A-9.028	Post Procedure Follow-up Care for Patients Receiving Second Trimester Abortions
59A-9.029	Abortion Clinic Incident Reporting for Second Trimester Abortions
59A-9.030	Disposal of Fetal Remains
59A-9.031	Clinical Records
59A-9.034	Reports

PURPOSE AND EFFECT: The Agency proposes to revise Chapter 59A-9, Florida Administrative Code, consistent with provisions of Chapter 2005-95, Laws of Florida, which revised Section 390.012, F.S. The law provides for adoption of rules for regulation of clinics providing abortions after the first trimester of pregnancy.

SUMMARY: The proposed rule revisions establish criteria for abortion clinic's physical facilities, supplies and equipment, clinic personnel, medical screening and evaluation, abortion procedures, recovery room standards, follow up care and incident reporting.

SPECIFIC AUTHORITY: 390.012 FS.

LAW IMPLEMENTED: 390.012 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE HELD AT THE DATE, TIME AND PLACE SHOWN BELOW (IF NOT REQUESTED, THIS HEARING WILL NOT BE HELD):

DATE AND TIME: June 22, 2006, 1:00 p.m. – 5:00 p.m.

PLACE: Agency for Health Care Administration, 2727 Mahan Drive, Building #3, Conference Room A, Tallahassee, FL 32308

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULES IS: M. Riley Gibson, Bureau of Health Facility Regulation, 2727 Mahan Drive, Tallahassee, Florida, or call (850)922-7752

THE FULL TEXT OF THE PROPOSED RULES IS:

59A-9.018 Purpose.

The agency adopts the following minimum rules and standards governing services in the first and second trimesters provided in an abortion clinic to comply with the requirements of Chapters 381 and 390, F.S.

Specific Authority 390.012 FS. Law Implemented 381.0012, 382, 390.011, 390.012, 390.013 FS. History–New 6-13-90, Formerly 10D-72.018, Repromulgated

59A-9.019 Definitions.

The following definitions shall apply specifically to abortion clinics.

(1) "Abortion" means the termination of human pregnancy with the intention other than to produce a live birth or to remove a dead fetus.

(2) "Abortion Clinic" or "Clinic" means a facility, institution, or place in which abortions are performed other than a hospital or a physician's office that is not used primarily for the performance of abortions.

(3) "Anesthesiologist" means a person currently licensed to practice medicine or osteopathy pursuant to Chapter 458 or 459, F.S., and certified by the American Board of Anesthesiology. "Consultant" means an individual who provides professional services either upon request or on the basis of a prearranged schedule, usually on a contract basis, who is neither a member of the employed staff of the facility, nor whose services are provided within the terms of an affiliation agreement.

(4) "Advanced Registered Nurse Practitioner (ARNP)" means a person currently licensed pursuant to Chapter 464, F.S.

(5)(4) "Agency" "AHCA" means the Agency for Health Care Administration.

(5) "F.A.C." means the Florida Administrative Code.

(6) "Certified Registered Nurse Anesthetist (CRNA)" means a person currently licensed pursuant to Chapter 464, F.S., and certified by the Council on Certification of Nurse Anesthetists.

(7) "Clinical staff" means the individuals employed full or part time by an abortion clinic who are licensed or certified to provide care prior to, during, or after an abortion.

(8) "Department" means the Department of Health.

(9) "F.A.C." means the Florida Administrative Code.

(10)(6) "Facility" means those objects, including physical plant, equipment, and supplies necessary for providing required services.

(11)(7) "Hospital" means a facility licensed under Chapter 395, F.S.

(12)(8) "License" means the certificate issued by the agency for the operation of the facility. This document constitutes the authority to receive patients and to perform the services included within the scope of this rule and as specified on the license.

(13)(9) "Licensed" means that person or facility to which the term is applied has a current or valid license, certificate or registration issued by the State of Florida to follow his profession or vocation within the State of Florida, and when applied to a health care facility means that the facility has a current license issued by the agency AHCA.

(14)(10) "Licensee" means the person who has been granted a license to operate an abortion clinic and who has ultimate authority and responsibility for the operation, management, control, conduct, and functioning of the abortion clinic.

(15)(11) "Licensure" means the process of obtaining official or legal permission to operate an abortion clinic.

(12) "Clinical staff" means the individuals employed full or part-time by an abortion clinic who are licensed or certified to provide care prior to, during, or after an abortion.

(16) "Licensed Practical Nurse (L.P.N.);" means a person currently licensed as an L.P.N. pursuant to Chapter 464, F.S.

(17) "Medical Director" means a physician licensed under Chapter 458 or Chapter 459, F.S., and who has admitting privileges at a licensed hospital in this state or has a transfer agreement with a licensed hospital within reasonable proximity of the abortion clinic.

(18)(13) "Patient" means any woman receiving services in an abortion clinic.

(19)(14) "Person" means any individual, firm, partnership, corporation, or association.

(20) "Physician Assistant (P.A.);" means a person currently licensed as a P.A. pursuant to Chapter 458 or 459, F.S.

(21)(15) "Physician" means a person currently physician licensed to practice medicine or osteopathy pursuant to Chapter 458 or 459, F.S., under Chapter 458 or Chapter 459, F.S., or a physician practicing medicine or osteopathy in the employment of the United States or this state.

(22)(16) "Premises" means those buildings, beds, and facilities of the clinic and all other buildings, beds, and facilities for the performance of abortions located in such reasonable proximity to the main address of the licensee and appear to the public to be under the domain and the control of the licensee.

(23) "Reasonable proximity" means a distance not to exceed thirty (30) minutes transport time by emergency vehicle.

(24) "Registered Professional Nurse (R.N.);" means a person currently licensed as a R.N. pursuant to Chapter 464, F.S.

(25) "Trimester" means a 12-week period of pregnancy.

(a) First Trimester. The first 12 weeks of pregnancy.

(b) Second Trimester. That portion of a pregnancy following the 12th week and extending through the 24th week of gestation.

(c) Third Trimester. That portion of pregnancy beginning with the 25th week of gestation.

(26) "Volunteer" means a person who is not employed by the facility who interacts with patients on behalf of the abortion clinic.

Specific Authority 390.012 FS. Law Implemented 390.011, 390.012, 390.013 FS. History—New 6-13-90, Amended 4-17-91, Formerly 10D-72.019, Amended 8-24-94.

59A-9.020 Licensure Procedures.

(1) All persons planning or contemplating 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, Office of Health Facility Regulation,

Tallahassee, Florida, on Agency Form 3130-1000-revised July 2005 MAR-94, "Abortion Clinic Licensure Application", hereby incorporated by reference, which can be obtained from the Agency for Health Care Administration, Bureau Office of Health Facility Regulation, Tallahassee, Florida, or on the agency website, and must shall receive a license prior to the acceptance of patients for care and treatment. The application shall be made under oath and shall contain such information as the agency AHCA reasonably requires, which may include evidence of the applicant's ability to comply with applicable laws and rules.

(2) A license fee of \$250 shall accompany the application for a license or a license renewal. The license fee shall be made payable to the agency and is not refundable.

(3) Each license shall be valid only for the persons to whom it is issued and shall not be subject to sale, assignment, or other transfer, voluntary or involuntary, nor shall a license be valid for any premises other than for which it was originally issued.

(4) A current license shall be posted in a conspicuous place within on the licensed premises where it can be viewed by patients.

(5) A license, unless sooner suspended or revoked, shall automatically expire one year from the date of issuance, and shall be renewable annually upon application for renewal and payment of the fee prescribed by these rules, provided that the applicant and abortion clinic meet the requirements established under Chapter 390, F.S., and Chapter 59A-9, F.A.C. Application for renewal of a license shall be made not less than 60 days prior to expiration of a license on agency Form 3130-1000-revised July 2005 MAR-94, provided by the Agency for Health Care Administration AHCA, Office of Health Facility Regulation, Tallahassee, Florida. The application is also available on-line at the agency website.

(6) Where the agency finds that there has been a failure to comply with the requirements established under this part or in rules promulgated hereunder, the agency is authorized to deny, modify, suspend, or revoke a license.

Specific Authority 390.012 FS. Law Implemented 20.42(2)(n), 390.011, 390.012, 390.014, 390.015, 390.016, 390.017, 390.018, 390.019, 390.021 FS. History-New 6-13-90, Amended 4-17-91, 10-9-91, Formerly 10D-72.020, Amended 8-24-94, \_\_\_\_\_.

59A-9.021 Investigations and License and Validation Inspections.

