DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF HEALTH CARE QUALITY

Statutory Authority: 16 Delaware Code, Section 1119C (16 **Del.C.** §1119C)
16 **DE Admin. Code** 4403

FINAL

ORDER

4403 Free Standing Birthing Centers

Nature of The Proceedings

The Delaware Department of Health and Social Services ("DHSS") initiated proceedings to adopt revised Regulations Governing Free Standing Birthing Centers. The DHSS proceedings to adopt regulations were initiated pursuant to 29 Delaware Code Chapter 101 and authority as prescribed by 16 Delaware Code, Section 1119C.

On December 1, 2021 (Volume 25, Issue 6), DHSS published in the *Delaware Register of Regulations* its notice of proposed regulations, pursuant to 29 **Del.C.** § 10115. It requested that written materials and suggestions from the public concerning the proposed regulations be delivered to DHSS by January 3, 2022, after which time the DHSS would review information, factual evidence and public comment to the proposed regulations.

No written comments were received during the public comment period.

Summary of Proposal

On February 1, 2022, DHSS/Division of Health Care Quality (DHCQ) is publishing the final regulations governing Free Standing Birthing Centers.

Background

Rapid and widespread transmission of COVID-19 significantly impacted many vulnerable individuals receiving healthcare services throughout the community. Emergency regulations to require an infection prevention and control program were published in the July 2021 *Register* at 25 **DE Reg.** 25 (07/01/21) and extended in the November 2021 *Register* at 25 **DE Reg.** 460 (11/01/21).

Statutory Authority

16 **Del.C.** §1119C

Purpose

Rapid and widespread transmission of COVID-19 significantly impacted many vulnerable individuals receiving healthcare services throughout the community. While the availability of COVID-19 vaccines has helped to mitigate some of the risk, health and safety protocols must continue. To protect our most vulnerable citizens from COVID-19, Free Standing Birthing Centers must add infection prevention and control program requirements. A comprehensive infection control and prevention program based upon guidance from the Centers for Disease Control and Prevention and other nationally recognized sources is imperative for facilities to prevent or significantly decrease transmission of COVID-19 and other infections within facilities. In addition, staff at Free Standing Birthing Centers must either provide evidence of COVID-19 vaccination or undergo regular testing to prevent the transmission of COVID-19. While the state's requirements will offer employees the choice between getting vaccinated or getting tested, employers should encourage vaccination and federal guidance permits employers to require vaccinations.

Fiscal Impact

N/A

Findings of Fact:

The Department finds that the proposed regulation, as set forth in the attached copy should be adopted in the best interest of the general public of the State of Delaware.

THEREFORE, IT IS ORDERED, that the proposed State of Delaware Regulation Governing Free Standing Birthing Centers shall become effective February 11, 2022, after publication of the final regulations in the *Delaware Register of Regulations*.

1/14/2022 Molly Magarik, Secretary, DHSS
Date

~~4403~~ 3365 Free Standing Birthing Centers

1.0 Definitions

1.1 The following words and terms, when used in this regulation, should have the following meaning unless the context clearly indicates otherwise:

"**Acute Postpartum Period**" means a minimum of two hours following delivery of the placenta and until the patient is clinically stable.

"**Administrator**" means a person who is delegated the responsibility for the implementation and proper application of policies, programs and services established for the birthing center.

"**Birthing Center**" means a public or private health facility other than a hospital which is established for the purpose of delivering babies and providing immediate postpartum care. Non-emergency births are planned to occur away from the mother's usual residence following a documented period of prenatal care for a normal uncomplicated pregnancy which has been determined to be low risk through a formal risk scoring examination.

"**Birthing Service**" means the prenatal, intrapartum and postpartum care provided for individuals with uncomplicated pregnancy, labor and vaginal birth and newborns during the recovery period. Services provided in a birthing center shall be provided by a licensed physician, certified nurse midwife or certified professional midwife and a registered nurse. Services provided in a birthing center shall be limited in the following manner:

(1) surgical services shall be limited to those normally performed during uncomplicated childbirth, such as episiotomy and repair, and shall not include operative obstetrics or cesarean sections;

(2) surgical repair of a fourth degree laceration is beyond the scope of practice for the midwife;

(3) labor shall not be inhibited, stimulated or augmented with chemical agents during the first or second stage of labor;

(4) systemic analgesia may be administered and local anesthesia for pudendal block and episiotomy repair may be performed;

(5) general and conductive anesthesia shall not be administered at birthing centers;

(6) patients shall not routinely remain in the facility in excess of twenty-four (24) hours.

"**Bylaws**" means a set of rules adopted by a birthing center for governing the facility's operation.

"**Certified Midwife**" means either a Certified Nurse Midwife or a Certified Professional Midwife as defined in these regulations.

"**Certified Nurse Midwife**" means an individual who is currently licensed to practice nursing as a nurse midwife pursuant to 24 **Del.C.** Ch. 19.

"**Certified Professional Midwife**" means an individual who is currently certified to practice midwifery pursuant to 16 **Del.C.** §122(3)h and who holds a permit from the Division of Public Health.

"**Change of Ownership (CHOW)**" see "Modification of Ownership and Control (MOC)".

"Clinical Record" means a written account of all services provided to a patient by the birthing center, as well as other pertinent information necessary to provide care.

"**Department**" means the Delaware Department of Health and Social Services.

"**Governing Body or Other Legal Authority**" means the individual, partnership, agency, group, or corporation designated to assume full legal responsibility for the policy determination, management, operation and financial liability of the birthing center.

