

NOTICE OF INTENT

**Department of Health
Bureau of Health Services Financing**

**Free-Standing Birth Centers
Licensing Standards
(LAC 48:I.Chapter 67)**

The Department of Health, Bureau of Health Services Financing proposes to repeal and replace the provisions of LAC 48:I.Chapter 67 as authorized by R.S. 36:254. This proposed Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

Act 332 of the 2019 Regular Session of the Louisiana Legislature authorized the Department of Health to promulgate Rules relative to the licensing of free-standing birth centers (FSBCs). In compliance with Act 332, the Department of Health, Bureau of Health Services Financing proposes to repeal the existing LAC 48:I.Chapter 67 governing the licensing of hospitals in its entirety as these provisions are incorporated elsewhere in the *Louisiana Administrative Code* and replace it with provisions governing the licensing of FSBCs.

Title 48

**PUBLIC HEALTH-GENERAL
Part I. General Administration
Subpart 3. Licensing and Certification**

Chapter 67. Free-Standing Birth Centers

Subchapter A. General Provisions

§6701. Introduction

A. These regulations contain the minimum licensing standards for free-standing birth centers (FSBCs). Free-standing birth centers are established for the purpose of rendering birthing procedures to its clients outside of a traditional hospital.

B. The care and services to be provided by an FSBC shall include:

1. birth-related procedures;
2. criteria for admission to, continuation in, and transfer out of, the birth center;
3. medications as needed for clinical procedures rendered;
4. services necessary to provide for the physical and emotional well-being of the clients served;
5. established consultation, assessment of emergency conditions, and transfer as needed; and
6. organized administrative structure and support services.

C. Each entity that meets the definition of free-standing birth center shall submit an initial licensing application and the required fee to the department within 90 days of the promulgation of these initial rules, regulations, and licensing standards. If the entity is not licensed within 120 days after

submission of its initial licensing application and fee, the entity shall cease operations until such time as it is licensed as a free-standing birth center by the department.

D. FSBCs that apply for their initial FSBC license or receive plan review approval for initial construction or major renovations, or change their geographic address after the effective date of the promulgation of this Rule, shall be required to comply with all of the provisions herein.

E. Recognized FSBCs in existence on the effective date of the promulgation of this rule, shall be exempt only from the provisions of §6701.D.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services and Financing, LR 47:

§6703. Definitions

Active Labor—contractions resulting in progressive effacement and dilation of the cervix.

Administrator—the person responsible for the on-site, daily implementation and supervision of the overall free-standing birth center's operation commensurate with the authority conferred by the governing body.

Apgar Score—an accepted and convenient method for reporting the status of the newborn infant immediately after birth and the response to resuscitation if it is needed.

Board—the Louisiana State Board of Medical Examiners (LSMBE).

Certified Nurse Midwife (CNM)—an advanced practice registered nurse educated in the disciplines of nursing and midwifery and certified according to a nationally recognized certifying body, such as the American College of Nurse Midwives Certification Council, as approved by the Louisiana State Board of Nursing (LSBN) and who is authorized to manage the nurse midwifery care of newborns and women in the antepartum, intrapartum, postpartum and/or gynecological periods pursuant to LAC 46:XLVII.4503.B.1. et seq.

Cessation of Business—center is non-operational and/or has stopped offering or providing services to the community.

Change of Ownership (CHOW)—the addition, substitution, or removal, whether by sale, transfer, lease gift, or otherwise, of a licensed health care provider subject to this rule by a person, corporation, or other entity, which results in a CHOW or change of controlling interest of assets or other equity interests of the licensed entity may constitute a CHOW of the licensed entity. An example of an action that constitutes a CHOW

includes, but is not limited to, the leasing of the licensed entity.

Client—an individual who is receiving services from a licensed free-standing birth center (FSBC).

Department—the Louisiana Department of Health (LDH) or any of its sections, bureaus, offices or its contracted designee.

Division of Administrative Law (DAL)—the agency authorized to conduct fair hearings and take actions on appeals of departmental decisions as provided for in the Administrative Procedure Act, or its successor.

Employed—performance of a job or task for compensation, such as wages or a salary. An employed person may be one who is contracted or one who is hired for a staff position.

Family—individuals selected by the pregnant woman to be present and/or in attendance during her admission to the free-standing birth center.

Free-Standing Birth Center (FSBC)—a facility, place, center, agency, person, institution, corporation, partnership, unincorporated association, group, or other legal entity which provides free-standing birth center services and at which a person is anticipated to have an uncomplicated vaginal delivery following a low-risk pregnancy. A free-standing birth center does not include a hospital licensed pursuant to R.S. 40:2100 et

seq., nor does it include the place of residence of the person giving birth.

Free-Standing Birth Center Services—peripartum care, including prenatal, labor, delivery, and postpartum, and services for people with low-risk pregnancies provided at free-standing birth centers. This includes any ancillary ambulatory service provided to a person at low risk for pregnancy complications, if such services are within the scope of practice of the individual providing the service.

Governing Body—the individual or group of individuals who are legally responsible for the operation of the FSBC, including management, control, conduct and functioning of the FSBC, also known as the governing authority.

Health Standards Section (HSS)—Department of Health, Office of the Secretary, Health Standards Section.

Intrapartum—the period beginning with active labor to the expulsion of the placenta.

Licensed Midwife—an individual who has completed all the requirements of R.S. 37:3247, 3253, and 3255, has successfully completed the examination process, is certified as a midwife by the North American Registry of Midwives (NARM), is licensed by the board, and is not a licensed physician or a licensed CNM.

Licensed Practitioner—a licensed physician and/or a CNM, or a licensed midwife.

Lochia—the normal discharge from the uterus after childbirth occurring three to ten days after delivery.

Low-Risk Pregnancy—a normal, uncomplicated, singleton pregnancy that has vertex presentation and is at low risk for development of complications during labor and birth, absent of any maternal, fetal or obstetric complications, including active labor less than 16 to 20 hours, as determined from an evaluation and examination conducted by a physician or other practitioner or individual acting within the scope of his or her practice.

Miscarried Child—the fetal remains resulting from a spontaneous fetal death that does not require compulsory registration pursuant to the provisions of R.S. 40:47.

Non-Operational—when the FSBC is not open for business operations on designated days and hours as stated on the licensing application.

Office of the State Fire Marshal (OSFM)—an agency of the Department of Public Safety responsible for architectural and licensing plan review and inspections for life safety codes.

Other Qualified Licensed Professional Practitioner—a CNM, advanced practice registered nurse (ARPN), or licensed physician's assistant (PA).

Perineal Laceration—a tear of the skin and other soft tissue structures which, in women, separate the vagina from the

anus. Perineal tears mainly occur in women as a result of vaginal childbirth and vary in severity.

Physician—an individual licensed to practice medicine in this state who is actively engaged in a clinical obstetrical practice and has hospital privileges in obstetrics in a hospital accredited by the Joint Commission.

Physician Evaluation and Examination—physician evaluation and examination as provided in R.S. 37:3244 to determine whether, at the time of such evaluation and examination, the individual is at low or normal risk of developing complications during pregnancy and childbirth.

Postmature—gestational age of greater than 42 weeks.

Postpartum—the period beginning immediately after childbirth in accordance with current standards of practice.

Practice of Midwifery—holding oneself out to the public as being engaged in the business of attending, assisting, or advising a woman during the various phases of the interconceptional and childbearing periods.

Prenatal Care (Antepartum Care)—occurring or existing before birth. The prenatal period (also known as antenatal care) refers to the regular care recommended for women during pregnancy. Prenatal care is preventative care with the goal of providing regular check-ups that allow licensed health care

practitioners to treat and prevent potential health problems throughout the course of pregnancy.

Preterm—prior to the thirty-seventh week of gestation.

Qualified Personnel—means that the individual is trained and competent in the services which he or she provides and is licensed or certified when required by statute or professional standard.

Scope of Practice—licensed midwives may provide care in hospitals, birth centers, clinics, offices and home birth settings, only to low risk clients determined by physician evaluation and examination to be normal for pregnancy and childbirth, and at low risk for the development of medical complications. Such care includes:

1. prenatal supervision and counseling;
2. preparation for childbirth;
3. supervision and care during labor and delivery

and care of the mother and the newborn in the immediate postpartum period, if progress meets criteria generally accepted as normal as defined by the board; and

4. referral or consultation with a physician when a client's medical condition deviates from normal.

Secretary—the secretary of LDH, or designee.

Standards—policies, procedures, rules, guidelines, and standards of current practice contained in this Part in addition

to those rules and standards promulgated by LDH for the licensing and operation of free-standing birth centers.

Term—gestational age of greater or equal to 37 weeks but less than 42 weeks.

Transfer Agreement—arrangements made with at least one receiving hospital in the community and with a local ambulance service for the timely transport of emergency clients to a licensed hospital that will provide obstetric/newborn acute care should an emergency arise which would necessitate hospital care and services.

Uterine Atony—a loss of tone in the uterine musculature.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254, R.S. 40:2180.21-2180.28, R.S. 37:1270 and R.S. 37:3241-3259.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR:

§6705. General Requirements

A. All FSBCs shall be licensed by LDH. No facility, place, center, agency, person, institution, corporation, partnership, unincorporated association, group, or other legal entity providing free-standing birth center services shall be established or operated unless licensed as a FSBC by the department to perform such services.

B. A license issued to a FSBC shall be valid for one geographic location and issued to the entity or person and premises named in the license application.

C. A license issued pursuant to these regulations shall be valid for 12 months unless revoked or otherwise suspended prior to that date, commencing with the month of issuance.

D. Unless otherwise renewed or stayed in the rules promulgated by the department, a license issued pursuant to this Part shall expire on the last day of the twelfth month after the date of issuance.

E. A license issued pursuant to this Part shall be on a form prescribed by the department.

F. A license issued pursuant to this Part shall not be transferable or assignable.

G. A license issued to a FSBC shall be posted in a conspicuous place on the licensed premises.

H. Each FSBC shall be located within a 20 minutes' transport time from a general acute care hospital providing obstetric services which allows for an emergency cesarean delivery to begin within 30 minutes of the decision by a licensed OB/GYN physician in the receiving facility that a cesarean delivery is necessary.

I. Each FSBC shall have agreements or written policies and procedures with other agencies, institutions, or

individuals, for services to clients including, but not limited to:

1. laboratory and diagnostic services;
2. obstetric consultation services;
3. pediatric consultation services;
4. transport services;
5. obstetric/newborn acute care in hospitals; and
6. pharmaceutical services.

J. Each FSBC shall have an established consultation, collaboration, or referral system, for both emergency and non-emergency circumstances, that fall outside the scope of birth center practice, to meet the needs of a mother or the newborn infant.

K. Each FSBC shall have requirements and protocols for assessing, transferring, and transporting clients to a licensed hospital and arrangements with a local ambulance service for the transport of emergency clients to a licensed hospital.

L. Each FSBC shall have requirements for documentation of adequate prenatal care and for documentation and evidence that the delivery is expected to be low risk, singleton birth, and vertex presentation.

M. Each FSBC shall meet the national standards for birth centers published or established by the American Association of

Birth Centers, as well as requirements for accreditation published by the Commission for Accreditation of Birth Centers.

N. The FSBC staff shall not administer general or epidural anesthesia services.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6707. Licensing

A. The LDH HSS is the only licensing authority for FSBCs in the state of Louisiana.

B. Each FSBC license shall:

1. be issued only to the person or entity named in the license application;

2. be valid only for the FSBC to which it is issued and only for the specific geographic address of that FSBC;

3. be valid for one year from the date of issuance, unless revoked, suspended, modified or terminated prior to that date, or unless a provisional license is issued:

a. a provisional license shall be valid for a period not to exceed six months if the department determines that there is no immediate and serious threat to the health and safety of clients;

4. expire on the last day of the twelfth month after the date of issuance, unless timely renewed by the FSBC;

5. not be subject to sale, assignment, donation, or other transfer, whether voluntary or involuntary; and

6. be posted in a conspicuous place on the licensed premises at all times.

C. The FSBC shall abide by and adhere to any federal, state, and local laws, rules, policies, procedures, manuals, or memorandums applicable to such facilities.

D. A separately licensed FSBC shall not use a name which is the same as the name of another such FSBC licensed by the department as determined by the secretary of state.

E. Each existing entity that meets the definition of FSBC as defined in this Chapter shall submit an initial licensing application and fee to the department within 90 days of the promulgation of the initial rules, regulations, and licensing standards. If the existing entity is not licensed within 120 days after submission of its initial licensing application and fee, the existing entity shall cease operations until such time as it is licensed as a free-standing birth center by the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6709. Initial Licensure Application Process

A. An initial application for licensing as an FSBC shall be obtained from the department. A completed initial license application packet for an FSBC shall be submitted to, and approved by the department, prior to an applicant providing services.