(1) The agency AHCA has the right to enter an abortion clinic to make or cause to be made such inspections and investigations, including the review of all medical records, policies, procedures, personnel records and training records, as are necessary to:

(a) Assure compliance with the licensure requirements; and standards as specified in statute and rule;

(b) Respond to complaints; and

(c) Protect the public health and safety.

(2) The agency shall conduct an annual unannounced licensure inspection of all abortion clinics facilities.

(3) The fee for the renewal license shall be \$250.

(4) Representatives of the agency shall have the right to enter upon the premises of any facility licensed or applying for license, pursuant to this Chapter, at any reasonable time in order to determine the state of compliance with the provisions of Chapter 390, F.S., and these rules, providing that such entry and inspection shall be made with the least possible disruption to clinic activities and in a manner considerate of the privacy and confidentiality of any patient who is present therein. All inspections shall be unannounced.

Specific Authority 390.012 FS. Law Implemented 381.0012, 382, 390.011, 390.012, 390.014, 390.019 FS. History-New 6-13-90, Amended 4-17-91, 10-9-91, Formerly 10D-72.021, Amended \_\_\_\_\_.

59A-9.022 Physical Plant Requirements for Abortion Clinics When Providing Second Trimester Abortions.

The following are minimum standards of construction and specified minimum essential physical plant requirements which must be met when providing second trimester abortions. These requirements shall apply to all new abortion clinic construction and shall apply to any abortion clinics receiving an initial license after the effective date of these rules when the abortion clinic provides second trimester abortions. Any abortion clinic which provides second trimester abortions and is in operation at the time of adoption of this rule shall be given one year within which to comply with the physical plant requirements.

(1) Consultation room(s) with adequate private space specifically designated for interviewing, counseling, and medical evaluations;

(2) Dressing rooms designated for staff and patients;

(3) Handwashing station(s) equipped with a mixing valve and wrist blades and located in each patient exam/procedure room or area;

(4) Private procedure room(s) with adequate light and ventilation for abortion procedures;

(5) Post procedure recovery room(s) equipped to meet the patient's needs;

(6) Emergency exits wide enough to accommodate a standard stretcher or gurney;

(7) Cleaning and sterilizing area(s) adequate for the cleaning and sterilizing of instruments;

(8) Adequate and secure storage area(s) for the storage of medical records and necessary equipment and supplies; and

(9) If not otherwise required by the Florida Building Code, at least one general use toilet room equipped with a hand washing station.

Specific Authority 390.012(1) FS. Law Implemented 390.012(3)(a), 390.013 FS. History-New \_\_\_\_\_.

59A-9.0225 Clinic Supplies and Equipment Standards for Second Trimester Abortions.

(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.
- (3) Anesthesia.

(a) The clinic shall have anesthesia equipment maintained in proper working order for the appropriate administering of general and local anesthesia, analgesia, and sedation if ordered by the physician.

(b) All reusable anesthesia equipment in direct contact with the patient shall be cleaned or sterilized as appropriate after each use and such cleaning and sterilization shall be documented.

(4) Resuscitative Medications Required. The clinic shall have a crash cart at the location the anesthetizing is being carried out. The crash cart must include, at a minimum, those emergency medications to support the procedures performed as determined by the medical director.

(5) Sterilization Equipment. Sterilizing equipment of appropriate type shall be available and of adequate capacity to properly sterilize instruments and materials. The sterilizing equipment shall have approved control and safety features.

(6) Ultrasound equipment shall be located in the clinic.

(7) Equipment Maintenance.

(a) When patient monitoring equipment is utilized, a written preventive maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with manufacturer's specifications at periodic intervals, not less than annually, to insure proper operation, and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper calibration before returning it to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance.

(b) All anesthesia and surgical equipment shall have a written preventive maintenance program developed and implemented. Equipment shall be checked and tested in accordance with the manufacturer's specifications at designated intervals, not less than annually, to ensure proper operation and a state of good repair.

(c) All surgical instruments shall have a written preventive maintenance program developed and implemented. Surgical instruments shall be cleaned and checked for function after use to ensure proper operation and a state of good repair.

Specific Authority 390.012(1) FS. Law Implemented 390.012(3)(a), 390.013 FS. History-New

59A-9.023 Clinic Personnel Clinic Staff and Consultants.

Abortions shall be performed only by a licensed physician. Each abortion clinic providing second trimester abortions shall have a staff that is adequately trained and capable of providing appropriate service and supervision to the patients. The clinic will have a position description for each position delineating duties and responsibilities and maintain personnel records for all employees performing or monitoring patients receiving a second trimester abortion. Any abortion clinic which is in operation at the time of adoption of this rule and performing second trimester abortions shall be given six months within which to comply with these clinical staff requirements as follows:

(1) Physicians. The clinic shall designate a licensed physician to serve as a medical director.

(2) Nursing Personnel. Nursing personnel in the clinic shall be governed by written policies and procedures relating to patient care, establishment of standards for nursing care and mechanisms for evaluating such care, and nursing services.

(3) Allied health professionals, working under appropriate direction and supervision, may be employed to work only within areas where their competency has been established.

(4) Orientation. Each facility shall have and execute a written orientation program to familiarize each new staff member, including volunteers, with the facility and its policies and procedures, to include, as a minimum, fire safety and other safety measures, medical emergencies, and infection control.

(5) In-service Training. In-service training programs shall be planned and provided for all employees including full time, part time and contract employees, at the beginning of



employment and at least annually thereafter and will also apply to all volunteers to insure and maintain their understanding of their duties and responsibilities. Records shall be maintained to reflect program content and individual attendance. The following training shall be provided at least annually, and for surgical assistants and volunteers, must include training in counseling, patient advocacy and specific responsibilities associated with the services they provide:

(a) Infection control, to include as a minimum, universal precautions against blood-borne diseases, general sanitation, personal hygiene such as hand washing, use of masks and gloves, and instruction to staff if there is a likelihood of transmitting a disease to patients or other staff members.

(b) Fire protection, to include evacuating patients, proper use of fire extinguishers, and procedures for reporting fires;

(c) Confidentiality of patient information and records, and protecting patient rights;

(d) Licensing regulations; and

(e) Incident reporting.

Specific Authority 390.012 FS. Law Implemented 381.0012, 382, 390.011, 390.012, 390.013 FS. History--New 6-13-90, Amended 4-17-91, Formerly 10D-72.023, Amended \_\_\_\_\_.

59A-9.024 Clinic Policies and Procedures for Second Trimester Abortions.

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. Any abortion clinic which is in operation at the time of adoption of this rule and providing second trimester abortions shall be given six months within which to comply with these clinic policies and procedure requirements which 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;

(19) Volunteers; and

(20) Visitors.

Specific Authority 390.012(1) FS. Law Implemented 390.012(3)(c), 390.013 FS. History--New \_\_\_\_\_.

59A-9.025 Medical Screening and Evaluation of Patients Receiving Second Trimester Abortions.

(1) Each abortion clinic that provides second trimester abortions shall formulate and adhere to written patient care policies and procedures designed to ensure professional and safe care for patients undergoing second trimester abortions and shall maintain a medical record for each such patient that records history, care and services. Any abortion clinic that performs second trimester abortions which is in operation at the time of adoption of this rule shall be given six months within which to comply with these patient care policies and procedures for patients undergoing second trimester abortions, to include but not limited to the following:

(a) Admission criteria and procedures;

(b) Identification in the medical record of physician(s) and nurse(s) involved in providing the services offered for patients undergoing second trimester abortions;

(c) Specific details regarding the pre-operative procedures performed, to include:

1. History and physical examination, to include verification of pregnancy, estimation of gestational age, identification of any preexisting conditions or complications: including allergies to medications, antiseptic solutions, or latex; and a complete obstetric and gynecological history.

2. Special examinations, lab procedures, and/or consultations required, to include ultrasonography to confirm gestational age and a physical examination including a bimanual examination estimating uterine size and palpation of the adnexa. The physician shall keep original prints of each ultrasound examination of a patient in the patient's medical history file. For an abortion in which an ultrasound examination is not performed before the abortion procedure, urine or blood tests for pregnancy shall be performed before the abortion procedure.

(2) 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, Florida Statutes.

(b) All laboratory services provided on-site shall be performed in compliance with state of Florida clinical laboratory licensure and federal CLIA provisions.

(3) Laboratory Equipment and Supplies.

(a) All equipment and supplies for the collection, storage, and testing of specimens shall meet the provisions of Chapter 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.

(4) Rh factor. Rh testing for Rh negative patients shall be conducted, unless reliable written documentation of blood type is available.