"**Hospital**" means a place devoted primarily to the maintenance and operation of facilities for the diagnosis, treatment or care for not less than 24 hours in any week of 4 or more non-related individuals suffering from illness, disease, injury or deformity or a place devoted primarily to providing for not less than 24 hours in any week of obstetrical or other medical or nursing care for 2 or more non-related individuals but does not include sanatoriums, rest homes, nursing homes or boarding homes.

"**Immediate Jeopardy**" means a crisis situation in which the health and safety of patients is at risk. It is a deficient practice which indicates an inability to furnish safe care and services.

"**Legal Entity**" means a business organizational structure that is recognized as such by 6 **Del.C.** or 8 **Del.C**.

"**License**" means the document issued by the Department which constitutes the authority to receive patients and perform services included within the scope of these regulations.

"**Licensee**" means the individual, corporation, or public entity with whom rests the ultimate responsibility for maintaining approved standards for the birthing center.

"**Low Risk**" means normal, uncomplicated prenatal course as determined by adequate prenatal care and prospects for a normal, uncomplicated birth as defined by reasonable and generally accepted criteria of maternal and fetal health.

"**Majority Interest**" means the largest percentage of ownership interest.

"**Minority Interest**" means any percentage of ownership less than the majority interest.

"**Modification of Ownership and Control (MOC)**" means the sale, purchase, transfer or re-organization of ownership rights.

"**Owner**" means an individual or legal entity with ownership rights of the facility.

"**Ownership**" means the state or fact of exclusive possession and control of the facility.

"**Ownership Interest**" means the percentage of ownership an individual or legal entity possesses.

"**Patient**" means a pregnant female who plans to deliver away from her usual residence following a documented period of prenatal care for a normal uncomplicated pregnancy which has been determined to be low risk through risk status criteria.

"**Physician**" means an individual currently licensed as such pursuant to 24 **Del.C.** Ch. 17.

"**Plan of Correction**" means a birthing center's written response to findings of regulatory non-compliance. Plans must adhere to the format specified by the licensing agency, must include acceptable timeframes in which deficiencies will be corrected and must be approved by the licensing agency.

"**Recovery Period**" means that period of time starting at the birth and ending with the discharge of the patient from the birthing center.

"**Registered Nurse**" means an individual who is currently licensed to practice nursing pursuant to 24 **Del.C.** Ch. 19.

"**Risk Status Criteria**" means

(1) patients are limited to those women who are initially determined to be at low maternity risk and who are evaluated regularly throughout pregnancy to assure that they remain at low risk for a poor pregnancy outcome;

(2) an established written risk assessment system;

(3) determination of general health status and risk assessment by a physician or certified midwife after obtaining a detailed medical history, performing a physical examination and taking into account family circumstances and other social and psychological factors;

(4) acceptance for and continuation of care throughout pregnancy and labor is limited to those women for whom it is appropriate to give birth in a setting where anesthesia is limited to local infiltration of the perineum or a pudendal block and where analgesia is limited;

(5) minimum risk factor criteria shall be applied to all patients prior to acceptance for birthing center services and throughout the pregnancy for continuation of services.

"**Survey**" means an inspection conducted by a representative of the Department to determine if a licensee is in compliance with **Del.C.** and this chapter.

"**Transfer Agreement**" means an agreement with a hospital which has an organized obstetrical services with an obstetrician and a pediatrician on active staff and 24-hour emergency care and cesarean section capability within thirty (30) minutes, providing such service on a continuing basis, stating that said hospital agrees to accept from the birthing center such cases as may need to be referred for whatever reason, and agrees to accept phone consultation for problems that arise in the birthing center.

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2.0 Licensing Requirements and Procedures

2.1 General Requirements

2.1.1 No person shall establish, conduct, or maintain in this State any birthing center without first obtaining a license from the Department.

2.1.2 Separate licenses are required for facilities maintained in separate locations, even though operated under the same management.

2.1.3 A license is not transferable from person to person or from one location to another.

2.1.4 The license shall be posted in a conspicuous place on the licensed premises.

2.1.5 Any facility that undergoes a change of ownership is required to re-apply as a new facility.

2.2 Application Process

2.2.1 All persons or entities applying for a license shall submit a written statement of intent to the Department describing the services to be offered by the facility and requesting a licensure application from the Department.

2.2.1.1 The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the Department.

2.2.1.2 Patients shall not be admitted to a facility until a license has been issued.

2.2.1.3 Applicants shall not hold themselves out to the public as being a birthing center until a license has been issued.

2.2.2 Applicants shall submit to the Department the following information:

2.2.2.1 The names, addresses and types of facilities owned or managed by the applicant;

2.2.2.2 Identity of:

2.2.2.2.1 Each officer and director of the corporation if the entity is organized as a corporation;

2.2.2.2.2 Each general partner or managing member if the entity is organized as an unincorporated entity;

2.2.2.2.3 The governing body;

2.2.2.2.4 Proof of not-for-profit status if claiming tax-exempt status; and,

2.2.2.2.5 Any officers/directors, partners, or managing members, or members of a governing body who have a financial interest of five percent (5%) or more in a licensee's operation or related businesses.

2.2.2.3 Disclosure of any officer, director, partner, employee, managing member, or member of the governing body with a felony criminal record;

2.2.2.4 Name of the individual (administrator) who is responsible for the management of the birthing center;

2.2.2.5 Policy and procedure manuals as requested;

2.2.2.6 A list of management personnel, including qualifications; and,

2.2.2.7 Any other information required by the Department.

2.3 Issuance of Licenses

2.3.1 Probationary license

2.3.1.1 A probationary license shall be granted for a period of one (1) year to all birthing centers:

2.3.1.1.1 Which have completed the blueprint and construction approval processes; and

2.3.1.1.2 Which have completed the application process and whose policies and procedures have demonstrated willingness to comply with the rules and regulations pertaining to birthing center licensure; or

2.3.1.1.3 Which have experienced a change of ownership (CHOW) and have completed the application process demonstrating a willingness to continue to comply with the rules and regulations pertaining to birthing center licensure.