B. The initial licensing application packet shall include:

1. a completed licensure application and the non-refundable licensing fee as established by statute;

2. a copy of the approval letter(s) of the architectural and licensing facility plans from the OSFM and any other office/entity designated by the department to review and approve the center's architectural and licensing plan review;

3. a copy of the on-site inspection report with approval for occupancy by the OSFM, if applicable;

4. a copy of the on-site health inspection report with approval for occupancy from the Office of Public Health (OPH);

5. proof of each insurance coverage as follows:

a. general liability insurance of at least \$300,000 per occurrence;

b. worker's compensation insurance as required by state law;

c. professional liability insurance of at least \$100,000 per occurrence/\$300,000 per annual aggregate, or proof of self-insurance of at least \$100,000, along with proof of enrollment as a qualified health care provider with the Louisiana Patient's Compensation Fund (PCF):

i. if the FSBC is not enrolled in the PCF, professional liability limits shall be \$1,000,000 per occurrence/\$3,000,000 per annual aggregate; and

d. the LDH HSS shall specifically be identified as the certificate holder on any policies and any certificates of insurance issued as proof of insurance by the insurer or producer (agent);

6. proof of a line of credit issued from a federally insured, licensed lending institution in the amount of at least \$100,000;

7. disclosure of ownership and control information;

8. the usual and customary days and hours of operation;

9. an organizational chart and names, including position titles, of key administrative personnel and governing body;

10. fiscal intermediary, if applicable;

11. secretary of state's articles of incorporation;
12. clinical laboratory improvement amendments (CLIA) certificate or CLIA certificate of waiver, if applicable;
13. an 8.5 by 11-inch mapped floor plan; and
14. any other documentation or information required by the department for licensure.

C. If the initial licensing packet is incomplete, the applicant shall be notified of the missing information, and shall have 90 days from receipt of the notification to submit the additional requested information. If the additional requested information is not submitted to the department within 90 days, the application shall be closed. If an initial licensing application is closed, an applicant who is still interested in becoming an FSBC shall be required to submit a new initial licensing application packet with the required fee to start the initial licensing process.

D. Once the initial licensing application packet has been approved by the department, notification of such approval shall be forwarded to the applicant. Within 90 days of receipt of the approval of the application, the applicant shall notify the department that the FSBC is ready and is requesting an initial licensing survey. If an applicant fails to notify the department within 90 days, the initial licensing application shall be closed. After an initial licensing application is closed, an

applicant who is still interested in becoming a licensed FSBC shall be required to submit a new initial licensing packet with the required fee to start the initial licensing process.

E. Applicants shall be compliant with applicable federal, state, departmental or local statutes, laws, ordinances, rules, regulations and fees before the FSBC will be issued an initial license to operate.

F. Fire Protection. All FSBCs required to be licensed by the law shall comply with the rules, established fire protection standards and enforcement policies as promulgated by the OSFM. It shall be the primary responsibility of the OSFM to determine if applicants are complying with those requirements. No license shall be issued to an applicant seeking licensure after the effective date of the promulgation of this rule or license renewed without the applicant furnishing a certificate from the OSFM stating that the applicant is complying with its provisions.

G. Sanitation and Client Safety. All FSBCs required to be licensed by the law shall comply with the Rules, *Sanitary Code* and enforcement policies as promulgated by the Office of Public Health (OPH). It shall be the primary responsibility of the OPH to determine if applicants are complying with those requirements. No initial license shall be issued to an applicant seeking licensure or license renewal after the effective date of

the promulgation of this rule without the applicant furnishing a certificate from the OPH stating that the applicant is complying with its provisions.

H. For those existing facilities that get a conditional certificate from OPH/OSFM, a provisional license may be issued to the applicant if the OPH or the OSFM issues the applicant a conditional certificate.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6711. Initial Licensing Surveys

A. Prior to the initial license being issued, an initial onsite licensing survey shall be conducted to ensure compliance with the licensing laws and standards.

1. The initial licensing survey of an FSBC shall be an announced survey.

2. Follow-up surveys to the initial licensing surveys may be announced or unannounced surveys depending on the outcome of the initial survey.

B. The FSBC shall not provide services to any client until the initial licensing survey has been performed and the FSBC has been determined to be compliant with these licensing regulations and has received written approval from the HSS.

EXCEPTION: For FSBCs in operation at the time of the promulgation of this Rule, the requirement for non-admittance of clients prior to survey does not apply.

C. If the initial licensing survey finds that the FSBC is compliant with all licensing laws, regulations, and other required statutes, laws, ordinances, rules, regulations, and fees, the department shall issue a full license to the center. The license shall be valid until the expiration date shown on the license, unless the license is modified, revoked, suspended or terminated.

D. If the initial licensing survey finds that the FSBC is noncompliant with any licensing laws or regulations, or any other required rules or regulations that present a potential threat to the health, safety, or welfare of the clients, the department shall deny the initial license.

E. In the event that the initial licensing survey finds that the FSBC is noncompliant with any licensing laws or regulations, or any other required rules or regulations, but the department in its sole discretion determines that the noncompliance does not present a threat to the health, safety or welfare of the clients, the department may issue a provisional initial license for a period not to exceed six months. The FSBC shall submit a plan of correction to the department for approval

and shall be required to correct all such noncompliance or deficiencies prior to the expiration of the provisional license.

1. If all such noncompliance or deficiencies are corrected on the follow-up survey, a full license may be issued.

2. If all such noncompliance or deficiencies are not corrected on the follow-up survey, or new deficiencies affecting the health, safety, or welfare of a client are cited, the provisional license shall expire, and the facility shall be required to begin the initial licensing process again by submitting a new initial license application packet and the required licensing fee.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6713. Types of Licenses and Expiration Dates

A. The department shall have the authority to issue the following types of licenses.

1. Full Initial License. The department shall issue a full license to the FSBC when the initial licensing survey finds that the FSBC is compliant with all licensing laws and regulations, and is compliant with all other required statutes, laws, ordinances, rules, regulations, and fees. The license shall be valid until the expiration date shown on the license,

unless the license is modified, revoked, suspended, or terminated.

2. Provisional Initial License. The department may issue a provisional initial license for a period not to exceed six months to a FSBC when the initial licensing survey finds that the FSBC is noncompliant with any licensing laws or regulations or any other required statutes, laws, ordinances, rules, regulations or fees, but the department determines that the noncompliance does not present a threat to the health, safety or welfare of the clients.

3. Full Renewal License. The department may issue a full renewal license to an existing licensed FSBC that is in substantial compliance with all applicable federal, state, departmental, and local statutes, laws, ordinances, rules, regulations, and fees. The license shall be valid until the expiration date shown on the license, unless the license is modified, revoked, suspended, or terminated.

4. Provisional License. The department, in its sole discretion, may issue a provisional license to an existing licensed FSBC for a period not to exceed six months for any of the following reasons.

a. The existing FSBC has more than five deficient practices or deficiencies cited during any one survey.

b. The existing FSBC has more than three substantiated complaints in a 12-month period.

c. The existing FSBC has been issued a deficiency that involved placing a client at risk for serious harm or death.

d. The existing FSBC has failed to correct deficient practices within 60 days of being cited for such deficient practices or at the time of a follow-up survey.

e. The existing FSBC is not in substantial compliance with all applicable federal, state, departmental and local statutes, laws, ordinances, rules, regulations, and fees at the time of renewal of the license.

f. When the department issues a provisional license, the FSBC shall submit a plan of correction to the department for approval and shall be required to correct all such noncompliance or deficiencies prior to the expiration of the provisional license. The department shall conduct a follow-up survey, either on-site or by desk review, of the FSBC prior to the expiration of the provisional license.

g. If the follow-up survey determines that the FSBC has corrected the deficient practices and has maintained compliance during the period of the provisional license, the department may issue a full license for the remainder of the year until the anniversary date of the FSBC license.

h. If the follow-up survey determines that all noncompliance or deficiencies have not been corrected, or if new deficiencies that are a threat to the health, safety, or welfare of a client are cited on the follow-up survey, the provisional license shall expire, and the facility shall be required to begin the initial licensing process again.

i. If the follow-up survey determines that most but not all noncompliance or deficiencies have been corrected, or if new deficiencies that are not a threat to the health, safety, or welfare of a client are cited on the follow-up survey, a one-time extension of the provisional license may be granted at the discretion of the department.

j. The department shall issue written notice to the FSBC of the results of the follow-up survey.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6715. Changes in Licensee Information or Personnel

A. An FSBC license shall be valid only for the person or entity named in the license application and only for the specific geographic address listed on the license application.

B. Any permanent change regarding the entity FSBC's name, "doing business as" name, mailing address, telephone number,

stated days and hours of operation, or any combination thereof, shall be reported in writing to the department within five business days of the change.

1. For any temporary closures of the FSBC greater than 24 hours, other than weekends or holidays, the FSBC shall notify HSS in advance.

2. At any time that the FSBC has an interruption in services or a change in the licensed location due to an emergency, the FSBC shall notify HSS no later than the next stated business day.

C. Any change regarding the FSBC's key administrative personnel shall be reported in writing to the department within 10 days of the change.

1. Key administrative personnel include the:

- a. administrator; and
- b. director of clinical midwifery services.

2. The FSBC's notice to the department shall include the individual's:

- a. name;
- b. address;
- c. hire date; and
- d. qualifications.

D. A CHOW of the FSBC shall be reported in writing to the department within five days of the change.

E. The license of an FSBC is not transferable or assignable and cannot be sold. The new owner shall submit the legal CHOW document, all documents required for a new license and the applicable licensing fee. Once all application requirements are completed and approved by the department, a new license shall be issued to the new owner.

1. An FSBC that is under license revocation, provisional licensure and/or denial of license renewal may not undergo a CHOW.

2. If the CHOW results in a change of geographic address, an on-site physical environment survey by the HSS, an on-site inspection by the OPH and the OSFM shall be required prior to issuance of the new license.

F. If the FSBC changes its name without a change in ownership, the FSBC shall report such change to the department in writing five days prior to the change. The change in the FSBC's name requires a change in the license and payment of the required fee for a name change and reissuance of a license.

G. Any request for a duplicate license shall be accompanied by the applicable required fee.

H. If the FSBC changes the physical address of its geographic location without a change in ownership, the FSBC shall report such change to the department in writing at least six weeks prior to the change. Because the license of an FSBC is

valid only for the geographic location of that FSBC, and is not transferrable or assignable, the FSBC shall submit a new licensing application and the required fees, licensing inspection reports, and licensing plan reviews for the new location.

1. An on-site physical environment survey by the HSS, an on-site inspection by the OPH and the OSFM shall be required prior to the issuance of the new license.

2. The change in the FSBC's physical address results in a new anniversary date and the full licensing fee shall be paid.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6717. Renewal of License

A. The FSBC shall submit a completed license renewal application packet to the department at least 30 days prior to the expiration of the current license. The license renewal application packet shall include the:

1. license renewal application;
2. non-refundable license renewal fee;
3. stated days and hours of operation;
4. current State Fire Marshal report;

5. current OPH inspection report;
6. proof of each insurance coverage as follows:
 - a. general liability insurance of at least \$300,000 per occurrence;
 - b. worker's compensation insurance of at least \$100,000 as required by state law;
 - c. professional liability insurance of at least \$100,000 per occurrence/\$300,000 per annual aggregate, or proof of self-insurance of at least \$100,000, along with proof of enrollment as a qualified health care provider with the PCF:
 - i. if the FSBC is not enrolled in the PCF, professional liability limits shall be \$1,000,000 per occurrence/\$3,000,000 per annual aggregate;
 - d. the LDH HSS shall specifically be identified as the certificate holder on any policies and any certificates of insurance issued as proof of insurance by the insurer or producer (agent);
7. proof of a line of credit issued from a federally insured, licensed lending institution in the amount of at least \$100,000; and
8. any other documentation required by the department, if applicable.

B. The department may perform an on-site survey and inspection upon annual renewal of a license.

C. Failure to submit a completed license renewal application packet prior to the expiration of the current license will result in the voluntary non-renewal of the FSBC license. There are no appeal rights for such surrender or non-renewal of the license, as this is a voluntary action on the part of the FSBC.

D. If an existing licensed FSBC has been issued a notice of license revocation, suspension or termination, and the FSBC's license is due for annual renewal, the department shall deny the license renewal application and shall not issue a renewal license.

1. Subject to the provisions in D.2 of this section, if a timely administrative appeal has been filed by the FSBC regarding the license revocation, suspension, or termination, the administrative appeal shall be suspensive, and the FSBC shall be allowed to continue to operate and provide services until such time as the administrative tribunal or department issues a decision on the license revocation, suspension, or termination.

2. If the secretary of the department determines that the violations of the FSBC pose an imminent or immediate threat to the health, welfare, or safety of a client, the imposition of such action may be immediate and may be enforced during the pendency of the administrative appeal. If the

secretary of the department makes such a determination, the FSBC will be notified in writing.

3. The denial of the license renewal application does not affect in any manner the license revocation, suspension, or termination.

E. The renewal of a license does not in any manner affect any sanction, civil monetary penalty, or other action imposed by the department against the FSBC.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6719. Deemed Status

A. A licensed FSBC may request deemed status once the center becomes accredited by an LDH authorized accreditation organization, or if the applicant has achieved accreditation prior to initial licensure and becomes licensed.