(5) All laboratory test reports shall be placed in the patient's medical record.

(6) All laboratory test and storage areas, records and reports shall be available for inspection by the agency.

(7) If a person who is not a physician performs an ultrasound examination, that person shall have 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.

(8) A test for anemia shall be performed.

Specific Authority 390.012(1) FS, Law Implemented 390.012(3)(d), 390.013 FS, History-New

59A-9.026 Second Trimester Abortion Procedure.

Any abortion clinic which is providing second trimester abortions must be in compliance with the following standards relative to second trimester abortion procedures. Any abortion clinic in operation at the time of adoption of this rule, when performing second trimester abortions, shall be given six months within which to comply.

(1) A physician, registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant shall be available to all patients throughout the abortion procedure.

(2) The abortion procedure will be performed in accordance with obstetric standards and in keeping with established standards of care regarding the estimation of gestational age of the fetus.

(3) Anesthesia service shall be organized under written policies and procedures relating to anesthesia staff privileges, the administration of anesthesia, and the maintenance of strict safety controls.

(4) Prior to the administration of anesthesia, patients shall have a history and physical examination by the individual administering anesthesia, including laboratory analysis when indicated.

(5) Appropriate precautions, such as the establishment of intravenous access at least for patients undergoing post-first trimester abortions.

(6) Appropriate monitoring of the patient's vital signs by professionals licensed and qualified to assess the patient's condition will occur throughout the abortion procedure and during the recovery period until the patient's condition as specified by the type of abortion procedure performed, is deemed to be stable in the recovery room.

Specific Authority 390.012(1) FS, Law Implemented 390.012(3)(e), 390.013 FS, History-New

59A-9.027 Recovery Room Standards for Second Trimester Abortions.

Each abortion clinic which is providing second trimester abortions shall comply with the following recovery room standards when providing second trimester abortions. Any abortion clinic providing second trimester abortions and in operation at the time of adoption of this rule shall be given one year within which to comply with these standards.

(1) Following the procedure, post procedure recovery rooms will be supervised and staffed to meet the patient's needs. A physician or physician assistant, a licensed registered nurse, a licensed practical nurse or an advanced registered nurse practitioner who is trained in the management of the recovery area shall be available to monitor the patient in the recovery room until the patient is discharged. The individual must be certified in basic cardiopulmonary resuscitation. A patient in the post-operative or recovery room shall be observed for as long as the patient's condition warrants.

(2) The clinic shall arrange hospitalization if any complication beyond the medical capability of the staff occurs or is suspected. The clinic shall ensure that all appropriate equipment and services are readily accessible to provide appropriate emergency resuscitative and life support procedures pending the transfer of the patient or a viable fetus to the hospital. A physician shall sign the discharge order and be readily accessible and available until the last patient is discharged to facilitate the transfer of emergency cases if hospitalization of the patient or viable fetus is necessary. The clinic medical records documenting care provided shall accompany the patient. These records will include the contact information for the physician who performed the procedure at the clinic.

(3) A physician shall discuss Rho (D) immune globulin with each patient for whom it is indicated and will ensure that it is offered to the patient in the immediate postoperative period or that it will be available to the patient within 72 hours following completion of the abortion procedure. If the patient

refuses the Rho (D) immune globulin, refusal Form 3130-1002, herein incorporated by reference, shall be signed by the patient and a witness, and shall be included in the patient's medical record.

(4) Written instructions with regard to post abortion coitus, signs of possible medical complications, and general aftercare shall be given to each patient. Each patient shall have specific written instructions regarding access to medical care for complications, including a telephone number to call for medical emergencies. The physician will ensure that either a registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant from the abortion clinic makes a good faith effort to contact the patient by telephone, with the patient's consent, within 24 hours after surgery to assess the patient's recovery. A contact for post-operative care from the facility shall be available to the patient on a 24-hour basis.

(5) Facility procedures must specify the minimum length of time for recovery as warranted by the procedure type and gestation period.

Specific Authority 390.012(1) FS. Law Implemented 390.012(3)(f), 390.013 FS. History-New

#### 59A-9.028 Post Procedure Follow-up Care for Patients Receiving Second Trimester Abortions.

Each abortion clinic which is providing second trimester abortions shall comply with the following post procedure follow-up care requirements when providing a second trimester abortion. Any abortion clinic operating at the time of adoption of this rule shall be given six months within which to comply.

(1) The clinic shall offer a post abortion medical visit that includes a medical examination and a review of the results of all laboratory tests.

(2) A urine pregnancy test will be obtained at the time of the follow-up visit to rule out continuing pregnancy. If a continuing pregnancy is suspected, the patient shall be evaluated and a physician who performs abortions shall be consulted.

(3) The clinic shall provide for the education of the patient in post-procedure care, including specific instructions in case of emergency.

Specific Authority 390.012(1) FS. Law Implemented 390.012(3)(g), 390.013 FS. History-New

#### 59A-9.029 Abortion Clinic Incident Reporting for Second Trimester Abortions.

This section shall apply to incidents involving patients receiving second trimester abortions in any abortion clinic providing second trimester abortions. Those abortion clinics providing second trimester abortions which are in operation at

the time of adoption of this rule shall be given six months within which to comply with the following clinic incident reporting requirements.

(1) At a minimum an abortion clinic shall record each incident that results in serious injury to a patient as defined in Section 390.012(3)(h)1, F.S., or a viable fetus at an abortion clinic and shall report an incident in writing to the agency within 10 days after the incident occurs.

(2) If a patient death occurs the abortion clinic shall report the death to the department and the appropriate regulatory board not later than the next workday. The report to the department shall be filed as required by Rule 64V-1.0061, F.A.C.

Specific Authority 390.012(1) FS. Law Implemented 390.012(3)(h), 390.013 FS. History-New

#### 59A-9.030 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 Chapter 64E-16 40D-104, F.A.C.

Specific Authority 390.012 FS. Law Implemented 381.0012, 382, 390.011, 390.012, 390.013 FS. History-New 6-13-90, Amended 4-17-91, Formerly 10D-72.030, Amended

#### 59A-9.031 Clinical Records.

(1) A permanent individual clinical record shall be kept on each clinic patient.

(a) Clinical records shall be complete, accurately documented, and systematically organized to facilitate storage and retrieval.

(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.

(2) Clinical records shall be kept on file for a minimum of five years from the date of the last entry.

Specific Authority 390.012 FS. Law Implemented 381.0012, 382, 390.011, 390.012, 390.013 FS. History-New 6-13-90, Amended 4-17-91, Formerly 10D-72.031, Amended

#### 59A-9.034 Reports.

Pursuant to Chapters 382 and 390, F.S., an abortion clinic must submit a report each month to the Office of Vital Statistics of the Department of Health and Rehabilitative Services, regardless of the number of terminations of pregnancy. Monthly reports must be received by the department within 30 days following the preceding month using DOH HRS Form 1578, November 1999 May-94, "Report of Induced Terminations of Pregnancy", hereby incorporated by reference,

and which can be obtained from the Department of Health and Rehabilitative Services, Office of Vital Statistics, Jacksonville, Florida.

Specific Authority 390.012 FS. Law Implemented 20.42(2)(a), 382.002, 390.002, 390.011, 390.012 FS. History-New 6-13-90, Formerly 10D-72.034, Amended 8-24-94, \_\_\_\_\_.

NAME OF PERSON ORIGINATING PROPOSED RULE: M. Riley Gibson, Bureau of Health Facility Regulation, Division of Health Quality Assurance

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Elizabeth Dudek, Deputy Secretary, Health Quality Assurance, Agency for Health Care Administration

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: May 15, 2006

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: October 21, 2005

**DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION**

Division of Hotels and Restaurants

RULE CHAPTER NO.: RULE CHAPTER TITLE:

61C-5 Florida Elevator Safety Code

RULE NO.: RULE TITLE:

61C-5.007 Fees; Certificates of Competency, Renewal

PURPOSE AND EFFECT: The purpose of this rule amendment is to implement the statutory requirements of Section 399.01(14)-(15), Florida Statutes, through the adoption of the insurance requirements for independent certified elevator inspectors and certified elevator technicians.

SUMMARY: This proposed rule amendment provides insurance requirements to be carried by certified elevator inspectors and certified elevator technicians working independent of a registered elevator company.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COST: No Statement of Estimated Regulatory Costs has been prepared.

Any person who wishes to provide information regarding the statement of estimated regulatory costs, or to provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 399.001, 399.01(14), (15), 399.10 FS.