2.3.1.2 All birthing centers shall have an on-site survey during the first year of operation.

2.3.1.3 A probationary license will permit a facility to hire personnel and establish a patient caseload.

2.3.1.4 A probationary license may not be renewed. A birthing center, at the time of an initial on-site survey, must meet the definition of a birthing center as contained within these regulations and must be in operation and caring for patients.

2.3.1.5 Birthing centers which, at the time of an on-site survey, do not meet the definition of a birthing center or which are not in substantial compliance with these regulations will not be granted a license.

2.3.2 Provisional license

2.3.2.1 A provisional license shall be granted, for a period of less than one year, to all birthing centers

2.3.2.1.1 Which are not in substantial compliance with these rules and regulations; or

2.3.2.1.2 Which fail to renew a license within the timeframe prescribed by these regulations.

2.3.2.2 The Department shall designate the conditions and the time period under which a provisional license is issued.

2.3.2.3 A provisional license may not be renewed unless a Plan of Correction for coming into substantial compliance with these rules and regulations, has been approved by the Department and implemented by the birthing center.

2.3.2.4 A license will not be granted pursuant to 2.3.3. after the provisional licensure period to any facility that is not in substantial compliance with these rules and regulations.

2.3.3 License

2.3.3.1 A license shall be granted, for a period of one year (12 months), to all birthing centers which are in substantial compliance with these rules and regulations at the time of application.

2.3.3.2 A license shall be effective for a twelve-month period following date of issue and shall expire one year following the issue date, unless it is: modified to a provisional, suspended or revoked, or surrendered prior to the expiration date.

2.3.3.3 Existing birthing centers must apply for renewal of licensure at least thirty (30) calendar days prior to the expiration date of the license.

2.3.3.4 A license may not be issued to a birthing center which is not in substantial compliance with these regulations or whose deficient practices present an immediate threat to the health and safety of its patients.

2.4 Disciplinary proceedings

2.4.1 The Department may impose any of the following sanctions (subsection 2.4.2 of this section) singly or in combination when it finds a licensee or former licensee is guilty of any offense described herein:

2.4.1.1 Violated any of these regulations;

2.4.1.2 Failed to submit a reasonable timetable for correction of deficiencies;

2.4.1.3 Exhibited a pattern of cyclical deficiencies which extends over a period of two or more years;

2.4.1.4 Failed to correct deficiencies in accordance with a timetable submitted by the applicant and agreed upon by the Department;

2.4.1.5 Engaged in any conduct or practices detrimental to the welfare of the patients;

2.4.1.6 Exhibited incompetence, negligence, or misconduct in operating the birthing center or in providing services to patients;

2.4.1.7 Mistreated or abused patients cared for by the birthing center; or

2.4.1.8 Refused to allow the Department access to the facility or records for the purpose of conducting surveys as deemed necessary by the Department.

2.4.2 Disciplinary sanctions:

2.4.2.1 Permanently revoke a license.

2.4.2.2 Suspend a license.

2.4.2.3 Issue a letter of reprimand.

2.4.2.4 Place a licensee on provisional status and require the licensee to:

2.4.2.4.1 Report regularly to the Department upon the matters which are the basis of the provisional status.

2.4.2.4.2 Limit practice to those areas prescribed by the Department.

2.4.2.4.3 Suspend all admissions.

2.4.2.5 Refuse a license.

2.4.2.6 Refuse to renew a license.

2.4.2.7 Otherwise discipline.

2.4.3 Imposition of Disciplinary Action

2.4.3.1 Before any disciplinary action under this chapter is taken (except as authorized by 2.4.4):

2.4.3.1.1 The Department shall give twenty (20) calendar days written notice to the holder of the license, setting forth the reasons for the determination.

2.4.3.1.2 The suspension or revocation shall become final twenty (20) calendar days after the mailing of the notice unless the licensee, within such twenty (20) calendar day period, shall give written notice of the facility's desire for a hearing.

2.4.3.1.3 If the licensee gives such notice, the facility shall be given a hearing before the Secretary of the Department or her/his designee and may present such evidence as may be proper.

2.4.3.1.4 The Secretary of the Department or her/his designee shall make a determination based upon the evidence presented.

2.4.3.1.5 A written copy of the determination and the reasons upon which it is based shall be sent to the facility.

2.4.3.1.6 The decision shall become final twenty (20) calendar days after the mailing of the determination letter unless the licensee, within the twenty (20) calendar day period, appeals the decision to the appropriate court of the State.

2.4.4 Order to immediately suspend a license

2.4.4.1 In the event the Department identifies activities which the Department determines present an immediate or imminent danger to the public health, welfare and safety requiring emergency action, the Department may issue an order temporarily suspending the licensee's license, pending a final hearing on the complaint. No order temporarily suspending a license shall be issued by the Department, with less than 24 hours prior written or oral notice to the licensee or the licensee's attorney so that the licensee may be heard in opposition to the proposed suspension. An order of temporary suspension under this section shall remain in effect for a period not longer than 60 calendar days from the date of the issuance of said order, unless the suspended licensee requests a continuance of the date for the final hearing before the Department. If a continuance is requested, the order of temporary suspension shall remain in effect until the Department has rendered a decision after the final hearing.

2.4.4.2 The licensee, whose license has been temporarily suspended, shall be notified forthwith in writing. Notification shall consist of a copy of the deficiency report and the order of temporary suspension pending a hearing and shall be personally served upon the licensee or sent by certified mail, return receipt requested, to the licensee's last known address.