B. The department may approve the deemed status request and accept accreditation in lieu of periodic licensing surveys when the provider provides documentation to the department that shows:

1. the accreditation is current and was obtained through an LDH authorized accreditation organization;

2. all FSBC services provided under the FSBC license are accredited; and

3. the accrediting organization's findings.

C. If deemed status is approved, accreditation will be accepted as evidence of satisfactory compliance with this Chapter in lieu of conducting periodic re-licensure surveys. Accreditation will not replace annual renewal of licensure. The FSBC shall annually apply to renew the provider license and meet licensure requirements.

D. To maintain deemed status, the center shall submit a copy of current accreditation documentation with its annual license renewal application.

E. The department may conduct unannounced complaint investigations on all FSBCs including those with deemed status.

F. The department may rescind deemed status and conduct a licensing survey for the following:

1. a valid complaint is received within the preceding 12 months;
2. the FSBC begins offering additional services;
3. a CHOW occurs;
4. a provisional license has been issued within the preceding 12-month period;
5. deficiencies have been identified within the preceding 12-month period that placed clients at risk for harm;

6. a treatment or service results in death or serious injury; or

7. a change in geographic location occurs.

G. The center shall notify HSS upon change in accreditation status within two business days.

H. The department shall rescind deemed status when the center loses its accreditation.

I. An FSBC approved for deemed status is subject to and shall comply with all provisions of this Chapter, except §6709.F and §6709.G.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6721. Survey Activities

A. The department may conduct periodic licensing surveys and other surveys as deemed necessary to ensure compliance with all laws, rules, and regulations governing FSBCs and to ensure client health, safety, and welfare. These surveys may be conducted on-site or by administrative review and shall be unannounced.

B. The department may require an acceptable plan of correction from the FSBC for any survey where deficiencies have been cited, regardless of whether the department takes other

action against the FSBC for the deficiencies cited in the survey. The acceptable plan of correction shall be submitted for approval to the department within the prescribed timeframe.

C. A follow-up survey may be conducted for any survey where deficiencies have been cited to ensure correction of the deficient practices.

D. The department may issue appropriate sanctions for noncompliance, deficiencies and violations of law, rules, and regulations. Sanctions may include, but are not limited to:

1. civil fines;
2. directed plans of correction;
3. denial of license renewal; and/or
4. license revocation.

E. LDH surveyors and staff shall be:

1. given access to all areas of the FSBC and all relevant files and other documentation as necessary or required to conduct the survey:

- a. for any records or other documentation stored onsite, such shall be provided within one to two hours of surveyor request; and

- b. for any records or other documentation stored off-site, such shall be provided to the surveyor for review no later than 24 hours from the time of the surveyor's request.

2. allowed to interview any facility staff, client or other persons as necessary or required to conduct the survey; and

3. allowed to photocopy any records/files requested by surveyors during the survey process.

F. The department shall conduct complaint surveys in accordance with R.S. 40:2009.13 et seq.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6723. Statement of Deficiencies

A. Any statement of deficiencies issued by the department to an FSBC shall be available for disclosure to the public 30 days after the FSBC submits an acceptable plan of correction to the deficiencies or 90 days after the statement of deficiencies is issued to the FSBC, whichever occurs first.

B. Unless otherwise provided in statute or in these licensing provisions, the FSBC shall have the right to an informal reconsideration of any deficiencies cited as a result of a survey or investigation.

1. Correction of the violation, noncompliance, or deficiency shall not be the basis for the reconsideration.

2. The informal reconsideration of the deficiencies shall be requested in writing within 10 calendar days of receipt of the statement of deficiencies, unless otherwise provided in these standards.

3. The request for informal reconsideration of the deficiencies shall be made to HSS and will be considered timely if received by HSS within 10 calendar days of the FSBC's receipt of the statement of deficiencies.

4. If a timely request for an informal reconsideration is received, the department shall schedule and conduct the informal reconsideration. The FSBC shall be notified in writing of the results of the informal reconsideration.

5. Except as provided for complaint surveys pursuant to R.S. 40:2009.13 et seq., and as provided in these licensing provisions for initial license denials, license revocations, and denial of license renewals, the decision of the informal reconsideration team shall be the final administrative decision regarding the deficiencies.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6725. Denial of Initial License, Revocation of License, Denial of License Renewal

A. The department may deny an application for an initial license or a license renewal, or the department may revoke a license in accordance with the provisions of the Administrative Procedure Act.

B. Denial of an Initial License.

1. The department shall deny an initial license if the initial licensing survey finds that the FSBC is noncompliant with any licensing laws or regulations, or any other required statutes or regulations that present a potential threat to the health, safety or welfare of the clients.

2. The department shall deny an initial license for any of the reasons that a license may also be revoked or denied renewal pursuant to these licensing provisions.

3. If the department denies an initial license, the applicant for an FSBC license shall not render services to clients.

C. Voluntary Non-Renewal of a License. If the FSBC fails to timely renew its license, the license expires on its face and is considered voluntarily surrendered. There are no appeal rights for such surrender or non-renewal of the license, as this is a voluntary action on the part of the facility.

D. Revocation of License or Denial of License Renewal. An FSBC license may be revoked or denied renewal for any of the following reasons, including but not limited to:

1. failure to be in substantial compliance with the FSBC licensing laws, rules, and regulations;
2. failure to be in substantial compliance with other required statutes, laws, ordinances, rules, or regulations;
3. failure to uphold client rights whereby deficient practices result in harm, injury, or death of a client;
4. failure to protect a client from a harmful act by an FSBC employee or other client on the premises including, but not limited to:
 - a. any action which poses a threat to client or public health and safety;
 - b. coercion;
 - c. threat or intimidation;
 - d. harassment;
 - e. abuse; or
 - f. neglect;
5. failure to notify the proper authorities, as required by federal or state law or regulations, of all suspected cases of the acts outlined in §6725.D.4.a-f;
6. failure to employ qualified personnel;
7. failure to submit an acceptable plan of correction for deficient practices cited during an on-site survey within the stipulated timeframes;

8. failure to submit the required fees, including but not limited to:
 - a. fees for address or name changes;
 - b. any fine assessed by the department; or
 - c. fee for a CHOW;
9. failure to allow entry into the FSBC or access to requested records during a survey;
10. failure to protect clients from unsafe care by an individual employed by the FSBC;
11. when the FSBC staff or owner knowingly (or with reason to know) makes a false statement of a material fact in any of the following:
 - a. the application for licensure;
 - b. data forms;
 - c. clinical records;
 - d. matters under investigation by the department;
 - e. information submitted for reimbursement from any payment source; or
 - f. advertising;
12. conviction of a felony or entering a plea of guilty or nolo contendere to a felony by an owner, administrator, or clinical director, as evidenced by a certified copy of the conviction;

13. failure to comply with all reporting requirements in a timely manner as requested by the department;

14. failure to comply with the terms and provisions of a settlement agreement with the department or an educational letter;

15. failure to repay an identified overpayment to the department or failure to enter into a payment agreement to repay such overpayment; or

16. failure to timely pay outstanding fees, fines, sanctions or other debts owed to the department.

E. In the event an FSBC license is revoked, renewal is denied, or the license is surrendered in lieu of an adverse action, any owner, officer, member, manager, director, or administrator of such FSBC is prohibited from owning, managing, directing, or operating another FSBC for a period of two years from the date of the final disposition of the revocation, denial action, or surrender.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6727. Notice and Appeal of Initial License Denial, License Revocation, or Denial of License Renewal

A. Notice of an initial license denial, license revocation, or denial of license renewal shall be given to the FSBC in writing.

B. The FSBC has a right to an administrative reconsideration of the initial license denial, license revocation, or denial of license renewal. There is no right to an informal reconsideration of a voluntary non-renewal or surrender of a license by the FSBC.

1. The request for the administrative reconsideration shall be submitted within 15 days of the receipt of the notice of the initial license denial, license revocation, or denial of license renewal. The request for administrative reconsideration shall be in writing and shall be forwarded to HSS.

2. The request for administrative reconsideration shall include any documentation that demonstrates that the determination was made in error.

3. If a timely request for an administrative reconsideration is received by HSS, an administrative reconsideration shall be scheduled, and the FSBC will receive written notification of the date of the administrative reconsideration.

4. The FSBC shall have the right to appear in person at the administrative reconsideration and may be represented by counsel.

5. Correction of a violation or deficiency which is the basis for the initial license denial, revocation, or denial of license renewal shall not be a basis for reconsideration.

6. The administrative reconsideration process is not in lieu of the administrative appeals process.

7. The FSBC will be notified in writing of the results of the administrative reconsideration.

C. The FSBC has a right to an administrative appeal of the initial license denial, license revocation, or denial of license renewal. There is no right to an administrative appeal of a voluntary non-renewal or surrender of a license by the FSBC.

1. The FSBC shall request the administrative appeal within 30 days of the receipt of the results of the administrative reconsideration.

a. The FSBC may forego its rights to an administrative reconsideration, and if so, shall request the administrative appeal within 30 days of the receipt of the notice of the initial license denial, license revocation, or denial of license renewal.

2. The request for administrative appeal shall be in writing and shall be submitted to the DAL. The request shall include any documentation that demonstrates that the determination was made in error and shall include the basis and specific reasons for the appeal.

3. Subject to the provisions in C.3.a. of this Section, if a timely request for an administrative appeal is received by the DAL, the administrative appeal of the license revocation or denial of license renewal shall be suspensive, and the FSBC shall be allowed to continue to operate and provide services until such time as the department issues a final administrative decision.

a. If the secretary of the department determines that the violations of the FSBC pose an imminent or immediate threat to the health, welfare, or safety of a client, the imposition of the license revocation or denial of license renewal may be immediate and may be enforced during the pendency of the administrative appeal. If the secretary of the department makes such a determination, the FSBC will be notified in writing.

4. Correction of a violation or a deficiency which is the basis for the denial of initial licensure, revocation, or denial of license renewal shall not be a basis for an administrative appeal.

D. If an existing licensed FSBC has been issued a notice of license revocation, and the FSBC's license is due for annual renewal, the department shall deny the license renewal application. The denial of the license renewal application does not affect, in any manner, the license revocation.

E. If a timely administrative appeal has been filed by the FSBC on an initial license denial, denial of license renewal, or license revocation, the DAL shall conduct the hearing in accordance with the Administrative Procedure Act.

1. If the final decision is to reverse the initial license denial, denial of license renewal or license revocation, the FSBC's license will be re-instated or granted upon the payment of any licensing fees, outstanding sanctions, or other fees due to the department.

2. If the final decision is to affirm the denial of license renewal or license revocation, the FSBC shall stop rendering services to clients.

a. Within 10 days of the final decision, the FSBC shall notify HSS, in writing, of the secure and confidential location where the client records will be stored.

F. There is no right to an informal reconsideration or an administrative appeal of the issuance of a provisional initial license to a new FSBC or the issuance of a provisional license to an existing FSBC. An FSBC that has been issued a provisional

license is licensed and operational for the term of the provisional license. The issuance of a provisional license is not considered to be a denial of initial licensure, a denial of license renewal, or a license revocation.

G. An FSBC with a provisional initial license or an existing FSBC with a provisional license that expires due to noncompliance or deficiencies cited at the follow-up survey shall have the right to an informal reconsideration and the right to an administrative appeal of the validity of the deficiencies cited at the follow-up survey.

1. The correction of a violation, noncompliance, or deficiency after the follow-up survey shall not be the basis for the informal reconsideration or for the administrative appeal.

2. The informal reconsideration and the administrative appeal are limited to whether the deficiencies were properly cited at the follow-up survey.

3. The FSBC shall request the informal reconsideration in writing, which shall be received by the HSS within five calendar days of receipt of the notice of the results of the follow-up survey from the department.

4. The FSBC shall request the administrative appeal within 15 days of receipt of the notice of the results of the follow-up survey from the department. The request for

administrative appeal shall be in writing and shall be submitted to the DAL.

5. An FSBC with a provisional initial license or an existing FSBC with a provisional license that expires under the provisions of this Chapter shall cease providing services to clients unless the DAL issues a stay of the expiration.

a. The stay may be granted by the DAL upon application by the FSBC at the time the administrative appeal is filed and only after a contradictory hearing is held, and the FSBC shows that there is no potential harm to the clients being served by the FSBC.

6. If a timely administrative appeal has been filed by the FSBC with a provisional initial license that has expired, or by an existing FSBC whose provisional license has expired under the provisions of this Chapter, the DAL shall conduct the hearing in accordance with the Administrative Procedure Act.

a. If the final decision is to remove all deficiencies, the FSBC's license will be re-instated upon the payment of any outstanding sanctions and licensing or other fees due to the department.

b. If the final decision is to uphold the deficiencies thereby affirming the expiration of the provisional license, the FSBC shall cease rendering services to clients.

i. Within 10 days of the final decision, the FSBC shall notify HSS in writing of the secure and confidential location where the client records will be stored.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6729. Cessation of Business

A. Except as provided in §6787 and §6789 of these licensing regulations, a license shall be immediately null and void if an FSBC ceases to operate.

B. A cessation of business is deemed to be effective the date on which the FSBC stopped offering or providing services to the community.