LAW IMPLEMENTED: 399.01(14), (15) FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW:

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: John Calpini, Bureau Chief, Department of Business and Professional Regulation, Division of Hotels and Restaurants, 1940 North Monroe Street, Tallahassee, FL 32399-1012; telephone: (850)488-1133

THE FULL TEXT OF THE PROPOSED RULE IS:

61C-5.007 Fees; Certificates of Competency, Renewal.  
(1) through (5) No change.

(6) Each elevator company employing a person or persons to construct, install, inspect, maintain, or repair any vertical conveyance regulated by the bureau, must register and have on file with the division a valid Certificate of Comprehensive General Liability Insurance evidencing coverage limits in the minimum amounts of \$100,000 per person and \$300,000 per occurrence and the name of at least one employee who holds a current Certificate of Competency issued pursuant to Section 399.01(17) 399.045, F.S.

(7) No change.

(8) Each certified elevator inspector and each certified elevator technician who, independent of a registered elevator company as defined in Section 399.01(13), F.S., performs any services on any vertical conveyance regulated by the bureau must have on file with the division a valid Certificate of Comprehensive General Liability Insurance evidencing coverage limits in the minimum amounts of \$100,000 per person and \$300,000 per occurrence prior to performing any services independent of a registered elevator company.

Specific Authority 399.001, 399.049, 399.02(5)(d), 399.10, 399.105(2) FS. Law Implemented 399.01(13), 399.01(14), 399.01(15), 399.01(17) 399.04(5)(d) FS. History-New 10-8-81, Amended 11-27-83, 2-19-84, Formerly 7C-5.07, Amended 4-11-91, Formerly 7C-5.007, Amended 2-2-94, \_\_\_\_\_.

NAME OF PERSON ORIGINATING PROPOSED RULE: John Calpini, Bureau Chief, Division of Hotels and Restaurants, Department of Business and Professional Regulation

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Simone Marsteller, Secretary, Department of Business and Professional Regulation

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: May 3, 2006

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: February 24, 2006

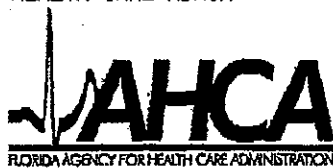
**DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION**

Board of Cosmetology

RULE NO.: RULE TITLE:

61G5-24.020 Special Assessment Fee

PURPOSE AND EFFECT: The rule will impose a one-time fee assessment on all license and registration holders.



JEB BUSH, GOVERNOR

CHRISTA CALAMAS, SECRETARY

August 24, 2006

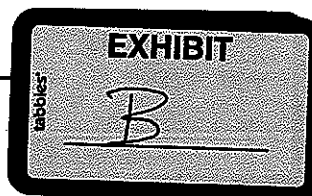
Brian T. Moore
Chief Attorney
Joint Administrative Procedures Committee
120 Holland Building
600 South Calhoun Street
Tallahassee, Florida 32399-1300

RECEIVED
2006 AUG 24 PM 1:40
JOINT ADMINISTRATIVE
PROCEDURES COMMITTEE

Dear Mr. Moore:

This letter is in response to your letter of August 22, 2006, wherein you commented on and had questions about portions of the proposed changes to Chapter 59A-9, F.A.C. The Agency responds to each point as follows:

- 9.019(25) In the definition of "first trimester," the parenthetical "(the first 14 completed weeks from the last normal menstrual period)" is equivalent to "the first 12 weeks of pregnancy."
9.020(1) The Agency has added the mailing address and complete website address for this form.
9.020(5) See 9.020(1).
9.023(4) The Agency has corrected this typographical error.
9.027(3) The form's title, effective date, and complete address where it can be obtained are included in the attached revised rule.
9.034 A copy of the Department of Health form was provided to you at today's meeting; another copy is attached for your convenience.



Having responded to these concerns and made the necessary corrections and additions, it is my understanding that your office would certify the rule for the Department of State. The Agency intends to file this rule for final adoption on September 5, 2006. Please let me know if there is any further information I can provide to you as you prepare to certify this rule.

Finally, I want to thank you again for meeting at our office today. Your comments and questions were very helpful, as we continue in the rulemaking process.

Sincerely,



Lorraine M. Novak  
Assistant General Counsel

Attachments

RECEIVED  
2006 AUG 24 PM 1:40  
AGENCY ADMINISTRATIVE  
PROCEDURES COMMITTEE

**CHAPTER 59A-9 ABORTION CLINICS**

59A-9.018 Purpose.

59A-9.019 Definitions.

59A-9.020 Licensure Procedures.

59A-9.021 Investigations and License and Validation Inspections.

59A-9.022 Physical Plant Requirements for Abortion Clinics When Providing Second Trimester Abortions.

59A-9.0225 Clinic Supplies and Equipment Standards for Second Trimester Abortions.

59A-9.023 Clinic Personnel, Clinic Staff and Consultants

59A-9.024 Clinic Policies and Procedures for Second Trimester Abortions.

59A-9.025 Medical Screening and Evaluation of Patients Receiving Second Trimester Abortions.

59A-9.026 Second Trimester Abortion Procedure.

59A-9.027 Recovery Room Standards for Second Trimester Abortions.

59A-9.028 Post Procedure Follow-up Care for Patients Receiving Second Trimester Abortions.

59A-9.029 Abortion Clinic Incident Reporting for Second Trimester Abortions.

59A-9.030 Disposal of Fetal Remains.

59A-9.031 Clinical Records.

59A-9.034 Reports.

RECEIVED  
2006 AUG 24 PM 1:40  
AGENCY HEALTH CARE ADMIN  
PROCESSES COMMITTEE

**59A-9.018 Purpose.**

The agency adopts the following minimum rules and standards governing services in the first and second trimesters provided in an abortion clinic to comply with the requirements of Chapters 381 and 390, F.S.

*Specific Authority 390.012 F.S. Law Implemented 381.0012, 382, 390.011, 390.012, 390.013 FS. History—New 6-13-90, Formerly 10D-72.018.*

**59A-9.019 Definitions.**

The following definitions shall apply specifically to abortion clinics.

- (1) "Abortion" means the termination of human pregnancy with the intention other than to produce a live birth or to remove a dead fetus.
- (2) "Abortion Clinic" or "Clinic" means a facility, institution, or place in which abortions are performed other than a hospital or a physician's office that is not used primarily for the performance of abortions.
- (3) "Anesthesiologist" means a person currently licensed to practice medicine or osteopathy pursuant to Chapter 458 or 459, Florida Statutes, and certified by the American Board of Anesthesiology.
- (3) "~~Consultant~~" means ~~an individual who provides professional services either upon request or on the basis of a prearranged schedule, usually on a contract basis, who is neither a member of the employed staff of the facility, nor whose services are provided within the terms of an affiliation agreement.~~



(4) "Advanced Registered Nurse Practitioner, (ARNP)" means a person currently licensed pursuant to Chapter 464, Florida Statutes.

(5) (4) "Agency" "AHCA" means the Agency for Health Care Administration.

(6) "Certified Registered Nurse Anesthetist, (CRNA)" means a person currently licensed pursuant to Chapter 464, Florida Statutes, and certified by the Council on Certification of Nurse Anesthetists.

(7) (12) "Clinical staff" means the individuals employed full or part time by an abortion clinic who are licensed or certified to provide care prior to, during, or after an abortion.

(8) "Department" means the Department of Health.

(9) (5) "F.A.C." means the Florida Administrative Code.

(10) (6) "Facility" means those objects, including physical plant, equipment, and supplies necessary for providing required services.

(11) (7) "Hospital" means a facility licensed under Chapter 395, F.S.

(12) (8) "License" means the certificate issued by the agency for the operation of the facility. This document constitutes the authority to receive patients and to perform the services included within the scope of this rule and as specified on the license.

(13) (9) "Licensed" means that person or facility to which the term is applied has a current or valid license, certificate or registration issued by the State of Florida to follow his profession or vocation within the State of Florida, and when applied to a health care facility means that the facility has a current license issued by the agency AHCA.

(14) (10) "Licensee" means the person who has been granted a license to operate an abortion clinic and who has ultimate authority and responsibility for the operation, management, control, conduct, and functioning of the abortion clinic.

(15) (11) "Licensure" means the process of obtaining official or legal permission to operate an abortion clinic.

(16) "Licensed Practical Nurse, (L.P.N.)" means a person currently licensed as an L.P.N. pursuant to Chapter 464, Florida Statutes.