2.4.4.3 A licensee whose license has been temporarily suspended pursuant to this section may request an expedited hearing. The Department shall schedule the hearing on an expedited basis provided that the Department receives the licensee's request for an expedited hearing within 5 calendar days from the date on which the licensee received notification of the Department's decision to temporarily suspend the licensee's license.

2.4.4.4 As soon as possible, but in no event later than 60 calendar days after the issuance of the order of temporary suspension, the Department shall convene for a hearing on the reasons for suspension. In the event that a licensee, in a timely manner, requests an expedited hearing, the Department shall convene within 15 calendar days of the receipt by the Department of such a request and shall render a decision within 30 calendar days.

2.4.4.5 In no event shall an order of temporary suspension remain in effect for longer than 60 calendar days unless the suspended licensee requests an extension of the order of temporary suspension pending a final decision of the Department. Upon a final decision of the Department, the order of temporary suspension shall be vacated in favor of the disciplinary action ordered by the Department.

2.4.5 Termination of license

2.4.5.1 Termination of a license to provide services as a birthing center occurs secondary to:

2.4.5.1.1 Revocation of a license or the voluntary surrender of a license in avoidance of revocation action.

2.4.5.2 Termination of rights to provide services extends to:

2.4.5.2.1 Facility;

2.4.5.2.2 Owner(s);

2.4.5.2.3 Officers/Directors, partners, managing members, or members of a governing body who have a financial interest of five percent (5%) or more in the birthing center; and

2.4.5.2.4 Corporation officers.

2.5 Modification of Ownership and Control (MOC)

2.5.1 Any proposed MOC must be reported to the Department a minimum of thirty (30) calendar days prior to the change.

2.5.2 A MOC voids the current license in possession of the facility.

2.5.3 A MOC may include but is not limited to:

2.5.3.1 Transfer of full ownership rights to a new owner;

2.5.3.2 Transfer of the majority interest to a new owner;

2.5.3.3 Transfer of ownership interests that result in the owner with the majority interest becoming a minority interest owner;

2.5.3.4 Transfer or re-organization that results in an additional majority interest that is equal in ownership rights; or,

2.5.3.5 Transfer resulting in a measurable impact upon the operational control of the facility.

2.6 Fees

2.6.1 Fees shall be in accordance with 16 **Del.C.** §122 (3)p.

2.7 Inspection

2.7.1 A representative of the Department shall periodically inspect every birthing center for which a license has been issued under this chapter. Inspections by authorized representatives of the Department may occur at any time and may be scheduled or unannounced.

2.8 Notice to Patients

2.8.1 The birthing center shall notify each patient, the patient's attending physician (as appropriate) and any third-party payers at least thirty (30) calendar days before the voluntary surrender of its license, or as directed under an order of denial, revocation, or suspension of license issued by the Department.

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3.0 General Requirements

3.1 The birthing center shall not admit, nor continue to care for, patients whose needs cannot be met by the facility.

3.1.1 A physician or certified midwife shall make a determination of general health status and risk factors after obtaining a detailed medical history, performing a physical examination and taking into account family circumstances and other social and psychological factors.

3.1.2 Acceptance for and continuation of care throughout pregnancy and labor is limited to those women for whom it is appropriate to give birth in a setting where anesthesia is limited to local infiltration of the perineum or a pudendal block and where analgesia is limited.

3.2 The birthing center shall utilize an established written risk assessment system.

3.2.1 Minimum risk factor criteria shall be applied to all patients prior to acceptance for birthing center services and throughout the pregnancy for continuation of services.

3.2.2 Patients with any minimum risk factors, including but not limited to those listed in 3.2.3, shall be referred to a physician for continuing maternity care and hospital delivery.

3.2.3 Minimum risk factors include but may not be limited to:

3.2.3.1 Patient is less than 16 years of age.

3.2.3.2 Major medical problems including but not limited to:

3.2.3.2.1 Chronic hypertension;

3.2.3.2.2 Chronic heart disease;

3.2.3.2.3 Pulmonary embolus;

3.2.3.2.4 Congenital heart defects;

3.2.3.2.5 Severe renal disease;

3.2.3.2.6 Lupus erythematosus;

3.2.3.2.7 Drug or alcohol addiction;

3.2.3.2.8 Required use of anticonvulsant drugs;

3.2.3.2.9 Bleeding disorder or hemolytic disease;

3.2.3.2.10 Paraplegia/quadriplegia;

3.2.3.2.11 Diabetes mellitus;

3.2.3.2.12 Cognitive impairment that would interfere with the ability to follow directions;

3.2.3.2.13 Morbid obesity;

3.2.3.2.14 Active genital herpes, syphilis or HIV positive;

3.2.3.2.15 The need for general or conduction anesthesia;

3.2.3.2.16 The need for a caesarian section; or

3.2.3.2.17 Serious congenital anomaly in a previous birth whose recurrence cannot be ruled out by antenatal evaluation.

3.2.3.3 Previous history of significant obstetrical complications including but not limited to:

3.2.3.3.1 Rh sensitization;

3.2.3.3.2 Previous uterine wall surgery including cesarean section;

3.2.3.3.3 Five or more term pregnancies with other risk factors;

3.2.3.3.4 Nullipara of greater than 40 years of age with other risk factors;

3.2.3.3.5 Multipara over 45 years of age with other risk factors; or

3.2.3.3.6 Previous placenta abruption.

3.2.3.4 Significant signs or symptoms of:

3 2.3.4.1 Hypertension;

3.2.3.4.2 Toxemia;

3.2.3.4.3 Polyhydramnios or oligohydramnios;

3.2.3.4.4 Abruption placenta;

3.2.3.4.5 Chorioamnionitis;

3.2.3.4.6 Malformed fetus;

3.2.3.4.7 Fetal distress;

3.2.3.4.8 Multiple gestation;

3.2.3.4.9 Intrauterine growth retardation or macrosomia;

3.2.3.4.10 Thrombophlebitis; or

3.2.3.4.11 Pyelonephritis.

3.3 All records maintained by the birthing center shall at all times be open to inspection by the authorized representatives of the Department.