C. Upon the cessation of business, the FSBC shall immediately return the original license to the department.

D. Cessation of business is deemed to be a voluntary action on the part of the FSBC. The FSBC does not have a right to appeal a cessation of business.

E. The FSBC shall notify the department in writing 30 days prior to the effective date of the closure or cessation. In addition to the notice, the FSBC shall submit a written plan for the disposition of client clinical records for approval by the department. The plan shall include the following:

1. the effective date of the closure;
2. provisions that comply with federal and state laws on storage, maintenance, access and confidentiality of the closed provider's clients' clinical records; and
3. appointed custodian(s) who shall provide the following:
 - a. access to records and copies of records to the client or authorized representative, upon presentation of proper authorization(s); and
 - b. physical and environmental security that protects the records against fire, water, intrusion, unauthorized access, loss and destruction;
4. public notice regarding access to records, in the newspaper with the largest circulation near the closing provider, at least 15 days prior to the effective date of closure.

F. If an FSBC fails to follow these procedures, the owners, managers, officers, directors, and administrators may be prohibited from opening, managing, directing, operating, or owning an FSBC for a period of two years.

G. Once the FSBC has ceased doing business, the center shall not provide services until the FSBC has obtained a new initial license.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

Subchapter B. Administration and Organization

§6735. Governing Body

A. An FSBC shall have an identifiable governing body with responsibility for, and authority over, the policies and activities of the FSBC, which shall include all contracts. The governing body is the ultimate governing authority of the FSBC and shall adopt bylaws which address its responsibilities. No contract or other arrangements shall limit or diminish the responsibilities of the governing body.

B. An FSBC shall have documents identifying the following information regarding the governing body:

1. names and addresses of all members;
2. terms of membership;
3. officers of the governing body; and
4. terms of office for any officers.

C. The governing body shall be comprised of one or more persons and shall hold formal meetings at least twice a year. There shall be written minutes of all formal meetings, and the bylaws shall specify the frequency of meetings and quorum requirements.

D. The governing body of an FSBC shall:

1. ensure the FSBC's continual compliance and conformity with all relevant federal, state, local, and municipal laws and regulations;

2. ensure that the FSBC is adequately funded and fiscally sound which entails:

a. verification of sufficient assets equal to \$100,000 or the cost of three months of operation, whichever is less; or

b. a letter of credit issued from a federally insured, licensed lending institution in the amount of at least \$100,000 or the cost of three months of operation, whichever is less;

3. review and approve the FSBC's annual budget;

4. designate a person to act as the administrator and delegate enough authority to this person to manage the day-to-day operations of the FSBC;

5. annually evaluate the administrator's performance;

6. have the authority to dismiss the administrator;

7. formulate and annually review, in consultation with the administrator, written policies and procedures concerning the FSBC's philosophy, goals, current services,

personnel practices, job descriptions, fiscal management, and contracts:

a. the FSBC's written policies and procedures shall be maintained within the FSBC and made available to all staff during hours of operation;

8. determine, in accordance with state law, which licensed practitioners are eligible candidates for appointment to the FSBC staff;

9. ensure and maintain quality of care, inclusive of a quality assurance/performance improvement process that measures client, process, and structural (e.g. system) outcome indicators to enhance client care;

10. ensure that birthing procedures shall not be performed in areas other than the birthing rooms or other designated and approved treatment rooms;

11. ensure that birthing procedures are initiated in accordance with acceptable standards of practice.

12. meet with designated representatives of the department whenever required to do so;

13. inform the department, or its designee, prior to initiating any substantial changes in the services provided by the FSBC; and

14. ensure that pursuant to R.S. 40:1191.2, prior to the final disposition of a miscarried child, but not more than

24 hours after a miscarriage occurs in an FSBC, the FSBC shall notify the client, or if the client is incapacitated, the spouse of the client, both orally and in writing, of both of the following:

a. the parent's right to arrange for the final disposition of the miscarried child using the notice of parental rights form as provided for in R.S. 40:1191.3; and

b. the availability of a chaplain or other counseling services concerning the death of the miscarried child, if such services are provided by the FSBC.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6737. Policies and Procedures

A. An FSBC shall develop, implement, and maintain written policies and procedures governing all services rendered at the FSBC. The FSBC shall comply with all federal and state laws, rules, and regulations in the development and implementation of its policies and procedures.

B. All policies and procedures shall be reviewed at least annually and revised as needed.

C. Direct care staff shall have access to information concerning clients that is necessary for effective performance of the employee's assigned tasks.

D. The FSBC shall have written policies and procedures for the maintenance and security of records, specifying who shall supervise the maintenance of records, who shall have custody of records, and to whom records may be released.

E. The FSBC shall allow designated representatives of the department, in the performance of their mandated duties, to:

1. inspect all aspects of an FSBC's operations which directly or indirectly impact clients; and
2. interview any staff member or client.

F. An FSBC shall make any required information or records, and any information reasonably related to assessment of compliance with these provisions, available to the department.

G. An FSBC shall, upon request by the department, make available the legal ownership documents and any other legal contracts or agreements in place.

H. The FSBC shall have written policies and procedures approved by the governing body, which shall be implemented and followed, that address, at a minimum, the following:

1. confidentiality and confidentiality agreements;
2. security of files;

3. publicity and marketing, including the prohibition of illegal or coercive inducement, solicitation, and kickbacks;

4. personnel;

5. client rights;

6. grievance procedures;

7. emergency preparedness;

8. abuse and neglect;

9. incidents and accidents, including clinical emergencies;

10. universal precautions;

11. documentation, whether electronic or in paper form;

12. admission and discharge policies and procedures, inclusive of criteria for admission to, continuation in, and transfer out, of the FSBC;

13. hours outside of stated usual and customary operation, including, but not limited to early closures, extended business hours, and holidays; and

14. conditions for coverage, if applicable.

I. An FSBC shall have written personnel policies, which shall be implemented and followed, that include:

1. written job descriptions for each staff position, including volunteers;

2. policies which provide for staff, upon offer of employment, to have a health assessment as defined by the FSBC and in accordance with LAC Title 51, *Public Health-Sanitary Code* requirements;

3. policies which verify that all clinic employees, including contracted personnel, prior to, and at the time of employment and annually thereafter, shall be free of tuberculosis in a communicable state, in accordance with the current LAC Title 51, *Public Health-Sanitary Code*;

4. an employee grievance procedure;

5. abuse reporting procedures that require all employees to report any incidents of abuse or mistreatment, whether that abuse or mistreatment is done by another staff member, a family member, a client, or any other person;

6. a written policy to prevent discrimination; and

7. a written policy to address prohibited use of social media. The policy shall ensure that all staff, either contracted or directly employed, receive training relative to the restrictive use of social media and include, at a minimum, ensuring confidentiality of client information and preservation of client dignity and respect, including protection of client privacy and personal and property rights.

J. The FSBC shall maintain, in force at all times, the requirements for financial viability under this Chapter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

Subchapter C. Admissions, Transfers and Discharges

§6743. Prohibitions to Admission or Continued Care in an FSBC

A. The FSBC shall not knowingly accept or thereafter maintain responsibility for the prenatal or intrapartum care of a woman who:

1. has had a previous cesarean section or other known uterine surgery such as hysterotomy or myomectomy;
2. has a history of difficult to control hemorrhage with previous deliveries;
3. has a history of thromboembolism, deep vein thromboembolism, or pulmonary embolism;
4. is prescribed medication for diabetes, or has hypertension, Rh disease isoimmunization with positive titer, active tuberculosis, active syphilis, active gonorrhea, HIV positive or is otherwise immunocompromised, epilepsy, hepatitis, heart disease, kidney disease, or blood dyscrasia;
5. contracts primary genital herpes simplex during the pregnancy or manifests active genital herpes during the last four weeks of pregnancy;
6. has a contracted pelvis;

7. has severe psychiatric illness or a history of severe psychiatric illness in the six-month period prior to pregnancy;
8. has been prescribed narcotics in excess of three months or is addicted to narcotics or other drugs;
9. ingests more than 2 ounces of alcohol or 24 ounces of beer a day on a regular day or participates in binge drinking;
10. smokes 20 cigarettes or more per day, and is not likely to cease in pregnancy;
11. has a multiple gestation;
12. has a fetus of less than 37 weeks gestation at the onset of labor;
13. has a gestation beyond 42 weeks by dates and examination;
14. has a fetus in any presentation other than vertex at the onset of labor;
15. is a primigravida with an unengaged fetal head in active labor, or any woman who has rupture of membranes with unengaged fetal head, with or without labor;
16. has a fetus with suspected or diagnosed congenital anomalies that may require immediate medical intervention;
17. has preeclampsia;

18. has a parity greater than five with poor obstetrical history;
19. is younger than 16 or a primipara older than 40;
20. has been taking medications known to cause Neonatal Abstinence Syndrome;
21. has history of congenital heart disease;
22. has history of cardiac surgery(ies);
23. has history of gastric bypass; or
24. takes any medication other than a prenatal vitamin, iron supplement, sleep aid or over the counter medication unless as prescribed by and approved for use by the licensed health care practitioner;
25. labors greater than 16-20 hours

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6745. Admissions and Assessments

A. Each FSBC shall have written admission and assessment policies and criteria in accordance with the licensed practitioner's scope of practice. The FSBC shall have policies/procedures and written criteria for the evaluation of risk status, admission, transfer, discharge, and complications requiring medical or surgical intervention. The policies and

procedures and written criteria shall be developed, implemented, enforced, monitored, and reviewed annually by the clinical staff and approved by the governing body.

B. An FSBC shall ensure that each client has the appropriate pre-natal and postpartum assessments completed, inclusive of suitability for less than 23-hour timeframe of client stay, ability of the FSBC to provide services needed in the postpartum period in accordance with the prescribed plan of care, and discharge plans to home or another licensed facility setting.

C. Within 30 days prior to the estimated due date, each client shall have a comprehensive clinical history and physical assessment completed by a physician or other qualified licensed professional practitioner in accordance with applicable state health and safety laws, FSBC policies, and standards of practice.

D. The history and physical assessment prior to delivery shall specify that the client is clinically cleared for delivery in an FSBC and meets the requirements for free-standing birth center services and this Chapter pursuant to applicable state statutes.

E. Upon admission, each client shall have a perinatal assessment completed by a qualified licensed health care

practitioner. The perinatal assessment shall include, at a minimum:

1. an updated clinical record entry documenting an examination for any changes in the client's condition since completion of the most recently documented clinical history and physical assessment;

2. documentation of any known allergies to drugs and/or biological agents; and

3. documentation of a standardized risk assessment for postpartum hemorrhage.

F. The client's clinical history and physical assessment shall be placed in the client's clinical record.

G. The client's postpartum condition shall be assessed and documented in the clinical record by a licensed health care practitioner in accordance with applicable state health and safety laws, FSBC policies, and standards of practice.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6747. Required Newborn Care

A. Each delivery shall be attended by two staff currently trained in adult cardiopulmonary resuscitation equivalent to American Heart Association Class C Basic Life Support and

Neonatal Resuscitation Program endorsed by American Academy of Pediatrics/American Heart Association.

B. The licensed midwife shall be responsible for care of the newborn immediately following the delivery only. Subsequent infant care should be managed by a pediatrician or primary care physician. This does not preclude the midwife from providing counseling regarding routine newborn care and breastfeeding and arranging for the neonatal tests required by state law. If any abnormality is suspected, the newborn shall be sent for medical evaluation as soon as possible.

C. Immediately following delivery, the midwife shall:

1. wipe face, then suction (with bulb syringe) mouth and nose if necessary;
2. prevent heat loss by the neonate;
3. determine Apgar scores at one minute and five minutes after delivery;
4. observe and record: skin color and tone, heart rate and rhythm, respiration rate and character, estimated gestational age (premature, term, or postmature), weight, length, and head circumference.

D. The midwife shall ensure that Vitamin K is available at the time of delivery and take appropriate measures designed to prevent neonatal hemorrhage.

E. The midwife is responsible for obtaining a phenylketonuria (PKU) test and all other neonatal tests required by state law, including all required metabolic newborn screens, between 24 hours and no later than 14 days after birth. If the parents object to such tests being performed on the infant, the midwife shall document this objection, notify and refer the newborn to the infant's pediatrician or primary care physician, and notify the appropriate authorities.

F. The licensed midwife shall leave clear instructions for follow-up care, including signs and symptoms of conditions that require medical evaluation, especially fever, irritability, generalized rash, and lethargy.

G. The licensed midwife is responsible for performing a glucose check for a newborn if weight is greater than nine pounds, four ounces.

H. They FSBC shall have a policy for oral glucose administration for the infant who does not respond to supplemental feedings in accordance with current standards of practice.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6749. Physician Evaluation of Newborn

A. The licensed midwife shall recommend that any infant delivered by the midwife be evaluated by a pediatrician or primary care physician within three days of age or sooner if it becomes apparent that the newborn needs medical attention for problems associated with, but not limited to, congenital or other anomalies.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6751. Required Physician Consultation, Postpartum Period

A. The licensed midwife shall obtain emergent medical consultation or refer for emergent medical care any woman who, during the postpartum period:

1. has a third-degree or fourth-degree perineal laceration;
2. has uterine atony;
3. bleeds in an amount greater than 300 milliliters and still continuing to bleed;
4. does not urinate or empty her genitourinary bladder within two hours of birth;
5. develops a fever greater than 100.4 degrees Fahrenheit or 38 degrees Centigrade on any two of the first 10 days postpartum, excluding the first 24 hours;

6. develops foul smelling lochia;

7. develops blood pressure below 100/50 if pulse exceeds 100, pallor, cold clammy skin, and/or weak pulse.