(17) "Medical Director" means a physician licensed under Chapter 458 or Chapter 459, F.S., and who has admitting privileges at a licensed hospital in this state or has a transfer agreement with a licensed hospital within reasonable proximity of the abortion clinic.

(18) (13) "Patient" means any woman receiving services in an abortion clinic.

(19) (14) "Person" means any individual, firm, partnership, corporation, or association.

(20) "Physician Assistant, (P.A.)" means a person currently licensed as a P.A. pursuant to Chapter 458 or 459, Florida Statutes.

(21) (15) "Physician" means a person ~~physician~~ currently licensed to practice medicine or osteopathy pursuant to Chapter 458 or 459, F.S. under Chapter 458 or Chapter 459, F.S., or a physician practicing medicine or osteopathy in the employment of the United States or this state.

(22) (16) "Premises" means those buildings, beds, and facilities of the clinic and all other buildings, beds, and facilities for the performance of abortions located in such reasonable proximity to the main address of the licensee and appear to the public to be under the domain and the control of the licensee.

(23) "Reasonable proximity" means a distance not to exceed thirty (30) minutes transport time by emergency vehicle.

(24) "Registered Professional Nurse, (R.N.)" means a person currently licensed as a R.N. pursuant to Chapter 464, Florida Statutes.

(25) "Trimester" means a 12-week period of pregnancy.

- (a) First Trimester. The first 12 weeks of pregnancy (the first 14 completed weeks from the last normal menstrual period).
- (b) Second Trimester. That portion of a pregnancy following the 12<sup>th</sup> week and extending through the 24<sup>th</sup> week of gestation.
- (c) Third Trimester. That portion of pregnancy beginning with the 25<sup>th</sup> week of gestation.

(26) "Volunteer" means a person who is not employed by the facility who interacts with patients on behalf of the abortion clinic.

*Specific Authority 390.012 F.S. Law Implemented 390.011, 390.012, 390.013 FS.*

*History--New*

*6-13-90, Amended 4-17-91, Formerly 10D-72.019, Amended 8-24-94, \_\_\_\_\_.*

**59A-9.020 Licensure Procedures.**

(1) All persons ~~planning~~ ~~contemplating~~ 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, Office of Health Facility Regulation, Tallahassee, Florida, on Agency Form 3130-1000-revised July, 2005 ~~MAR-94~~, "Abortion Clinic Licensure Application", hereby incorporated by reference, which can be obtained from the Agency for Health Care Administration, Hospital and Outpatient Services Unit, Mail Stop 31, 2727 Mahan Drive, Office of Health Facility Regulation, Tallahassee, Florida, 32308 or on the agency website at:

[http://ahca.myflorida.com/MCHO/Health\\_Facility\\_Regulation/Hospital\\_Outpatient/abort](http://ahca.myflorida.com/MCHO/Health_Facility_Regulation/Hospital_Outpatient/abort)

ion.shtml, and must shall receive a license prior to the acceptance of patients for care and treatment. The application shall be made under oath and shall contain such information as the agency AHCA reasonably requires, which may include evidence of the applicant's ability to comply with applicable laws and rules.

(2) A license fee of \$250 shall accompany the application for a license or a license renewal. The license fee shall be made payable to the agency and is not refundable.

(3) Each license shall be valid only for the persons to whom it is issued and shall not be subject to sale, assignment, or other transfer, voluntary or involuntary, nor shall a license be valid for any premises other than for which it was originally issued.

(4) A current license shall be posted in a conspicuous place within on the licensed premises where it can be viewed by patients.

(5) A license, unless sooner suspended or revoked, shall automatically expire one year from the date of issuance, and shall be renewable annually upon application for renewal and payment of the fee prescribed by these rules, provided that the applicant and abortion clinic meet the requirements established under Chapter 390, F.S., and Chapter 59A-9, F.A.C. Application for renewal of a license shall be made not less than 60 days prior to expiration of a license on agency Form 3130-1000-revised July 2005 ~~MAR 94~~, available from provided by the Agency for Health Care Administration, Hospital and Outpatient Services Unit, Mail Stop 31, 2727 Mahan Drive, AHCA Office of Health Facility Regulation, Tallahassee, Florida 32308. The application is also available on-line at the agency website at:  
<http://ahca.myflorida.com/MCHQ/Health Facility Regulation/Hospital Outpatient/abortion.shtml>.

(6) Where the agency finds that there has been a failure to comply with the requirements established under this part or in rules promulgated hereunder, the agency is authorized to deny, modify, suspend, or revoke a license.

*Specific Authority 390.012, F.S. Law Implemented 20.42(2)(a), 390.011, 390.012, 390.014, 390.015, 390.016, 390.017, 390.018, 390.019, 390.021 FS. History—New 6-13-90, Amended 4-17-91, 10-9-91, Formerly 10D-72.020, Amended 8-24-94, \_\_\_\_\_.*

**59A-9.021 Investigations and License and Validation Inspections.**

(1) The agency AHCA has the right to enter an abortion clinic to make or cause to be made such inspections and investigations as are necessary to:

(a) Assure compliance with the licensure requirements; and standards as specified in statute and rule;

(b) Respond to complaints; and

(c) Protect the public health and safety.

(2) The agency shall conduct an annual unannounced licensure inspection of all abortion clinics facilities.

(3) The fee for the renewal license shall be \$250.

(4) Representatives of the agency shall have the right to enter upon the premises of any facility licensed or applying for license, pursuant to this Chapter, at any reasonable time in order to determine the state of compliance with the provisions of Chapter 390, F.S., and these rules, providing that such entry and inspection shall be made with the least possible disruption to clinic activities and in a manner considerate of the privacy and

confidentiality of any patient who is present therein. All inspections shall be unannounced.

*Specific Authority 390.012 F.S. Law Implemented 381.0012, 382, 390.011, 390.012, 390.014, 390.019 FS. History—New 6-13-90, Amended 4-17-91, 10-9-91. Formerly 10D-72.021, Amended \_\_\_\_\_.*

**59A-9.022 Physical Plant Requirements for Abortion Clinics When Providing Second Trimester Abortions.**

The following are minimum standards of construction and specified minimum essential physical plant requirements which must be met when providing second trimester abortions. These requirements shall apply to all new abortion clinic construction and shall apply to any abortion clinics receiving an initial license after the effective date of these rules when the abortion clinic provides second trimester abortions. Any abortion clinic which provides second trimester abortions and is in operation at the time of adoption of this rule shall be given one year within which to comply with the physical plant requirements.

- (1) Consultation room(s) with adequate private space specifically designated for interviewing, counseling, and medical evaluations;
- (2) Dressing rooms designated for staff and patients;
- (3) Handwashing station(s) equipped with a mixing valve and wrist blades and located in each patient exam/procedure room or area;
- (4) Private procedure room(s) with adequate light and ventilation for abortion procedures;

- (5) Post procedure recovery room(s) equipped to meet the patient's needs;
- (6) Emergency exits wide enough to accommodate a standard stretcher or gurney;
- (7) Cleaning and sterilizing area(s) adequate for the cleaning and sterilizing of instruments;
- (8) Adequate and secure storage area(s) for the storage of medical records and necessary equipment and supplies; and
- (9) If not otherwise required by the Florida Building Code, at least one general use toilet room equipped with a hand washing station.

Specific Authority: 390.012(1), F.S. Law Implemented 390.012(3)(a), 390.013 F.S..

History-New \_\_\_\_\_.

**59A-9.0225 Clinic Supplies and Equipment Standards for Second Trimester**

**Abortions.**

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

(3) Anesthesia.

(a) The clinic shall have anesthesia equipment maintained in proper working order for the appropriate administering of general and local anesthesia, analgesia, and sedation if ordered by the physician.

(b) All reusable anesthesia equipment in direct contact with the patient shall be cleaned or sterilized as appropriate after each use and such cleaning and sterilization shall be documented.

(4) Resuscitative Medications Required.



The clinic shall have a crash cart at the location the anesthetizing is being carried out.

The crash cart must include, at a minimum, those emergency medications to support the procedures performed as determined by the medical director.

(5) Sterilization Equipment.

Sterilizing equipment of appropriate type shall be available and of adequate capacity to properly sterilize instruments and materials. The sterilizing equipment shall have approved control and safety features.

(6) Ultrasound equipment shall be located in the clinic.

(7) Equipment Maintenance.

(a) When patient monitoring equipment is utilized, a written preventive maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with manufacturer's specifications at periodic intervals, not less than annually, to insure proper operation, and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper calibration before returning it to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance.