3.4 No policies shall be adopted by the birthing center which are in conflict with these regulations.

3.5 The birthing center shall establish written policies regarding the rights and responsibilities of patients.

3.6 The birthing center shall establish policies and procedures that address the handling and documentation of incidents, accidents and medical emergencies.

3.7 Reports of incidents, accidents and medical emergencies shall be kept on file at the facility.

3.8 The birthing center shall establish policies which control the exposure of patients and staff to persons with communicable diseases.

3.9 The birthing center shall establish policies which require reporting of all reportable communicable diseases to the Department.

3.10 A procedure, approved by the Department and including the patients and families right to report concerns/ complaints to the Department at a telephone number established for that purpose, shall be established to enable patients and their families to have their concerns addressed without fear of reprisal.

3.11 The birthing center shall advise the Department in writing within fifteen (15) calendar days following any change in the designation of the director/administrator or other administrative personnel within the facility.

3.12 The birthing center may not establish separate facilities without first contacting and receiving approval from the Department.

3.13 The birthing center may contract for services to be provided to its patients. Individuals providing services under contract must meet the same requirements as those persons employed directly by the facility.

3.14 The director/designee shall be available at all times during the operating hours of the birthing center.

3.15 The birthing center must permit photocopying of any records or other information by, or on behalf of authorized representatives of the Department, as necessary to determine or verify compliance with these regulations.

3.16 Report of Major Adverse Incidents

3.16.1 The facility must report all major adverse incidents involving a patient to the Department within forty-eight (48) hours in addition to other reporting requirements required by law.

3.16.2 A major adverse incident includes but is not limited to:

3.16.2.1 Suspected abuse, neglect, mistreatment, financial exploitation of a patient, solicitation or harassment;

3.16.2.2 An accident that causes injury to a patient; and

3.16.2.3 The unexpected death of a patient.

3.16.3 Major adverse incidents must be investigated by the facility and a report must be generated.

3.16.4 A complete report will be forwarded to the Department within thirty (30) calendar days of occurrence or of the date that the facility first became aware of the incident.

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4.0 Governing Body

4.1 Each birthing center shall have an organized governing body (governing authority, owner or person(s) designated by the owner).

4.2 The governing body shall be ultimately responsible for:

4.2.1 The management and control of the facility;

4.2.2 The assurance of quality care and services;
4.2.3 Compliance with all federal, state and local laws and regulations;
4.2.4 Adoption of written policies and procedures which describe the functions and services of the birthing center;
4.2.5 Providing a sufficient number of appropriately qualified personnel;
4.2.6 Providing physical resources and equipment, supplies and services for the provision of safe, effective and efficient delivery of services for normal uncomplicated pregnancies to low risk mothers;
4.2.7 Developing an organizational structure establishing lines of authority and responsibility;
4.2.8 Appointing a qualified administrator;
4.2.9 Appointing members of the clinical staff, ensuring their competence and delineating their clinical privileges;
4.2.10 Conducting meetings, when the governing body is more than one person, at least annually and maintaining written minutes of the meeting(s);
4.2.11 Annual review and evaluation of the birthing center policies and services; and
4.2.12 Other relevant health and safety requirements.\

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5.0 Administration/Personnel

5.1 Administrator

5.1.1 There shall be a full-time facility administrator.
5.1.2 The administrator shall be responsible for implementing the policies adopted by the governing body.
5.1.3 The administrator shall have the overall authority and responsibility for the daily operation and management of the facility.
5.1.4 The administrator shall designate, in writing, a qualified person to act in her/his behalf during her/his absence.
5.1.5 The administrator shall review facility policies and procedures at least annually and report to the governing body on the review.
5.1.6 The authority, duties and responsibilities of the administrator shall be defined in writing and shall include but not be limited to:
5.1.6.1 Interpretation and execution of the policies of the facility;
5.1.6.2 Program planning, budgeting, management and evaluation;
5.1.6.3 Maintenance of the facility's compliance with licensure regulations and standards;
5.1.6.4 Preparation and submission of required reports;
5.1.6.5 Distribution of a written plan for the delegation of administrative responsibilities and functions in the absence of the director;
5.1.6.6 Documentation of complaints relating to the conduct or actions by licensed health care professionals and action taken secondary to the complaints; and
5.1.6.7 Conducting or supervising the resolution of complaints received from patients in the delivery of care or services received at the facility.

5.2 Clinical Director

5.2.1 The clinical director shall be responsible for implementing, coordinating and assuring quality of patient care services.
5.2.2 The clinical director shall:
5.2.2.1 Be currently licensed as a physician or nurse midwife; and
5.2.2.2 Have training and expertise in obstetric and newborn services to ensure adequate supervision of patient care services.
5.2.3 The authority, duties and responsibilities of the clinical director shall be defined in writing and shall include but not be limited to:
5.2.3.1 Review and update of facility policies, procedures and protocols;
5.2.3.2 Review and evaluate clinical staff privileges;
5.2.3.3 Recommend, to the governing body, names of qualified personnel to perform approved procedures and the corresponding clinical staff privileges to be granted;
5.2.3.4 Coordinate, direct and evaluate clinical operations of the facility;

5.2.3.5 Evaluate and recommend to the administrator the type and amount of equipment needed in the facility;

5.2.3.6 Ensure that qualified staff are on the premises when patients are in the facility;

5.2.3.7 Ensure clinical staff documentation is recorded immediately and reflects a description of care given;

5.2.3.8 Ensure that planned birthing center services are within the scope of privileges granted to the clinical staff;

5.2.3.9 Ensure the accuracy of public education information materials and activities in relation to pregnancy and birth, mother and infant care, and the facility; and,

5.2.3.10 Recommend to the administrator appropriate remedial action and disciplinary action, when necessary, to correct violations of clinical protocols.