B. The licensed midwife shall obtain emergent medical consultation or refer for emergent medical care any infant who:

1. has an Apgar score of seven or less at five minutes;

2. has any obvious anomaly;

3. develops grunting respirations, retractions, or cyanosis;

4. has cardiac irregularities;

5. has a pale, cyanotic, or grey color;

6. develops jaundice within 48 hours of birth;

7. has an abnormal cry;

8. weighs less than 5 pounds or weighs more than 10 pounds;

9. shows signs of prematurity, dysmaturity, or post maturity;

10. has meconium staining of the placenta, cord, and/or infant with signs or symptoms of aspiration pneumonia;

11. does not urinate or pass meconium in the first 24 hours after birth;

12. is lethargic or does not feed well;

13. has edema;

14. appears weak or flaccid, has abnormal feces, or appears not to be normal in any other respect;

15. has persistent temperature below 97 degrees Fahrenheit per FSBC policy;

16. has jitteriness not resolved after feeding; or

17. has a blood glucose level of less than 45mg/dL.

C. The center shall develop, implement, and enforce written policies to provide follow-up postpartum care to the newborn and the mother either directly or by referral. Follow up care may be provided in the center, at the mother's residence, by telephone, or by a combination of these methods in accordance with accepted standards of practice.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

Subchapter D. Service Delivery

§6757. Perinatal Services

A. Perinatal services shall be well organized and provided in accordance with current acceptable standards of practice adopted from national associations or organizations.

B. Private areas should include pre-delivery and post-delivery care areas.

C. The FSBC shall ensure that the scheduled deliveries do not exceed the capabilities of the FSBC, including the post-delivery care area, and any length of client care does not exceed 23 hours from client admission to discharge from the FSBC.

D. At least one licensed practitioner trained in the use of emergency equipment and certified in advanced cardiac life support (ACLS) shall be immediately available whenever there is a client in the FSBC.

E. A roster of licensed practitioners, specifying the delivery privileges of each, shall be kept in the FSBC and available to all staff.

F. Approved policies shall define which delivery procedures require a qualified physician or other licensed practitioner who is acting within the scope of practice of his/her respective licensing board(s) and/or certification(s).

G. A delivery room register shall be accurately maintained and kept up-to-date and complete. This register shall be maintained for a six-year period. The register shall include, at a minimum, the:

1. client's complete name;
2. client's FSBC individual identification number;
3. licensed practitioner's name;
4. date and time of the delivery; and

5. type of delivery performed.

H. There shall be enough staff assigned to the postpartum care area to meet the needs of the clients. At a minimum, one licensed and qualified staff person shall be onsite and available for the length of any client stay in the FSBC.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40: 2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6759. Transfer Agreements and Client Transfers

A. The FSBC shall secure a written transfer agreement with at least one receiving hospital in the community with policies and procedures for timely transport. A transfer agreement shall serve as evidence of a procedure whereby a client can be transferred to a hospital should an emergency arise which would necessitate hospital care and services.

B. The FSBC shall be located within 20 minutes' transport time to a general acute care hospital providing obstetric services 24 hours per day and 7 days a week, with which the FSBC has a written transfer agreement. The FSBC shall maintain a contractual relationship with the general acute care hospital, including a written transfer agreement, which allows for an emergency caesarian delivery to begin within 30 minutes of the

decision made by a licensed obstetrician at the receiving hospital that a caesarian delivery is necessary.

C. The licensed midwife shall accompany any mother or infant requiring hospitalization to the hospital, giving any pertinent written records and verbal report to the physician assuming care. If possible, the licensed midwife should remain with the mother and/or infant to ascertain outcome. In those instances where it is necessary to continue providing necessary care to the party remaining in the FSBC, the licensed midwife may turn over the care of the transport of mother or child to qualified emergency or hospital personnel. All necessary written records shall be forwarded with such personnel and a verbal report must be given.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40: 2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6761. Discharges.

A. Each FSBC shall have written discharge policies and procedures. The written description of discharge policies shall be provided to the department upon request and made available to the client or his/her legal representative. The FSBC shall ensure that all elements of the discharge requirements are completed.

B The mother and newborn shall not be discharged less than two hours from time of delivery of the placenta.

C. The postpartum needs of each client shall be addressed and documented in the discharge notes.

D. Upon discharge, the FSBC shall:

1. provide each client with written discharge instructions, including written guidelines detailing how the client may get emergency assistance for herself and her newborn;

2. provide each client with all supplies deemed clinically necessary per the discharge orders, excluding medications;

3. coordinate care with a licensed practitioner and/or provide care and support during the immediate and no later than 36 hours of birth including, but not limited to:

a. maternal and newborn assessments and follow-up plans;

b. current recommended newborn screenings;

c. breastfeeding support and referral;

d. screening for postpartum mental health issues;

e. psychological assessment;

f. family planning services; and

g. referral for ongoing health issues

4. ensure that all clients are informed, either in advance of their delivery or prior to leaving the FSBC, of the following:

a. necessary prescriptions;

b. postpartum instructions that includes but is not limited to the following post-birth warning signs:

i. *P*-pain in your chest;

ii. *O*-obstructed breathing or shortness of breath;

iii. *S*-seizures;

iv. *T*-thoughts of hurting yourself or your baby;

v. *B*-bleeding that is soaking through one pad/hour, or blood clots the size of an egg or bigger;

vi. *I*-incision that is not healing;

vii. *R*-red or swollen leg that is painful or warm to touch;

viii. *T*-temperature of 100.4 degrees Fahrenheit or higher; and

ix. *H*-headache that does not improve, even after taking medicine for relief, or a bad headache with vision changes; and

c. licensed practitioner(s) contact information for follow-up care of the mother and her newborn.

E. The FSBC shall ensure that each client has a discharge order signed by the licensed practitioner who performed the delivery;

F. The FSBC shall ensure and document that all clients are discharged in the company of a responsible adult, except those clients exempted by the attending licensed practitioner. Such exemptions shall be specific and documented for individual clients. Blanket exemptions are prohibited.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40: 2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

Subchapter E. Facility Responsibilities

§6767. General Provisions

A. FSBCs shall comply and show proof of compliance with all relevant federal, state, and local rules and regulations. It is the FSBC's responsibility to secure the necessary approvals from the following entities:

1. HSS;
2. OSFM architectural and licensing plan review;
3. OPH;
4. OSFM *Life Safety Code* inspection; and
5. the applicable local governing authority (e.g., zoning, building department or permit office).

B. The administrator, or designee, shall be accessible to FSBC staff or designated representatives of the department any time there is a client in the FSBC.

C. An FSBC shall have qualified staff sufficient in number to meet the needs of clients and to ensure provision of services.

D. The FSBC shall develop and maintain documentation of an orientation program for all employees, either contact or staff, that is of sufficient scope and duration to inform the individual about his/her responsibilities, how to fulfill them, review of policies and procedures, job descriptions, competency evaluations and performance expectations. An orientation program and documented competency evaluation and/or job expectations of assigned or reassigned duties shall be conducted prior to any assignments or reassignments.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6769. Staffing Requirements

A. Administrative Staff. The following administrative staff is required for all FSBCs:

1. a qualified administrator at each licensed geographic location who shall meet the qualifications as established in these provisions;

2. other administrative staff as necessary to operate the FSBC and to properly safeguard the health, safety, and welfare of the clients receiving services; and

3. an administrative staff person on-call after routine daytime or office hours for the length of any client stay in the FSBC.

B. Administrator

1. Each FSBC shall have a qualified administrator who is a full-time on-site employee responsible for the day-to-day management, supervision, and operation of the FSBC.

2. Any current administrator employed by a licensed FSBC, at the time these licensing provisions are adopted and become effective, shall be deemed to meet the qualifications of the position of administrator as long as that individual holds his/her current position. If that individual leaves his/her current position, he/she shall be required to meet the qualifications stated in these licensing provisions to be re-employed into such a position.

3. The administrator shall meet the following qualifications:

a. possess a college degree from an accredited university; and

b. have one year of previous work experience involving administrative duties in a healthcare facility.

4. Changes in the administrator shall be reported to the department within 10 days of the change on the appropriate form designated by the department.

C. The director of clinical midwifery services shall:

1. have a current, unrestricted Louisiana license as a physician, a CNM, or a licensed midwife;

2. be in good standing with the applicable state licensing board; and

3. shall have a minimum of one-year experience in a health care setting and possess the knowledge, skills and experience consistent with the complexity and scope of delivery services provided by the FSBC;

a. the director of clinical midwifery holding dual administrative/midwifery director roles shall meet the qualifications of each role; and

b. changes in the director of clinical midwifery shall be reported in writing to the department within 10 days of the change on the appropriate form designated by the department.

D. Responsibilities of the administrator and the director of clinical midwifery. The administrator and the director of clinical midwifery shall develop, adopt, implement, and monitor the policies and procedures of the FSBC and the professional services of the staff. The staff bylaws shall be maintained within the FSBC. The bylaws and rules shall contain provisions for at least the following:

1. developing the structure of the licensed practitioner staff, including allied health professionals and categories of membership;

2. developing, implementing, and monitoring policies and procedures to review credentials, at least every two years, and to delineate and recommend approval for individual privileges;

3. developing, implementing, and monitoring policies and procedures to ensure that all licensed practitioner staff possess current and unrestricted Louisiana licenses and that each member of the licensed practitioner staff is in good standing with his/her respective licensing board;

4. providing recommendations to the governing body for membership to the licensed practitioner staff with initial appointments and reappointments not to exceed two years;

5. developing, implementing, and monitoring policies and procedures for the suspension and/or termination of membership to the licensed practitioner staff;

6. developing, implementing, and monitoring criteria and frequency for review and evaluation of past performance of its individual staff members. This process shall include monitoring and evaluation of the quality of client care provided by each individual;

7. the appointment of committees as deemed appropriate;

8. reviewing and making recommendations for revisions to all policy and procedures at least annually; and

9. meeting at least semi-annually. One of these meetings shall be designated as the official annual meeting. A record of attendance and minutes of all licensed practitioner staff meetings shall be maintained within the FSBC.

E. Licensed Practitioner Staff

1. The FSBC shall have an organized licensed practitioner staff, inclusive of one or more of the following, who shall attend each woman in labor from the time of admission through birth and the immediate postpartum period:

- a. a licensed obstetrician;
- b. a certified nurse midwife; or
- c. a licensed midwife.

2. A physician providing birthing services within the FSBC shall:

a. hold a current, unrestricted state license issued by the LSBME;

b. be actively engaged in a clinical obstetrical practice;

c. have hospital privileges in obstetrics in a hospital accredited by the Joint Commission; and

d. practice within the scope of practice of a licensed physician in accordance with applicable state statutes and regulations.

3. A CNM providing birthing services within the FSBC shall be:

a. an advanced practice registered nurse holding a current, unrestricted state license issued by the Louisiana State Board of Nursing (LSBN);

b. educated in the disciplines of nursing and midwifery;

c. certified according to a nationally recognized certifying body, such as the American College of Nurse Midwives Certification Council, as approved by the LSBN;

d. authorized to manage the nurse midwifery care of newborns and women in the antepartum, intrapartum, and postpartum periods as well as primary care for women across

their lifespan and treatment of their male partners for sexually transmitted infections (STI); and

e. practicing within the scope of practice of a CNM in accordance with applicable state statutes and regulations.

4. A licensed midwife providing birthing services within the FSBC must:

a. have passed the national certification exam through the North American Registry of Midwives;

b. hold a current, unrestricted state license with the Louisiana State Board of Medical Examiners; and

c. practice within the scope of practice of a licensed midwife in accordance with applicable state statutes and regulations and national accreditation standards.

5. All licensed practitioner staff shall be accountable to the governing body for the quality of all perinatal care provided to clients and newborn infants, and for the ethical and professional practices of its members.

6. The licensed practitioner staff shall be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted.

7. A licensed practitioner staff shall remain within the FSBC until all clients are assessed as stable.

8. The client's attending licensed practitioner staff, or designated on-call licensed practitioner staff, shall be available by telephone for consultation and evaluation of the client, and available to be onsite within 30 minutes if needed, until the client is discharged from the FSBC.

9. Each client admitted to the FSBC shall be under the professional supervision of a member of the FSBC's licensed practitioner staff who shall assess, supervise, and evaluate the care of the client.

10. Credentialing files for each staff shall be kept current and maintained within the FSBC at all times.

F. Delivery Services Staff. The staffing pattern shall provide for sufficient personnel and for adequate supervision and direction by licensed practitioners consistent with the number of deliveries performed and throughout the length of any client stay in the FSBC.