(b) All anesthesia and surgical equipment shall have a written preventive maintenance program developed and implemented. Equipment shall be checked and tested in accordance with the manufacturer's specifications at designated intervals, not less than annually, to ensure proper operation and a state of good repair.

(c) All surgical instruments shall have a written preventive maintenance program developed and implemented. Surgical instruments shall be cleaned and checked for function after use to ensure proper operation and a state of good repair.

Specific Authority: 390.012(1), F.S. Law Implemented 390.012(3)(b), 390.013F.S.

History \_\_\_\_\_.

**59A-9.023 Clinic Personnel ~~Clinic Staff and Consultants~~**

Abortions shall be performed only by a licensed physician. Each abortion clinic providing second trimester abortions shall have a staff that is adequately trained and capable of providing appropriate service and supervision to the patients. The clinic will have a position description for each position delineating duties and responsibilities and maintain personnel records for all employees performing or monitoring patients receiving a second trimester abortion. Any abortion clinic which is in operation at the time of adoption of this rule and performing second trimester abortions shall be given six months within which to comply with these clinical staff requirements as follows:

(1) Physicians.

The clinic shall designate a licensed physician to serve as a medical director.

(2) Nursing Personnel.

Nursing personnel in the clinic shall be governed by written policies and procedures relating to patient care, establishment of standards for nursing care and mechanisms for evaluating such care, and nursing services.

(3) Allied health professionals, working under appropriate direction and supervision,

may be employed to work only within areas where their competency has been established.

(4) Orientation. Each facility shall have and execute a written orientation program to

familiarize each new staff member, including volunteers, with the facility and its policies

and procedures, to include, at a minimum, fire safety and other safety measures, medical emergencies, and infection control.

(5) In-service Training. In-service training programs shall be planned and provided for all employees including full time, part time and contract employees, at the beginning of employment and at least annually thereafter and will also apply to all volunteers to insure and maintain their understanding of their duties and responsibilities. Records shall be maintained to reflect program content and individual attendance. The following training shall be provided at least annually, and for surgical assistants and volunteers, must include training in counseling, patient advocacy and specific responsibilities associated with the services they provide:

(a) Infection control, to include at a minimum, universal precautions against blood-borne diseases, general sanitation, personal hygiene such as hand washing, use of masks and gloves, and instruction to staff if there is a likelihood of transmitting a disease to patients or other staff members.

(b) Fire protection, to include evacuating patients, proper use of fire extinguishers, and procedures for reporting fires:

(c) Confidentiality of patient information and records, and protecting patient rights:

(d) Licensing regulations; and

(e) Incident reporting.

*Specific Authority: 390.012, F.S. Law Implemented 381.0012, 382, 390.011, 390.012,*

*390.013 F.S. History—New 6-13-90, Amended 4-17-91, Formerly 10D-72.023,*

*Amended \_\_\_\_\_.*

**59A-9.024 Clinic Policies and Procedures for Second Trimester Abortions.**

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.

Any abortion clinic which is in operation at the time of adoption of this rule and providing second trimester abortions shall be given six months within which to comply with these clinic policies and procedure requirements which 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:

19. Volunteers: and

20. Visitors.

Specific Authority: 390.012(1), F.S. Law Implemented 390.012(3)(c), 390.013F.S.

History-New \_\_\_\_\_.

**59A-9.025 Medical Screening and Evaluation of Patients Receiving Second**

**Trimester Abortions.**

(1) Each abortion clinic that provides second trimester abortions shall formulate and adhere to written patient care policies and procedures designed to ensure professional and safe care for patients undergoing second trimester abortions and shall maintain a medical record for each such patient that records history, care and services. Any abortion clinic that performs second trimester abortions which is in operation at the time of adoption of this rule shall be given six months within which to comply with these patient care policies and procedures for patients undergoing second trimester abortions, to include but not limited to the following:

(a) Admission criteria and procedures;

(b) Identification in the medical record of physician(s) and nurse(s) involved in providing the services offered for patients undergoing second trimester abortions;

(c) Specific details regarding the pre-operative procedures performed, to include:

1. History and physical examination, to include verification of pregnancy, estimation of gestational age, identification of any preexisting conditions or complications; including allergies to medications, antiseptic solutions, or latex; and a complete obstetric and gynecological history.
2. Special examinations, lab procedures, and/or consultations required, to include ultrasonography to confirm gestational age and a physical examination including a bimanual examination estimating uterine size and palpation of the adnexa. The physician shall keep original prints of each ultrasound examination of a patient in the patient's medical history file. For an abortion in which an ultrasound examination is not performed before the abortion procedure, urine or blood tests for pregnancy shall be performed before the abortion procedure.

(2) 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, Florida Statutes.

- (b) All laboratory services provided on-site shall be performed in compliance with state of Florida clinical laboratory licensure and federal CLIA provisions.

(3) 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.
- (4) Rh factor. Rh testing for Rh negative patients shall be conducted, unless reliable written documentation of blood type is available.
- (5) All laboratory test reports shall be placed in the patient's medical record.
- (6) All laboratory test and storage areas, records and reports shall be available for inspection by the agency.
- (7) If a person who is not a physician performs an ultrasound examination, that person shall have 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.
- (8) A test for anemia shall be performed.

Specific Authority: 390.012(1), F.S. Law Implemented 390.012(3)(d), 390.013F.S.

History-New \_\_\_\_\_.

59A-9.026 Second Trimester Abortion Procedure .

Any abortion clinic which is providing second trimester abortions must be in compliance with the following standards relative to second trimester abortion procedures. Any

abortion clinic in operation at the time of adoption of this rule, when performing second trimester abortions, shall be given six months within which to comply.

(1) A physician, registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant shall be available to all patients throughout the abortion procedure.

(2) The abortion procedure will be performed in accordance with obstetric standards and in keeping with established standards of care regarding the estimation of gestational age of the fetus.

(3) Anesthesia service shall be organized under written policies and procedures relating to anesthesia staff privileges, the administration of anesthesia, and the maintenance of strict safety controls.

(4) Prior to the administration of anesthesia, patients shall have a history and physical examination by the individual administering anesthesia, including laboratory analysis when indicated.

(5) Appropriate precautions, such as the establishment of intravenous access at least for patients undergoing post-first trimester abortions.

(6) Appropriate monitoring of the patient's vital signs by professionals licensed and qualified to assess the patient's condition will occur throughout the abortion procedure and during the recovery period until the patient's condition as specified by the type of abortion procedure performed, is deemed to be stable in the recovery room.

Specific Authority: 390.012(1), F.S. Law Implemented 390.012(3)(e), 390.013 F.S.

History-New \_\_\_\_\_.



**59A-9.027 Recovery Room Standards for Second Trimester Abortions.**

Each abortion clinic which is providing second trimester abortions shall comply with the following recovery room standards when providing second trimester abortions. Any abortion clinic providing second trimester abortions and in operation at the time of adoption of this rule shall be given one year within which to comply with these standards.

(1) Following the procedure, post procedure recovery rooms will be supervised and staffed to meet the patient's needs. A physician or physician assistant, a licensed registered nurse, a licensed practical nurse or an advanced registered nurse practitioner who is trained in the management of the recovery area shall be available to monitor the patient in the recovery room until the patient is discharged. The individual must be certified in basic cardiopulmonary resuscitation. A patient in the post-operative or recovery room shall be observed for as long as the patient's condition warrants.

(2) The clinic shall arrange hospitalization if any complication beyond the medical capability of the staff occurs or is suspected. The clinic shall ensure that all appropriate equipment and services are readily accessible to provide appropriate emergency resuscitative and life support procedures pending the transfer of the patient or a viable fetus to the hospital. A physician shall sign the discharge order and be readily accessible and available until the last patient is discharged to facilitate the transfer of emergency cases if hospitalization of the patient or viable fetus is necessary. The clinic medical records documenting care provided shall accompany the patient. These records will include the contact information for the physician who performed the procedure at the clinic.

(3) A physician shall discuss Rho (D) immune globulin with each patient for whom it is indicated and will ensure that it is offered to the patient in the immediate postoperative period or that it will be available to the patient within 72 hours following completion of the abortion procedure. If the patient refuses the Rho (D) immune globulin, refusal Form 3130-1002, January 2006, "Refusal to Permit Administration of Rh(D) Immunoglobulin", herein incorporated by reference, shall be signed by the patient and a witness, and shall be included in the patient's medical record. The form can be obtained by written request from the Agency for Health Care Administration, Hospital and Outpatient Services Unit, Mail Stop 31, 2727 Mahan Drive, Tallahassee, Florida, 32308, or from the agency website at:

[http://ahca.myflorida.com/MCHO/Health\\_Facility\\_Regulation/Hospital\\_Outpatient/abortion.shtml](http://ahca.myflorida.com/MCHO/Health_Facility_Regulation/Hospital_Outpatient/abortion.shtml).