5.3 Clinical Staff

5.3.1 There shall be a single organized professional staff consisting of physicians, nurse midwives or certified professional midwives and registered nurses.

5.3.2 The organized professional staff shall have the overall responsibility for the quality of all clinical care provided to patients.

5.3.3 There shall be sufficient, qualified personnel available to perform the services offered by the facility.

5.3.4 All clinical staff who perform services in the facility who are required by state law to be licensed, registered or certified shall have valid licenses, registrations or certificates.

5.3.5 A physician certified by the American Board of Obstetrics and Gynecology or who is qualified and authorized by training and experience in obstetrics and gynecology shall be immediately available by telephone twenty-four hours a day.

5.3.6 Each physician providing services for the facility must demonstrate hospital admitting privileges for patients who develop complications.

5.3.7 Each certified mid-wife (nurse or professional) providing services for the facility must provide proof of a back-up agreement with a physician who will accept consultation calls and referrals twenty-four (24) hours a day, seven (7) days a week.

5.3.7.1 The back-up physician must demonstrate hospital admitting privileges for patients who develop complications.

5.3.8 The facility shall establish a job description for each classification of position, which clearly delineates qualifications, duties, authority, and responsibilities inherent in each position.

5.3.9 A physician or certified mid-wife shall be present at each birth and until the woman and newborn are stable postpartum.

5.3.9.1 A second person in addition to the above, who is a registered nurse with adult and infant resuscitation skills, shall be present during the delivery.

5.3.10 A certified mid-wife or registered nurse with adult and infant resuscitation skills shall be present at the facility at all times when a patient is present.

5.3.11 Clinical staff shall comply with facility policies and procedures.

5.3.12 Clinical staff shall comply with applicable professional practice standards.

5.4 Written Policies

5.4.1 Policy manuals shall be prepared and followed which outline the procedures and practices of the facility.

5.4.2 There shall be written policies regarding the screening criteria, risk status criteria and procedures for identifying:

5.4.2.1 Low-risk patients who shall be eligible for birthing services offered by the birthing center, and

5.4.2.2 Individuals who shall be ineligible for birthing services at the birthing center.

5.4.3 There shall be written policies regarding:

5.4.3.1 Identification and transfer of patients who, during the course of pregnancy, are determined to be ineligible, and

5.4.3.2 Identification and transfer of patients who, during the course of labor or recovery, are determined to be ineligible for continued care in the birthing center.

5.4.4 There shall be written policies for:

5.4.4.1 Consultation, back-up services, transfer and transport of a newborn or maternal patient to a hospital;

5.4.4.2 Routine and emergency care of both the maternal and the fetus or newborn patient until completion of care by the birthing center either through completion of the care program or through transfer to another level of care;

5.4.4.3 Care following discharge for both the patient and the newborn;

5.4.4.4 The provision of education to patients, family and support persons in childbirth and newborn care;

5.4.4.5 Birth reporting requirements; and

5.4.4.6 Infection control.

5.4.5 There shall be written personnel policies, including but not limited to:

5.4.5.1 Pre-employment requirements;

5.4.5.2 Position descriptions;

5.4.5.3 Orientation of all new employees;

5.4.5.4 Inservice education;

5.4.5.5 Annual performance review and competency; and

5.4.5.6 The process of appointment to the professional staff whereby it can satisfactorily be determined that the individual is appropriately licensed and qualified for the privileges and responsibilities to be given.

5.4.6 There shall be written policies designed to enhance safety within the facility and on its premises and to minimize hazards to patients, staff and visitors including:

5.4.6.1 Rules and practices pertaining to personnel, equipment, liquids, drugs and hazards to children including but not limited to electrical outlets, unsafe toys, stairs, storage cabinets, kitchen cabinets and outdoor areas;

5.4.6.2 Reporting and investigation of accidental events and corrective action taken;

5.4.6.3 Dissemination of safety-related information to employees and users of the facility;

5.4.6.4 Syringe and needle storage, handling and disposal;

5.4.6.5 Storage and handling of drugs and biologicals;

5.4.6.6 A preventative maintenance program which is implemented to keep the entire facility and equipment in good repair and to provide for the safety, welfare and comfort of the occupants of the building(s);

5.4.6.7 Housekeeping;

5.4.6.8 Safe storage of cleaning materials and pesticides and other potentially toxic materials;

5.4.6.9 Safe storage and handling of soiled linen and clothing;

5.4.6.10 Pest control; and

5.4.6.11 Waste disposal.

5.4.7 Policies shall be reviewed and dated annually and revised as necessary.

5.4.8 Policies shall be made available to representatives of the Department upon request.

5.5 Personnel Records

5.5.1 Records of each employee/contractor shall be kept current and available upon request by authorized representatives of the Department.