1. Delivery services shall be under the direction of a licensed practitioner that includes a plan of administrative authority with written delineation of responsibilities and duties for each category of staff members.

2. The FSBC shall ensure that the delivery services are directed under the leadership of licensed practitioner(s) sufficient in number, and on duty at all times that the FSBC is in operation and a client is in the center, to plan, assign,

supervise, and evaluate delivery services, as well as to give clients the high-quality care that requires the judgment and specialized skills of licensed practitioners.

a. There shall be sufficient staff with the appropriate qualifications to assure ongoing assessment of clients' needs and that these identified needs are addressed. The number and types of staff is determined by the volume and types of delivery the FSBC performs.

3. All professional staff employed, contracted, or working with the FSBC shall have a current, unrestricted, and valid Louisiana license to practice. Nonprofessional or unlicensed personnel employed, contracted, and performing delivery care services shall be under the supervision of a licensed practitioner.

4. There shall be, at minimum, one licensed practitioner with ACLS certification on duty, in the building, and immediately available at any time there is a client in the FSBC in accordance with national accreditation standards.

5. A formalized program on in-service training shall be developed and implemented for all categories of the FSBC staff. Training is required on a quarterly basis related to required job skills.

a. Documentation of such in-service training shall be maintained on-site in the FSBC's files. Documentation shall include the:

- i. training content;
- ii. date and time of the training;
- iii. names and signatures of personnel in attendance; and
- iv. name of the presenter(s).

6. General staffing provisions for the delivery rooms shall be the following:

a. each delivery procedure shall be performed by a licensed practitioner; and

b. appropriately trained practitioners may perform assistive functions during each delivery procedure.

G. General Personnel Requirements

1. All licensed practitioners and FSBC employees, including contracted personnel shall meet and comply with these personnel requirements.

2. All licensed practitioners and FSBC employees, including contracted personnel, prior to and at the time of employment and annually thereafter, shall be verified to be free of tuberculosis in a communicable state in accordance with the FSBC's policies and procedures and the current Centers for

Disease Control and Prevention (CDC) and the OPH recommendations.

3. All unlicensed staff involved in direct client care and/or services shall be supervised by a licensed practitioner.

4. A personnel file shall be maintained within the FSBC on every employee, including contracted employees. Policies and procedures shall be developed to determine the contents of each personnel file. At a minimum, all personnel files shall include the following:

- a. an application;
 - b. current verification of professional licensure;
 - c. health care screenings as defined by the FSBC;
 - d. orientation and competency verification;
 - e. annual performance evaluations;
 - f. criminal background checks for unlicensed staff, prior to offer of direct or contract employment, after the effective date of this Rule, as applicable and in accordance with state law. The criminal background check shall be conducted statewide by the Louisiana State Police or its authorized agent;
- and

g. any other screenings required of new applicants by state law.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6771. Medications for Mother and Newborn Infant

A. A licensed midwife may administer the following medications under the conditions indicated:

1. oxygen for fetal or maternal distress and infant resuscitation;

2. local anesthetic, by infiltration, only for the purpose of postpartum repair of tears, lacerations, or episiotomy (no controlled substances);

3. vitamin K, by injection, for control of bleeding in the newborn;

4. oxytocin (Pitocin) by injection or methergine orally, only for postpartum control of non-emergent maternal hemorrhage;

5. intravenous fluids for maternal hydration with additional medications as provided by a physician's order or protocol for the purpose of controlling maternal hemorrhage;

6. for prophylactic treatment where the client has tested positive for group B streptococcus;

7. prenatal Rh immunoglobulin (RhIg) for Rh negative clients and post-partum for Rh positive newborns.

8. Benadryl (diphenhydramine);

9. penicillin G, unless client is allergic, then consult with the physician;

10. or other additional medications as prescribed by a licensed physician or CNM's order or protocol as approved by the facility's governing body in accordance with state law and standards of practice for the perinatal period for the newborn and/or the mother.

B. A licensed midwife may lawfully obtain and have possession of small quantities of the above-named medications and the equipment normally required for administration. Each use of medication shall be recorded by the licensed midwife in the client's chart.

C. The licensed physician and the CNM may administer and/or order medications in accordance with their scope of practice and licensing regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6773. Clinical Records

A. Each FSBC shall make provisions for securing clinical records of all media types, whether stored electronically or in paper form. The identified area or equipment shall be secured to maintain confidentiality of client records and shall be restricted to staff movement and remote from treatment and public areas.

B. All client records shall be protected from loss or damage.

C. The FSBC shall have a designated area located within the FSBC which shall provide for the proper storage, protection and security for all clinical records and documents.

D. The FSBC shall develop a unique clinical record for each client. Records may exist in hard copy, electronic format or a combination thereof.

E. The FSBC shall ensure the confidentiality of client records, including information in a computerized clinical record system, in accordance with the Health Insurance Portability and Accountability Act (HIPAA) regulations and any state laws, rules and regulations.

1. If computerized records are used, the FSBC shall develop:

a. a back-up system for retrieval of critical clinical records;

b. safeguards/firewalls to prevent unauthorized use and access to information; and

c. safeguards/firewalls to prevent alterations of electronic records.

F. A unique clinical record shall be maintained for every client admitted and/or treated.

G. The clinical record cannot become part of any other clinical record associated with another entity.

H. The following data shall be documented and included as part of each client's basic clinical record:

1. unique client identification;
2. admission and discharge date(s) and times of mother and infant;
3. clinical and social history;
4. physical examination notes of mother and infant in accordance with clinical staff bylaws, policies and procedures;
5. diagnosis(es);
6. licensed practitioner's orders;
7. clinical laboratory report(s), if any;
8. pathology report(s), if any;
9. radiological report(s), if any;
10. consultation report(s), when appropriate;
11. delivery and treatment regimen;

12. licensed practitioner's progress notes;
13. nurses' records of care provided, and medications administered, if any;
14. authorizations, consents, or releases;
15. delivery report;
16. medication record to include, but not limited to:
 - a. type of medication or local anesthetic, if used;
 - b. route of medication administered, if any;
 - c. person administering the medication or local anesthetic, if used; and
 - d. post-medication assessment, when appropriate;
17. name(s) of the treating licensed practitioner(s);
18. start and end time of the delivery/procedure and time of birth of infant;
19. a current informed consent for delivery /procedure and anesthesia that includes the following:
 - a. name of the client;
 - b. client individual identification number;
 - c. name of the procedure being performed;
 - d. reasonable and foreseeable risks and benefits;

e. name of the licensed practitioner(s) who will perform the procedure or delivery;

f. signature of client or legal guardian or individual designated as having power of attorney for clinical decisions on behalf of the client, if any;

g. date and time the consent was obtained; and

h. signature and professional discipline of the person witnessing the consent;

20. delivery/procedures report(s);

21. client education and discharge instructions; and

22. a discharge summary, including:

a. licensed practitioner progress notes; and

b. discharge notes.

J. The clinical records shall be under the custody of the FSBC and maintained in its original, electronic, microfilmed or similarly reproduced form for a minimum period of 10 years from the date a client is discharged. The FSBC shall provide a means to view or reproduce the record in whatever format it is stored.

K. Clinical records may be removed from the premises for computerized scanning for the purpose of storage. Contracts, for the specific purpose of scanning at a location other than the FSBC, shall include provisions addressing how:

1. the clinical record shall be secured from loss or theft or destruction by water, fire, etc.; and

2. confidentiality shall be maintained.

L. Clinical records may be stored off-site provided that:

1. the confidentiality and security of the clinical records are maintained; and

2. a 12-month period has lapsed since the client was last treated in the FSBC.

M. Each clinical entry and all orders shall be signed by the licensed practitioner(s) and shall include the date and time. Clinical entries and any observations made by the licensed practitioner(s) shall be signed by the licensed practitioner and shall include the date and time.

1. If electronic signatures are used, the FSBC shall develop a procedure to assure the confidentiality of each electronic signature and shall prohibit the improper or unauthorized use of any computer-generated signature.

2. Signature stamps shall not be used.

N. All pertinent observations, treatments, and medications given to a client shall be entered in the staff notes as part of the clinical record. All other notes relative to specific instructions from the licensed practitioner shall be recorded.

O. Completion of the clinical record shall be the responsibility of the admitting licensed practitioner within 30 days of client discharge.

P. All hardcopy entries into the clinical record shall be legible and accurately written in ink. The recording person shall sign the entry to the record and include the date and time of entry. If a computerized clinical records system is used, all entries shall be authenticated, dated and timed, complete, properly filed and retained, accessible and reproducible.

Q. Written orders signed by a member of the licensed practitioner staff shall be required for all medications and treatments administered to clients and shall include the date and time ordered. Verbal orders shall include read-back verification. All verbal orders shall be authenticated by the ordering licensed practitioner within 48 hours to include the signature of the ordering licensed practitioner, date and time.

R. The use of standing orders is prohibited.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6774. Other Records and Reports

A. The following indexes, records and registers shall be required of the licensed FSBC:

1. a client's register;
2. a delivery room register;
3. a birth register;

4. daily census report of admissions and discharges;
5. records of reportable diseases, if any, as required by state and/or federal regulations;
6. a laboratory log denoting laboratory specimen(s) that are sent for pathology interpretation, if any, and a CLIA certificate in accordance with the type laboratory procedures conducted in the center;
 - a. the laboratory log shall include, at a minimum, the following information:
 - i. the client's name;
 - ii. the specimen site; and
 - iii. the date the specimen was sent for pathology interpretation;
7. mortality records, including in the event of a miscarried child.

B. Nothing in this Chapter is intended to preclude the use of automated or centralized computer systems or any other techniques provided the regulations stated herein are met.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6775. Quality Assurance and Performance Improvement

A. The governing body shall ensure that there is an implemented, maintained, effective, written, data-driven, and ongoing program designed to assess and improve the quality of client care. This program shall include all services, provided directly or through contract.

B. The governing body shall ensure that it allocates sufficient staff, time, information systems, and training to implement the quality assurance and performance improvement (QAPI) program and for participation in the state perinatal quality collaborative, which is under the authority of the Louisiana Commission on Perinatal Care and Prevention on Infant Mortality, defined as reporting perinatal measures determined by the Louisiana Commission on Perinatal Care and Prevention on Infant Mortality.

C. The FSBC shall ensure there is a written quality assurance plan for assessing and improving quality of care that is focused on high risk, high volume, and problem-prone areas, and which specifies the intervals that the FSBC shall actively collect data related to the quality indicators and show participation in the state perinatal quality collaborative as required. Performance improvement activities shall consider incidence, prevalence, and severity of problems and those that can affect health outcomes, client safety, and quality of care. The plan shall describe the system for overseeing and analyzing

the effectiveness of monitoring, evaluation, and sustained improvement activities. All services related to client care, including services furnished by a contractor shall be evaluated.

D. Nosocomial infections, client care outcomes, and perinatal and newborn care services performed in the FSBC shall be evaluated as they relate to appropriateness of care and services rendered.

E. The services provided by each licensed practitioner with FSBC privileges shall be periodically evaluated to determine whether they are of an acceptable level of quality and appropriateness in accordance with clinical staff bylaws/rules and regulations.

F. The QAPI program shall monitor, identify, and develop a plan for elimination of medication errors and adverse client (mother and infant) events.

G. Corrective actions to problems identified through the QAPI program, with on-going monitoring for sustained corrective action, shall be documented. All QAPI data shall be documented and remain within the FSBC. Staff education and training related to the correction of problems shall be documented.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

Subchapter F. Safety, Sanitization and Emergency Preparedness

§6779. General Provisions

A. The FSBC shall have policies and procedures, approved and implemented by the clinical staff and governing body, that address provisions for:

1. sanitizing, disinfecting, and sterilizing supplies, equipment, and utensils; and
2. the safe use of cleaning supplies and solutions that are to be used and the directions for use, including:
 - a. terminal cleaning of the birth rooms/suites; and
 - b. cleaning of the birth rooms/suites between delivery procedures.

B. Policies and procedures shall be developed, implemented, and approved by the FSBC's governing body for the types and numbers of sterilizing equipment and autoclaves sufficient to meet the sterilization needs of the FSBC.

1. Procedures for the proper use of sterilizing equipment for the processing of various materials and supplies shall be in writing, according to manufacturer's recommendations, and readily available to personnel responsible for the sterilizing process.

2. All sterilization monitoring logs shall be maintained within the FSBC for a minimum of 18 months.

C. All steam sterilizing equipment shall have live bacteriological spore monitoring performed at a frequency according to the manufacturer's instructions.

1. If tests are positive, a system shall be in place to recall supplies that have tested substandard in accordance with the FSBC's policies and procedures set forth by the FSBC's governing body.

D. All ethylene oxide sterilizing equipment shall have live bacteriological spore monitoring performed with each load and according to manufacturer's recommendation. There shall be ventilation of the room used for this sterilization to the outside atmosphere. There shall be a system in place to monitor trace gases of ethylene oxide with a working alert system which is tested and documented daily.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6781. Infection Control

A. The FSBC shall maintain an infection control program that minimizes infections and communicable diseases through prevention, investigation, and reporting of infections. This program shall include all contracted services.