(4) Written instructions with regard to post abortion coitus, signs of possible medical complications, and general aftercare shall be given to each patient. Each patient shall have specific written instructions regarding access to medical care for complications, including a telephone number to call for medical emergencies. The physician will ensure that either a registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant from the abortion clinic makes a good faith effort to contact the patient by telephone, with the patient's consent, within 24 hours after surgery to assess the patient's recovery. A contact for post-operative care from the facility shall be available to the patient on a 24-hour basis.

(5) Facility procedures must specify the minimum length of time for recovery as warranted by the procedure type and gestation period.

Specific Authority: 390.012(1), F.S. Law Implemented 390.012(3)(f), 390.013 F.S.

History--New

**59A-9.028 Post Procedure Follow-up Care for Patients Receiving Second Trimester Abortions.**

Each abortion clinic which is providing second trimester abortions shall comply with the following post procedure follow-up care requirements when providing a second trimester abortion. Any abortion clinic operating at the time of adoption of this rule shall be given six months within which to comply.

(1) The clinic shall offer a post abortion medical visit that includes a medical examination and a review of the results of all laboratory tests.

(2) A urine pregnancy test will be obtained at the time of the follow-up visit to rule out continuing pregnancy. If a continuing pregnancy is suspected, the patient shall be evaluated and a physician who performs abortions shall be consulted.

(3) The clinic shall provide for the education of the patient in post-procedure care, including specific instructions in case of emergency.

Specific Authority: 390.012(1), F.S. Law Implemented 390.012(3)(g), 390.013 F.S.

History--New

**59A-9.029 Abortion Clinic Incident Reporting for Second Trimester Abortions.**

This section shall apply to incidents involving patients receiving second trimester abortions in any abortion clinic providing second trimester abortions. Those abortion clinics providing second trimester abortions which are in operation at the time of

adoption of this rule shall be given six months within which to comply with the following clinic incident reporting requirements.

(1) At a minimum an abortion clinic shall record each incident that results in serious injury to a patient as defined in s. 390.012(3)(h)1, F.S. or a viable fetus at an abortion clinic and shall report an incident in writing to the agency within 10 days after the incident occurs.

(2) If a patient death occurs the abortion clinic shall report the death to the department and the appropriate regulatory board not later than the next workday. The report to the department shall be filed as required by Rule 64V-1.0061, F.A.C.

Specific Authority: 390.012(1), F.S. Law Implemented 390.012(3)(h), 390.013 F.S.

History-New \_\_\_\_\_

#### **59A-9.030 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, 390, F.S., and ~~64E-16~~ ~~10D-104~~, F.A.C.

Specific Authority 390.012 FS. Law Implemented 381.0012, 382, 390.011, 390.012 F.S.

History-New 6-13-90, Amended 4-17-91, Formerly 10D-72.030, Amended \_\_\_\_\_.

#### **59A-9.031 Clinical Records.**

(1) A permanent individual clinical record shall be kept on each clinic patient.

(a) Clinical records shall be complete, accurately documented, and systematically organized to facilitate storage and retrieval.

(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.

(2) Clinical records shall be kept on file for a minimum of five years from the date of the last entry.

*Specific Authority 390.012 FS. Law Implemented 381.0012, 382, 390.011, 390.012,  
390.013 FS. History--New 6-13-90, Amended 4-17-91, Formerly 10D-72.031,  
Amended \_\_\_\_\_.*

#### **59A-9.034 Reports.**

Pursuant to Chapters 382 and 390, F.S., an abortion clinic must submit a report each month to the Office of Vital Statistics of the Department of Health and Rehabilitative Services, regardless of the number of terminations of pregnancy. Monthly reports must be received by the department within 30 days following the preceding month using DOH HRS Form 1578, May 2004 May-94, "Monthly Report of Induced Terminations of Pregnancy", hereby incorporated by reference, and which can be obtained by written request from the Department of Health and Rehabilitative Services, Office of Vital Statistics, Public Health Statistics, P.O. Box 210, Jacksonville, Florida 32231-0042, or by telephone request at (904) 359-6900, extension 1049.

*Specific Authority 390.012 FS. Law Implemented 20.42(2)(a), 382.002, 390.002,  
390.011, 390.012 FS. History--New 6-13-90, Formerly 10D-72.034,*

*Amended 8-24-94.* \_\_\_\_\_

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CHIEF ADMINISTRATIVE  
PROCEDURES COMMITTEE



**STATE OF FLORIDA**  
**Department of Health**

**MONTHLY REPORT OF INDUCED TERMINATIONS OF PREGNANCY**

THIS REPORT IS FOR THE MONTH AND YEAR OF: \_\_\_\_\_

1. FACILITY NAME		2. FACILITY ADDRESS (Street Address):			
3. CITY OF FACILITY:	4. COUNTY:	5. ZIP CODE:	6. TELEPHONE NUMBER AND AREA CODE:		
7. DIRECTOR, PHYSICIAN OR AUTHORIZED REPRESENTATIVE:		8. TITLE			
9. SIGNATURE		10. DATE SIGNED			

<input type="checkbox"/> PERSONAL CHOICE				
<input type="checkbox"/> PHYSICAL CONDITION				
<input type="checkbox"/> MENTAL CONDITION				
<input type="checkbox"/> ABNORMAL FETUS				
<input type="checkbox"/> OTHER (Specify):				

PLEASE SEND THIS REPORT TO: **DEPARTMENT OF HEALTH**  
**OFFICE OF VITAL STATISTICS**  
**PUBLIC HEALTH STATISTICS**  
**P.O. Box 210**  
**JACKSONVILLE, FL 32231-0042**

FLORIDA LAW REQUIRES THE DIRECTOR OF ANY MEDICAL FACILITY IN WHICH ANY PREGNANCY IS TERMINATED, OR PHYSICIAN PERFORMING THE PROCEDURE, TO SUBMIT A MONTHLY REPORT TO THE DEPARTMENT OF HEALTH, OFFICE OF VITAL STATISTICS, FOR RECEIPT WITHIN 30 DAYS FOLLOWING THE PRECEDING MONTH. ANY PERSON REQUIRED TO FILE A REPORT WHO WILLFULLY FAILS TO FILE SUCH, MAY BE SUBJECT TO A \$200 FINE FOR EACH VIOLATION (SECTION 390.002(1) AND (4)), FLORIDA STATUTES, AND CHAPTER 59-A-9.034, (FLORIDA ADMINISTRATIVE CODE).

OH Form 1570, May 04, (Replaces Nov 89, which may not be used)

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 PROCEDURE'S COMMITTEE

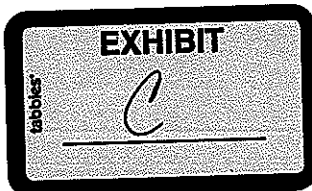
ATTACHMENT 2

**59A-9.019 Definitions.**

The following definitions shall apply specifically to abortion clinics.

- (1) "Anesthesiologist" means a person currently licensed to practice medicine or osteopathy pursuant to Chapters 458 or 459, F.S., and certified by the American Board of Anesthesiology.
- (2) "Certified Registered Nurse Anesthetist, (CRNA)" means a person currently licensed pursuant to Chapter 464, F.S., and certified by the Council on Certification of Nurse Anesthetists.
- (3) "Clinical staff" means the individuals employed full or part time by an abortion clinic who are licensed or certified to provide care prior to, during, or after an abortion.
- (4) "F.A.C." means the Florida Administrative Code.
- (5) "Facility" means those objects, including physical plant, equipment, and supplies necessary for providing required services.
- (6) "Licensed" means that person or facility to which the term is applied has a current or valid license, certificate or registration issued by the State of Florida to follow his profession or vocation within the State of Florida, and when applied to a health care facility means that the facility has a current license issued by the agency.
- (7) "Licensure" means the process of obtaining official or legal permission to operate an abortion clinic.
- (8) "Medical Director" means a physician licensed under Chapters 458 or 459, F.S., and who has admitting privileges at a licensed hospital in this state or has a transfer agreement with a licensed hospital within reasonable proximity of the abortion clinic.
- (9) "Patient" means any woman receiving services in an abortion clinic.
- (10) "Person" means any individual, firm, partnership, corporation, or association.
- (11) "Premises" means those buildings, beds, and facilities of the clinic and all other buildings, beds, and facilities for the performance of abortions located in such reasonable proximity to the main address of the licensee and appear to the public to be under the domain and the control of the licensee.
- (12) "Reasonable proximity" means a distance not to exceed thirty (30) minutes transport time by emergency vehicle.
- (13) "Registered Professional Nurse, (R.N.)" means a person currently licensed as a R.N. pursuant to Chapter 464, F.S.
- (14) "Trimester" means a 12-week period of pregnancy.
  - (a) First Trimester. The first 12 weeks of pregnancy (the first 14 completed weeks from the last normal menstrual period).
  - (b) Second Trimester. That portion of a pregnancy following the 12th week and extending through the 24th week of gestation.
  - (c) Third Trimester. That portion of pregnancy beginning with the 25th week of gestation.
- (15) "Volunteer" means a person who is not employed by the facility who interacts with patients on behalf of the abortion clinic.