5.5.2 The facility shall maintain individual personnel records which shall contain at least:

5.5.2.1 Written verification of compliance with pre-employment requirements;

5.5.2.2 Documentation of participation in a formal orientation program to the facility;

5.5.2.3 Copies of professional licenses, registrations or certifications;

5.5.2.4 Documentation of competence;

5.5.2.5 Educational preparation and work history;

5.5.2.6 Written performance reviews (annually); and

5.5.2.7 A letter of appointment specifying conditions of employment.

5.6 Employment Practices

5.6.1 Health History

5.6.1.1 All new personnel shall be required to have a physical examination prior to providing care.

5.6.1.1.1 The physical examination must have been completed within 3 months prior to initial employment.

5.6.1.1.2 A copy of the physical examination shall be maintained in individual files.

5.6.1.2 Minimum requirements for tuberculosis (TB) testing are those currently recommended by the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services. Testing must be completed within ninety (90) calendar days prior to provision of birthing center services and annually thereafter.

5.6.1.2.1 No person found to have active TB in an infectious stage shall be permitted to give care or service to patients.

5.6.1.2.2 Any person having a positive skin test but a negative chest X-ray must complete a statement annually attesting that they have experienced no symptoms which may indicate active TB infection.

5.6.1.2.3 A report of all TB test results and all attestation statements shall be on file.

5.6.2 It is the responsibility of the birthing center to ensure that personnel are proficient to carry out the care assigned in a safe, effective and efficient manner.

5.6.3 Any individual who cannot adequately perform her/his duties or who may jeopardize the health or safety of the patients shall be relieved of his duties and removed from the facility until such time as the condition is resolved. This includes infections of a temporary nature.

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6.0 Patient Care

6.1 Admissions

6.1.1 Only those mothers who demonstrate the potential for a normal uncomplicated course of pregnancy and labor may be accepted for childbirth at the facility.

6.1.1.1 The facility must utilize a written risk assessment system to determine risk status criteria.

6.1.1.2 Those mothers determined to be at risk as defined in Sec. 3.2 must be referred to a physician for care.

6.1.2 All patients admitted to the facility shall be under the direct care of a member of the clinical staff and agree to remain at the facility not less than four (4) hours postpartum.

6.1.3 The facility and the patient shall have a written agreement for services which shall include:

6.1.3.1 An explanation of the services available;

6.1.3.2 An explanation of services not available, including types of anesthesia;

6.1.3.3 The location (distance and driving time) of the nearest hospital providing obstetrical/gynecological/ pediatric services; and

6.1.3.4 A statement of charges for services.

6.1.4 Every woman seeking birthing center services shall have an initial assessment by a professional member of the staff to determine eligibility for admission.

6.2 Prenatal Care

6.2.1 A childbirth education program shall be provided or made available by the birthing center. The program shall include but not be limited to:

6.2.1.1 Prenatal care and its outcome;

6.2.1.2 Care of the newborn;

6.2.1.3 Instruction regarding labor and delivery; and

6.2.1.4 Preparation for participation in the childbirth process.

6.2.2 Prenatal care shall be in accordance with acceptable standards.

6.2.3 When, in the course of prenatal care, risk factors are identified which preclude childbirth at the facility, the patient shall be referred for care to a qualified physician.

6.2.4 Prenatal visits shall be scheduled:

6.2.4.1 At least every four (4) weeks until the twenty-eighth (28th) week;

6.2.4.2 At least every two (2) weeks between the twenty-eighth (28th) week and the thirty-sixth (36th) week; and

6.2.4.3 At least every week between the thirty-sixth (36th) week and delivery.

6.3 Intrapartum Care

6.3.1 A professional staff member must be present and available to the patient at all times during her stay at the facility.

6.3.2 The professional staff shall monitor the progress of labor and the condition of the patient and fetus at sufficient frequent intervals to identify abnormalities or complications at the earliest possible time.

6.3.3 If complications occur in the course of labor and delivery, it is the responsibility of the professional staff to arrange for the patient to be transferred to the hospital.

6.3.4 The family or support persons shall be instructed as needed to assist the patient during labor and delivery.

6.3.5 Interventions shall be limited to those required to accomplish a vaginal delivery.

6.3.6 Labor shall not be inhibited, stimulated or augmented with chemical agents.

6.3.7 No surgical procedures shall be performed except episiotomy, repair of episiotomy or laceration, or circumcision.

6.3.8 Systemic analgesics and local anesthesia may be administered under the following conditions:

6.3.8.1 The professional staff member who administers the systemic analgesic is legally authorized to do so;

6.3.8.2 The dosage and drug are specifically noted in the protocols for clinical services; and

6.3.8.3 The use of such drugs is in conformance with the policies and procedures of the facility and with national standards.

6.3.9 General and conduction anesthesia shall not be administered.

6.4 Postpartum Care

6.4.1 The patient shall remain at the facility a minimum of four (4) hours postpartum after a normal uncomplicated birth.

6.4.2 Postpartum care shall be delivered in accordance with acceptable professional standards and legal requirements.

6.4.3 The newborn shall be referred to a physician or a hospital for any condition requiring medical care.

6.4.4 The condition of the patient shall be monitored frequently to detect signs of hemorrhage or other complications requiring prompt transfer to a hospital.

6.4.5 The patient shall be counseled regarding breast feeding, perineal care, family planning, signs of common complications, activities and exercise, sexual relations, care and feeding of the newborn and changing family relationships.

6.4.6 A member of the facility's professional staff must be accessible to patients by telephone, twenty-four (24) hours a day.