B. The FSBC shall provide a functional and sanitary environment for the provision of delivery services by adopting and adhering to professionally accepted standards of practice. The FSBC shall have documentation that the infection control program was considered, selected, and implemented based on nationally recognized infection control guidelines.

C. The infection control program shall be under the direction of a designated and qualified professional. The FSBC shall determine that the individual selected to lead the infection control program has had documented training in the principles and methods of infection control. The individual shall maintain his/her qualifications through ongoing education and training, which can be demonstrated by participation in infection control courses or in local and national meetings organized by a nationally recognized professional infection control society.

D. The FSBC shall develop, with the approval of the clinical director and the governing body, policies and procedures for preventing, identifying, reporting, investigating, controlling, and immediately implementing corrective actions relative to infections and communicable diseases of clients and personnel. At a minimum, the policies shall address:

1. hand sanitizers and hand hygiene;

2. use of all types of gloves and personal protective equipment, as appropriate;
3. scrub procedures;
4. linen cleaning and reuse;
5. waste management;
6. environmental cleaning;
7. reporting, investigating, and monitoring of infections;
8. sterilization and cleaning procedures and processes;
9. single use devices;
10. disinfecting procedures and processes;
11. breaches of infection control practices; and
12. utilization of clean and dirty utility areas.

E. The FSBC shall have policies and procedures developed and implemented which require immediate reporting, according to the latest criteria established by the CDC, OPH, and the Occupational Safety and Health Administration (OSHA), of the suspected or confirmed diagnosis of a communicable disease.

F. The FSBC shall maintain an infection control log of incidents related to infections. The log is to be maintained within the FSBC for a minimum of 18 months.

G. Any employee with a personal potentially contagious/or infectious illness shall report to his/her immediate supervisor

and/or clinical director of midwifery services for possible reassignment or other appropriate action to prevent the disease or illness from spreading to other clients or personnel.

1. Employees with symptoms of illness that have the potential of being potentially contagious or infectious (i.e. diarrhea, skin lesions, respiratory symptoms, infections, etc.) shall be either evaluated by a physician or another qualified licensed practitioner and/or restricted from working with clients during the infectious stage.

H. Provisions for isolation of clients with a communicable or contagious disease shall be developed and implemented according to FSBC policy and procedure.

I. Provisions for transfer of clients from the FSBC shall be developed and implemented according to FSBC policy and procedure.

J. The FSBC shall develop a system by which potential complications/infections that develop after discharge of a client from the FSBC are reported, investigated, and monitored by the infection control officer.

K. Procedures for isolation techniques shall be written and implemented when applicable.

L. The FSBC shall have a written and implemented waste management program that identifies, and controls wastes and hazardous materials to prevent contamination and the spread of

infection within the FSBC. The program shall comply with all applicable laws and regulations governing wastes and hazardous materials and the safe handling of these materials.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6783. Laundry Handling and Sanitation

A. The FSBC shall be responsible for ensuring the proper handling, cleaning, sanitizing, and storage of linen and other washable goods, whether provided by the FSBC or provided by a contracted vendor. All linen used in the FSBC shall be of sufficient quantity to meet the needs of the clients.

B. Laundry services shall be provided either in-house or through a contracted commercial laundry service in accordance with the FSBC's policies and procedures, as set forth by the governing body.

1. Contracted Laundry Service

a. If laundry service is contracted, the FSBC shall assess the cleaning and sanitizing processes that are used by the commercial laundry service.

2. In-House Laundry Service

a. If laundry services are provided in-house, policies and procedures shall be developed which follow

manufacturer's recommended guidelines for water temperature, the method for cleaning and sanitizing reusable laundry, and the type of cleaning products utilized to prevent the transmission of infection through the FSBC's multi-use of these washable goods.

b. The water temperature shall be monitored and documented on a daily use log and maintained for a minimum of 18 months.

C. Procedures shall be developed for the proper handling and distribution of linens to minimize microbial contamination from surface contact or airborne deposition.

D. Cross contamination of clean and dirty linen shall be prevented. Provisions shall be made for the separation of clean and soiled linen. All contaminated laundry shall be handled according to the FSBC's written protocols in accordance with current applicable OSHA and CDC guidelines.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6785. Emergency Preparedness and Emergency Procedures

A. Disaster and emergency plans shall be developed by the governing body, updated annually, and shall be based on a risk assessment using an all hazards approach for both internal and

external occurrences. Disaster and emergency plans shall include provisions for persons with disabilities.

B. The FSBC shall develop and implement policies and procedures based on the emergency plan, risk assessment, and communication plan, which shall be reviewed and updated at least annually. Such policies shall include a system to track on duty staff and sheltered clients, if any, during the emergency.

C. The FSBC shall develop and maintain an emergency preparedness communication plan that complies with state and local laws. Client care shall be well-coordinated within the FSBC, across health care providers, and with state and local public health departments and emergency systems.

D. The FSBC shall develop and maintain training and testing programs, including initial training in policies and procedures that demonstrate knowledge of emergency procedures. Such training shall be provided at least annually.

E. Additional Requirements

1. Each FSBC shall post exit signs and diagrams conspicuously through the facility.

2. Flashlights or battery-operated lamps for emergency use shall be available for FSBC personnel and clients in areas occupied by clients and visitors and kept in operational condition.

3. The FSBC shall ensure that emergency equipment is:

a. immediately available and sufficient in number for use during emergency situations;

b. appropriate for the FSBC's client population; and

c. maintained by appropriate personnel.

4. The FSBC shall have written policies and procedures that address the availability and relevant use of the following emergency equipment in the FSBC's delivery/procedure rooms sufficient in number to handle multiple simultaneous emergencies for the clients and their newborn infants:

a. emergency call system;

b. oxygen;

c. mechanical ventilatory assistance equipment,

including:

i. airways; and

ii. manual breathing bag;

d. cardiac defibrillator;

e. cardiac monitoring equipment;

f. suction equipment; and

i. any other emergency medical equipment

and supplies specified by the clinical staff and approved by the

governing body for treatment of clients and newborn infants serviced in the FSBC.

5. The FSBC shall have battery or an operable backup generator of sufficient size to support and maintain necessary life-sustaining medical equipment, emergency lighting, fire detection and extinguishing, gas monitoring systems, and alarm and security systems to provide for the health, safety, welfare, and the well-being of persons receiving services at free-standing birth centers; and to provide for the safe operation and maintenance of free-standing birth centers.

6. The FSBC is responsible for:

a. developing and implementing policies and procedures for the safe emergency transfer of clients and/or newborn infants from the FSBC if an emergency impacts the FSBC's ability to provide services to the client and/or the newborn infants;

b. developing policies that address what types of emergency procedures, equipment and medications shall be available; and

c. providing trained staff to sustain the life of the client or newborn infant prior to the transfer.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6787. Inactivation of License due to a Declared Disaster or Emergency

A. An FSBC licensed in a parish which is the subject of an executive order or proclamation of emergency or disaster, issued in accordance with R.S. 29:724 or R.S. 29:766, may seek to inactivate its license for a period not to exceed one year, provided that the following conditions are met:

1. the FSBC shall submit written notification to the HSS within 60 days of the date of the executive order or proclamation of emergency or disaster that:

a. the FSBC has experienced an interruption in the provisions of services as a result of events that are the subject of such executive order or proclamation of emergency or disaster issued in accordance with R.S. 29:724 or R.S. 29:766;

b. the FSBC intends to resume operation as an FSBC in the same service area; and

c. the FSBC attests that the emergency or disaster is the sole causal factor in the interruption of the provision of services.

NOTE: Pursuant to these provisions, an extension of the 60-day deadline for initiation of request may be granted at the discretion of the department.

EXCEPTION: If the FSBC requires an extension of the timeframe to complete construction or repairs due to circumstances beyond the FSBC's control, the department will consider an extended time period to complete. The written request for extension shall show the FSBC's active efforts to complete construction or repairs and the reasons for request for extension of the FSBC's inactive license. Any approvals for extension are at the sole discretion of the department.

2. the FSBC resumes operating in the same service area within one year of the issuance of an executive order or proclamation of emergency or disaster in accordance with R.S. 29:724 or R.S. 29:766;

3. the FSBC continues to pay all fees and costs due and owed to the department including, but not limited to, annual licensing fees and outstanding civil monetary penalties, if applicable; and

4. the FSBC continues to submit required documentation and information to the department.

B. Upon receiving a completed written request to inactivate an FSBC license, the department shall issue a notice of inactivation of license to the FSBC.

C. Upon completion of repairs, renovations, rebuilding, or replacement, an FSBC which has received a notice of inactivation of its license from the department shall be allowed

to reinstate its license upon the following conditions being met.

1. The FSBC shall submit a written license reinstatement request to HSS 60 days prior to the anticipated date of reopening.

a. The license reinstatement request shall inform the department of the anticipated date of reopening and shall request scheduling of a licensing survey.

b. The license reinstatement request shall include a completed licensing application with appropriate licensing fees.

c. The FSBC shall submit the following:

i. a copy of the approval letter of the architectural facility plans from the OSFM and any other office/entity designated by the department to review and approve the facility's architectural plans;

ii. a copy of the on-site inspection report with approval for occupancy by OSFM, if applicable; and

iii. a copy of the on-site health inspection report with approval of occupancy from OPH.

2. The FSBC resumes operating in the same service area within one year.

D. Upon receiving a completed written request to reinstate an FSBC license, the department shall conduct a

licensing survey. If the FSBC meets the requirements for licensure and the requirements under this Section, the department may issue a notice of reinstatement of the FSBC license.

E. No CHOW of the FSBC shall occur until such FSBC has completed repairs, renovations, rebuilding, or replacement construction and has resumed operations as an FSBC.

F. The provisions of this Section shall not apply to an FSBC which has voluntarily surrendered its license and ceased operation.

G. Failure to comply with any of the provisions of this Section shall be deemed a voluntary surrender of the FSBC license.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

**§6789. Inactivation of License due to a Non-Declared
Emergency or Disaster**

A. An FSBC in an area or areas which have been affected by a non-declared emergency or disaster may seek to inactivate its license, provided that the following conditions are met:

1. the FSBC shall submit written notification to the HSS within 30 days of the date of the non-declared emergency or disaster stating that:

a. the FSBC has experienced an interruption in the provisions of services as a result of events that are due to a non-declared emergency or disaster;

b. the facility intends to resume operation as an FSBC in the same service area;

c. the FSBC attests that the emergency or disaster is the sole causal factor in the interruption of the provision of services; and

d. the FSBC's initial request to inactivate does not exceed one year for the completion of repairs, renovations, rebuilding, or replacement of the facility;

NOTE: Pursuant to these provisions, an extension of the 30-day deadline for initiation of request may be granted at the discretion of the department.

EXCEPTION: If the FSBC requires an extension of the timeframe to complete construction or repairs due to circumstances beyond the FSBC's control, the department will consider an extended time period to complete such. Written request for extension shall show the FSBC's active efforts to complete construction or repairs and the reasons for request for extension of the FSBC's inactive license.

Any approvals for extension are at the sole discretion of the department.

2. the FSBC continues to pay all fees and costs due and owed to the department including, but not limited to, annual licensing fees and outstanding civil monetary penalties and/or civil fines; and

3. the FSBC continues to submit required documentation and information to the department, including but not limited to, cost reports.

B. Upon receiving a completed written request to temporarily inactivate the FSBC license, the department shall issue a notice of inactivation of license to the FSBC.

C. Upon the FSBC's receipt of the department's approval of request to inactivate the license, the FSBC shall have 90 days to submit plans for the repairs, renovations, rebuilding, or replacement of the FSBC to OSFM and OPH as required.

D. The FSBC shall resume operating as an FSBC in the same service area within one year of the approval of renovation/construction plans by OSFM and OPH as required.

E. Upon completion of repairs, renovations, rebuilding, or replacement of the FSBC, an FSBC which has received a notice of inactivation of its license from the department shall be allowed to reinstate its license upon the following conditions being met:

1. the FSBC shall submit a written license reinstatement request to the licensing agency of the department;

2. the license reinstatement request shall inform the department of the anticipated date of opening and shall request scheduling of a licensing or physical environment survey; and

3. the license reinstatement request shall include a completed licensing application with appropriate licensing fees.

F. Upon receiving a completed written request to reinstate an FSBC license, the department may conduct a licensing or physical environment survey. The department may issue a notice of reinstatement if the FSBC has met the requirements for licensure including the requirements of this Subsection.

G. No CHOW of the FSBC shall occur until such FSBC has completed repairs, renovations, rebuilding, or replacement construction and has resumed operations as an FSBC.

H. The provisions of this Section shall not apply to an FSBC which has voluntarily surrendered its license and ceased operation.

I. Failure to comply with any of the provisions of this Section shall be deemed a voluntary surrender of the FSBC license.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

Subchapter G. Physical Environment

§6793. General Requirements

A. The standards in this Subchapter shall apply to any FSBC constructed after the effective date of this rule, or an FSBC that makes alterations, additions, or substantial rehabilitation to an existing FSBC or adaptation of an existing building to create an FSBC. Cosmetic changes to the FSBC such as painting, flooring replacement, or minor repairs shall not be considered an alteration or substantial rehabilitation.