*Rulemaking Authority 390.012 FS. Law Implemented 390.011, 390.012 FS. History--New 6-13-90, Amended 4-17-91, Formerly 10D-72.019, Amended 8-24-94, 9-25-06, 1-6-15.*







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.

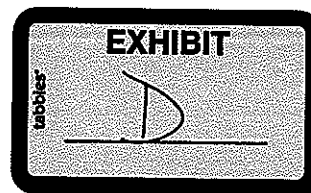
Under Florida law, it is unlawful for any person or entity to: own, operate, or maintain an unlicensed provider; or perform any services that require Agency licensure without proper licensure; or offer or advertise services that require Agency licensure to the public without first obtaining a valid license 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,

Patricia Reid Cauffman  
Field Office Manager



2727 Mahan Drive • Mail Stop #  
Tallahassee, FL 32308  
AHCA.MyFlorida.com



Facebook.com/AHCAFlorida  
Youtube.com/AHCAFlorida  
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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>
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 050	Continued From Page 1  Findings include:  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.  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).  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.  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	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>
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 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>
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	
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".

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

JS/cs

2727 Mahan Drive • Mail Stop #46  
Tallahassee, FL 32308  
AHCA.MyFlorida.com



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SlideShare.net/AHCAFlorida

Agency for Health Care Administration

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  AC13960081	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  08/05/2015
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NAME OF PROVIDER OR SUPPLIER  
**PLANNED PARENTHOOD OF SW & CENTRAL FL-FT #**

STREET ADDRESS, CITY, STATE, ZIP CODE  
**8595 COLLEGE PARKWAY SUITE 250  
FORT MYERS, FL 33919**

(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	<p><b>INITIAL COMMENTS</b></p> <p>An unannounced monitoring visit was conducted on 7/31/2015 at the facility. Additional information was received on 8/5/2015. The following deficient practice was found.</p>	A 000		
A 050	<p><b>Licensure Procedures</b></p> <p>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.</p> <p>Chapter 59A-9.020(1)</p> <p>A current license shall be posted in a conspicuous place within the licensed premises where it can be viewed by patients.</p> <p>Chapter 59A-9.020(4), F.A.C</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview and record review, the clinic failed to apply for and receive a license prior to the acceptance of 2 (#4, #5) of 5 sampled patients for care and treatment of second trimester procedures. Florida Administrative Code 59A-9.019(14) definitions specific to abortion clinics include "(b) Second Trimester. That portion of a pregnancy following</p>	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:  AC13980081	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  08/05/2015
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NAME OF PROVIDER OR SUPPLIER  PLANNED PARENTHOOD OF SW & CENTRAL FL-FT #	STREET ADDRESS, CITY, STATE, ZIP CODE 8595 COLLEGE PARKWAY SUITE 250 FORT MYERS, FL 33919
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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
A 050	<p>Continued From page 1</p> <p>the 12th week and extending through the 24th week of gestation ..."</p> <p>Findings include:</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> <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		
CZ828	408.813(3) FS Administrative Fines; Violations  (3) The agency may impose an administrative	CZ828		



Agency for Health Care Administration

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  AC13960081	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  08/05/2015
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NAME OF PROVIDER OR SUPPLIER  
PLANNED PARENTHOOD OF SW & CENTRAL FL-FT #

STREET ADDRESS, CITY, STATE, ZIP CODE  
8595 COLLEGE PARKWAY SUITE 250  
FORT MYERS, FL 33919

(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
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> <ul style="list-style-type: none"> <li>(a) Violating any term or condition of a license.</li> <li>(b) Violating any provision of this part, authorizing statutes, or applicable rules.</li> <li>(c) Exceeding licensed capacity.</li> <li>(d) Providing services beyond the scope of the license.</li> <li>(e) Violating a moratorium imposed pursuant to s. 408.814.</li> </ul> <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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  AC13960081	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  08/05/2015
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NAME OF PROVIDER OR SUPPLIER  PLANNED PARENTHOOD OF SW & CENTRAL FL-FT #	STREET ADDRESS, CITY, STATE, ZIP CODE 8595 COLLEGE PARKWAY SUITE 250 FORT MYERS, FL 33919
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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
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.

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".

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

JS/cs

2727 Mahan Drive • Mail Stop #46  
Tallahassee, FL 32308  
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SlideShare.net/AHCAFlorida

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 000	<b>INITIAL COMMENTS</b>  An unannounced monitoring visit was conducted on 7/31/2015 at the facility. Additional information was gathered on 8/5/15. The following deficient practice was found.	A 000			
A 050	<b>Licensure Procedures</b>  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 clinic failed to apply for and receive a license from the Agency prior to the acceptance of 3 (#1, #2, #3) of 3 sampled patients for care and treatment of second trimester procedures. Florida Administrative Code 59A-9.019(14) definitions specific to abortion clinics include "(b) Second Trimester. That portion of a pregnancy following the 12th week and extending through the 24th	A 050			

AHCA Form 3020-0001

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

TITLE

(X6) DATE

Agency for Health Care Administration

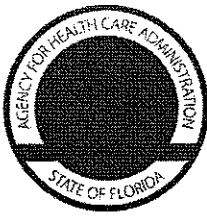
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>AC13960120</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>08/05/2015</b>
NAME OF PROVIDER OR SUPPLIER <b>PLANNED PARENTHOOD OF COLLIER COUNTY, INC.</b>		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

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
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. (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.</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>
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
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

**FOR IMMEDIATE RELEASE**  
August 5, 2015

**Contact:** AHCA Communications Office  
[AHCACommunications@ahca.myflorida.com](mailto:AHCACommunications@ahca.myflorida.com),  
850-412-3623

**Planned Parenthood Inspections Find Deficiencies at Clinics**

*- Agency findings include issues with the record keeping of fetal remains at one clinic and unlicensed procedures being performed at three clinics -*

**Tallahassee, FL** – Our investigations last week into Planned Parenthood clinics found three facilities performing procedures beyond their licensing authority, as well as one facility not keeping proper logs relating to fetal remains.

We will take immediate actions against these three facilities for performing second trimester abortions without a proper license. These facilities have been notified to immediately cease performing second trimester abortions. The Agency may take additional actions against these facilities including administrative sanctions.

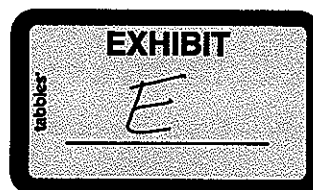
These three clinics are only licensed to perform first trimester abortions. The law requires clinics performing second trimester abortions meet additional requirements.

Licenses are in place to protect the patient from unscrupulous operators and the State of Florida will ensure every facility is held accountable for its actions.

Please find attached reports for the clinics cited for deficiencies.

*The Agency for Health Care Administration is committed to better health care for all Floridians. The Agency administers Florida's Medicaid program, licenses and regulates more than 45,000 health care facilities and 34 health maintenance organizations, and publishes health care data and statistics at [www.FloridaHealthFinder.gov](http://www.FloridaHealthFinder.gov). Additional information about Agency initiatives is available via Facebook (AHCAFlorida), Twitter (@AHCA\_FL) and YouTube (/AHCAFlorida).*

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2727 Mahan Drive • Mail Stop #2  
Tallahassee, FL 32308  
[AHCA.MyFlorida.com](http://AHCA.MyFlorida.com)



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[Youtube.com/AHCAFlorida](https://www.youtube.com/AHCAFlorida)  
[Twitter.com/AHCA\\_FL](https://twitter.com/AHCA_FL)  
[SlideShare.net/AHCAFlorida](https://www.slideshare.net/AHCAFlorida)