EXCEPTION: For those applicants for FSBC licensure who received plan review approval from the OSFM before the effective date of the promulgation of this Rule, or who have begun construction or renovation of an existing building before the effective date of the promulgation of this Rule, the physical environment requirements of §6793 shall not apply.

B. An applicant for an FSBC license shall furnish one complete set of architectural plans and specifications to the entity/office designated by the department to review and approve the facility's architectural plans and the OSFM.

1. The office designated by the department to review and approve architectural drawings and specifications and the OSFM shall review and approve the *Life Safety Code* plans before construction can begin.

2. When the plans and specifications have been reviewed and all inspections and investigations have been made, the applicant will be notified whether the plans for the proposed FSBC have been approved.

C. No alterations, other than minor alternations, shall be made to existing facilities without the prior written approval of, and in accordance with, architectural plans and specifications approved in advance by the department, or its designee, and the OSFM.

D. All new construction, additions and renovations, other than minor alterations, shall be in accordance with the specific requirements of the OSFM and the department, or its designee, who shall be responsible for the review and approval of architectural plans. Plans and specifications submitted to these offices shall be prepared by or under the direction of a licensed architect and/or a qualified licensed engineer and shall include scaled architectural plans stamped by an architect.

E. All designs and construction shall be in accordance with the provisions of LAC Title 51, *Public Health-Sanitary Code*.

F. Facility within a Facility

1. If more than one health care provider occupies the same building, premises, or physical location, all treatment facilities and administrative offices for each health care facility shall be clearly separated from the other by a clearly defined and recognizable boundary.

2. There shall be clearly identifiable and distinguishable signs posted inside the building as well as signs posted on the outside of the building for public identification of the FSBC. Compliance with the provisions of R.S. 40:2007 shall be required.

3. An FSBC that is located within a building that is also occupied by one or more other businesses and/or other healthcare facilities shall have all licensed spaces and rooms of the FSBC contiguous to each other and defined by cognizable boundaries.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

§6795. General Appearance and Space Requirements

A. The FSBC shall be constructed, arranged, and maintained to ensure the safety and well-being of the clients and the general public it serves in accordance with the current Facility Guidelines for Design and Construction of Hospitals and Outpatient Facilities approved by the OSFM.

B. The FSBC shall have a minimum of two birth rooms/suites and a minimum of one postpartum room to meet the needs of the clients being served. In addition to the birth rooms/suites and postpartum rooms, the FSBC may also have one or more treatment rooms.

C. The location of the birth rooms/suites within the FSBC, and the access to it, shall conform to professionally accepted standards of practice, particularly for infection control, with respect to the movement of people, equipment and supplies in and out of the delivery rooms.

1. The temperature and humidity of the birth rooms/suites shall be monitored and maintained in accordance with accepted standards of practice and documented on a daily use log that is maintained for a minimum of 18 months.

D. Birth Rooms/Suites

1. The birth rooms/suites shall be constructed in accordance with the current OSFM approved standards.

2. The area of the birth rooms/suites shall be in a segregated and secured section of the FSBC and shall be removed

from general lines of traffic of both visitors and other FSBC personnel, and from other departments to prevent traffic through them.

3. The birth rooms/suites shall be appropriately equipped to safely provide for the needs of the client and in accordance with accepted clinical practices. The birth rooms/suites shall consist of a clear and unobstructed floor area to accommodate the equipment and personnel required, allowing for aseptic technique. Only one birth procedure can be performed in a birth room/suite.

E. Postpartum/infant Recovery Care Area

1. The postpartum/infant recovery care area, if provided and/or required, shall be constructed in accordance with the current OSFM approved standards.

F. There shall be sufficient space between and around lounge chairs/stretchers and between fixed surfaces and lounge chairs/stretchers to allow for clinical staff access to each client.

G. The FSBC shall have a separate waiting area sufficient in size to provide adequate seating space for family members and/or guests of the client.

H. The FSBC shall meet the following requirements including, but not limited to:

1. a sign shall be posted on the exterior of the FSBC that can be viewed by the public which shall contain, at a minimum, the "doing business as" name that is stated on the FSBC's license issued by the department;

2. signs or notices shall be prominently posted in the FSBC stipulating that smoking is prohibited in all areas of the FSBC;

3. policies and procedures shall be developed for maintaining a clean and sanitary environment at all times;

4. there shall be sufficient storage space for all supplies and equipment. Storage space shall be located away from foot traffic, provide for the safe separation of items, and prevent overhead and floor contamination;

5. all client care equipment shall be clean and in working order. Appropriate inspections of client care equipment shall be maintained according to manufacturer's recommendations and FSBC policies and procedures; and

6. each FSBC shall provide for a covered entrance, well-marked, and illuminated for drop off and/or pick up of clients before and after delivery services are complete. The covered entrance shall extend to provide full overhead coverage of the entire transporting automobile and/or ambulance to permit protected transfer of clients. Vehicles in the loading area

should not block or restrict movement of other vehicles in the drive or parking areas immediately adjacent to the FSBC;

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180.21-2180.28.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 47:

Family Impact Statement

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that this proposed Rule will have a positive impact on family functioning, stability and autonomy as described in R.S. 49:972 because it will provide for the safety and welfare for those receiving these services.

Poverty Impact Statement

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the poverty impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on child, individual, or family poverty in relation to individual or community asset development as described in R.S. 49:973.

Small Business Statement

In compliance with Act 820 of the 2008 Regular Session of the Louisiana Legislature, the economic impact of this proposed Rule

on small businesses has been considered. It is anticipated that this proposed Rule may have a positive impact on small businesses, as described in R.S. 49:965.2 et seq. as it implements requirements for the licensing of free-standing birth centers.

Provider Impact Statement

In compliance with House Concurrent Resolution (HCR) 170 of the 2014 Regular Session of the Louisiana Legislature, the provider impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on the staffing level and qualifications required to provide the same level of service, no direct or indirect cost to the provider to provide the same level of service, and no impact on the provider's ability to provide the same level of service as described in HCR 170.

Public Comments

Interested persons may submit written comments to Tasheka Dukes, RN, Health Standards Section, P.O. Box 3767, Baton Rouge, LA 70821. Ms. Dukes is responsible for responding to inquiries regarding this proposed Rule. The deadline for submitting written comments is at 4:30 p.m. on August 29, 2021.

Public Hearing

Interested persons may submit a written request to conduct a public hearing by U.S. mail to the Office of the Secretary

ATTN: LDH Rulemaking Coordinator, Post Office Box 629, Baton Rouge, LA 70821-0629; however, such request must be received no later than 4:30 p.m. on August 9, 2021. If the criteria set forth in R.S. 49:953(A)(2)(a) are satisfied, LDH will conduct a public hearing at 9:30 a.m. on August 26, 2021 in Room 118 of the Bienville Building, which is located at 628 North Fourth Street, Baton Rouge, LA. To confirm whether or not a public hearing will be held, interested persons should first call Allen Enger at (225) 342-1342 after August 9, 2021. If a public hearing is to be held, all interested persons are invited to attend and present data, views, comments, or arguments, orally or in writing. In the event of a hearing, parking is available to the public in the Galvez Parking Garage which is located between North Sixth and North Fifth/North and Main Streets (cater-corner from the Bienville Building). Validated parking for the Galvez Garage may be available to public hearing attendees when the parking ticket is presented to LDH staff at the hearing.

Dr. Courtney N. Phillips

Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person
Preparing
Statement: Veronica Dent Dept.: Health

Phone: 342-3238 Office: Bureau of Health Services Financing

Return
Address: P.O. Box 91030 Rule
Title: Free-Standing Birth Centers

Baton Rouge, LA Licensing Standards

Date Rule
Takes Effect: October 20, 2021

SUMMARY
(Use complete sentences)

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

It is anticipated that implementation of this proposed rule will have no programmatic fiscal impact to the state other than the cost of promulgation for FY 21-22. It is anticipated that \$12,744 will be expended in FY 21-22 for the state's administrative expense for promulgation of this proposed rule and the final rule.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

It is anticipated that the implementation of this proposed rule will result in additional licensing fees collected, dependent upon the number of providers that may apply to the program.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NON-GOVERNMENTAL GROUPS (Summary)

In compliance with Act 332 of the 2019 Regular Session of the Louisiana Legislature, this proposed rule repeals the existing LAC 48:1.Chapter 67 governing the licensing of hospitals in its entirety as these provisions are incorporated elsewhere in the *Louisiana Administrative Code* and replaces it with provisions governing licensing of free-standing birth centers. This proposed rule will benefit patients by providing for the safety, health, welfare, and well-being of persons receiving these services. It is anticipated that implementation of this proposed rule will have economic cost for free-standing birth centers; however, the costs are indeterminable since there is no way to establish how many facilities will apply for licensure.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This rule has no known effect on competition and employment.


Signature of Agency Head or Designee

Tasheka Dukes, RN
Deputy Assistant Secretary
LDH Health Standards Section
Typed Name & Title of Agency Head or Designee

07/07/2021
Date of Signature


Legislative Fiscal Officer or Designee

7/8/21
Date of Signature

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberation on the proposed rule.

- A. Provide a brief summary of the content of the rule (if proposed for adoption, or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

In compliance with Act 332 of the 2019 Regular Session of the Louisiana Legislature, this proposed rule repeals the existing LAC 48:1.Chapter 67 governing the licensing of hospitals in its entirety as these provisions are incorporated elsewhere in the *Louisiana Administrative Code* and replaces it with provisions governing licensing of free-standing birth centers.

- B. Summarize the circumstances, which require this action. If the Action is required by federal regulation, attach a copy of the applicable regulation.

Act 332 of the 2019 Regular Session of the Louisiana Legislature authorized the Department of Health to promulgate Rules relative to the licensing of free-standing birth centers (FSBCs). In compliance with Act 332, the Department of Health, Bureau of Health Services Financing proposes to repeal the existing LAC 48:1.Chapter 67 governing the licensing of hospitals in its entirety as these provisions are incorporated elsewhere in the *Louisiana Administrative Code* and replace it with provisions governing licensing of FSBCs.

- C. Compliance with Act 11 of the 1986 First Extraordinary Session

- (1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

It is anticipated that implementation of this proposed rule will have no programmatic fiscal impact to the state other than the cost of promulgation for FY 21-22. In FY 21-22, \$12,744 is included for the state's administrative expense for promulgation of this proposed rule and the final rule.

- (2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?

(a) _____ Yes. If yes, attach documentation.

(b) _____ NO. If no, provide justification as to why this rule change should be published at this time

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

I. A. COSTS OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED

1. What is the anticipated increase (decrease) in costs to implement the proposed action?

COSTS	FY 22	FY 23	FY 24
Personal Services			
Operating Expenses	\$12,744	\$0	\$0
Professional Services			
Other Charges			
Equipment			
Major Repairs & Constr.			
TOTAL	\$12,744	\$0	\$0

POSITIONS (#)

2. Provide a narrative explanation of the costs or savings shown in "A. 1.", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

In FY 21-22, \$12,744 will be spent for the state's administrative expense for promulgation of this proposed rule and the final rule.

3. Sources of funding for implementing the proposed rule or rule change.

SOURCE	FY 22	FY 23	FY 24
State General Fund	\$12,744	\$0	\$0
Agency Self-Generated			
Dedicated			
Federal Funds			
Other (Specify)			
TOTAL	\$12,744	\$0	\$0

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

Yes, sufficient funds are available to implement this rule.

B. COST OR SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED.

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.

This proposed rule has no known impact on local governmental units.

2. Indicate the sources of funding of the local governmental unit, which will be affected by these costs or savings.

There is no known impact on the sources of local governmental unit funding.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

A. What increase (decrease) in revenues can be anticipated from the proposed action?

REVENUE INCREASE/DECREASE	FY 22	FY 23	FY 24
State General Fund			
Agency Self-Generated	Increase	Increase	Increase
Dedicated Funds*			
Federal Funds			
Local Funds			
TOTAL	Increase	Increase	Increase

*Specify the particular fund being impacted.

B. Provide a narrative explanation of each increase or decrease in revenues shown in "A." Describe all data, assumptions, and methods used in calculating these increases or decreases.

It is anticipated that the implementation of this proposed rule will result in additional licensing fees collected, dependent upon the number of providers that may apply to the program.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NONGOVERNMENTAL GROUPS

- A. What persons, small businesses, or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

In compliance with Act 332 of the 2019 Regular Session of the Louisiana Legislature, this proposed rule repeals the existing LAC 48:I.Chapter 67 governing the licensing of hospitals in its entirety as these provisions are incorporated elsewhere in the *Louisiana Administrative Code* and replaces it with provisions governing licensing of free-standing birth centers. This proposed rule will benefit patients by providing for the safety, health, welfare, and well-being of persons receiving these services.

- B. Also provide an estimate and a narrative description of any impact on receipts and/or income resulting from this rule or rule change to these groups.

It is anticipated that implementation of this proposed rule will have economic cost for free-standing birth centers; however, the costs are indeterminable since there is no way to establish how many facilities will apply for licensure.

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

This rule has no known effect on competition and employment.