6.4.7 The facility must make provisions for appropriate follow-up care for the patient and newborn after discharge.

6.5 Management of Emergencies

6.5.1 Criteria shall be established to determine risk status which requires medical consultation or transfer to a hospital and shall include but not be limited to:

6.5.1.1 Premature labor (occurring at less than thirty-seven (37) weeks gestation);

6.5.1.2 Development of hypertension or pre-eclampsia;

6.5.1.3 Non-vertex presentation

6.5.1.4 Failure to progress in labor

6.5.1.5 Evidence of an infectious process;

6.5.1.6 Suspected placenta previa or abruption;

6.5.1.7 Hemorrhage of greater than 500 cc of blood;

6.5.1.8 Premature rupture of the membranes (occurring within a timeframe agreed upon by the certified midwife and back-up physician in their collaborative agreement);

6.5.1.9 Suspected congenital anomaly;

6.5.1.10 Anemia consisting of less than ten (10) grams of hemoglobin per one hundred (100) milliliters of blood or thirty (30) percent hematocrit;

6.5.1.11 Persistent fetal tachycardia (heart rate greater than 160 beats per minute), repetitive fetal bradycardia (heart rate less than 120 beats per minute) or undiagnosed abnormalities of the fetal heart tones;

6.5.1.12 Rising antibody titre of any type that is known to affect fetal well-being;

6.5.1.13 Excessive need for analgesia during labor, or for anesthesia other than pudendal or local; or

6.5.1.14 Persistent hypothermia in the newborn.

6.5.2 Criteria shall be established to determine risk status which requires immediate emergency transfer to a hospital and shall include but not be limited to:

6.5.2.1 Prolapsed cord;

6.5.2.2 Uncontrolled hemorrhage;

6.5.2.3 Need for transfusion;
6.5.2.4 Placenta abruption;
6.5.2.5 Retained placenta greater than sixty (60) minutes;
6.5.2.6 Convulsions;
6.5.2.7 Thick meconium staining at the time of membrane rupture;
6.5.2.8 Apgar score of seven (7) or less at five (5) minutes;
6.5.2.9 Fetal heart rate of ninety (90) or less beats per minute for three (3) minutes;
6.5.2.10 Major anomaly of the newborn;
6.5.2.11 Respiratory distress in the newborn;
6.5.2.12 Newborn weight less than 2500 grams;
6.5.2.13 Newborn need for oxygen beyond five (5) minutes; or
6.5.2.14 Signs of prematurity.

6.6 Food Service

6.6.1 The facility may provide patients and families with nutritious liquids and snacks as needed.

6.6.2 When the facility policy allows for the preparation and/or storage of food brought in by the patients or families:

6.6.2.1 There shall be refrigerator able to maintain cold foods at a temperature of 45° Fahrenheit or lower;
6.6.2.2 There shall be a stove and/or a microwave oven;
6.6.2.3 There shall be dry storage and counter space; and
6.6.2.4 There shall be a dishwashing machine and/or a sink.

6.6.3 Food may not be stored together with medications requiring refrigeration.

6.6.4 All refrigerated food items must be labeled and dated.

6.6.5 If applicable, the facility's food services will be subject to the food establishment requirements.

6.7 Pharmaceutical Service

6.7.1 Medicines and drugs maintained at the facility shall be properly stored and secured in specifically designated cabinets, closets, drawers or storerooms.

6.7.2 Only authorized persons shall have access to storage enclosures.

6.7.3 Controlled drugs shall be stored in accordance with state and federal laws.

6.7.3.1 Records shall be kept on the receipt and disposition of all controlled substances.

6.7.4 Medicines and drugs shall not be administered to patients unless ordered by an independent licensed practitioner with prescriptive authority.

6.7.4.1 Orders for medicines and drugs must be in writing and must be signed by the prescribing licensed practitioner.

6.7.4.1.1 Verbal and telephone orders may only be received by a registered nurse, midwife, physician or pharmacist.

6.7.4.1.2 All verbal and telephone orders must be countersigned by the ordering practitioner within forty-eight (48) hours of the order.

6.7.4.2 Pain control should depend primarily on close emotional support and adequate preparation for the birth experience.

6.7.5 All medicines and drugs must be properly labeled according to state and federal law.

6.7.6 Medicines and drugs requiring refrigeration must be stored and secured in a refrigerator for that purpose.

6.7.7 Medicines and drugs shall be administered only by persons authorized and licensed to administer medicines and drugs.

6.7.8 When the facility maintains its own pharmaceutical services, it shall comply with applicable state laws and regulations.

6.8 Laboratory Service

6.8.1 Clinical pathology services shall be available as required by the needs of the patients and as determined by the facility staff.

6.8.2 The facility may either provide a clinical laboratory or make contractual arrangement with an outside laboratory.

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7.0 Clinical Record

7.1 A clinical record shall be maintained for every patient and newborn admitted to and cared for in the facility.

7.2 A person knowledgeable in the management of clinical records shall be responsible for the proper administration and functioning of the clinical records section.

7.3 There shall be an identified locked area for clinical record storage at the facility.

7.4 Clinical records shall be protected from loss, damage and unauthorized use.

7.5 The facility shall ensure that each clinical record is treated with confidentiality and is maintained according to professional standards of practice.

7.6 The clinical records shall contain sufficient accurate documentation of significant clinical information pertaining to the patient and newborn to justify the diagnosis and warrant the treatment and end results including but not limited to:

- 7.6.1 Complete patient identification including a unique identification number;
- 7.6.2 Admission date and time;
- 7.6.3 Discharge date and time;
- 7.6.4 Admission diagnosis;
- 7.6.5 Medical history;
- 7.6.6 Physical examination completed prior to the birth;
- 7.6.7 Labor and delivery record;
- 7.6.8 Diagnostic tests, laboratory and x-ray reports when appropriate;
- 7.6.9 Progress notes;
- 7.6.10 Properly executed informed consent;
- 7.6.11 Record of anesthesia, analgesia and medications administered during the course of labor, delivery and postpartum;
- 7.6.12 Condition upon discharge;
- 7.6.13 Final diagnosis;
- 7.6.14 Instructions for follow-up care of the patient and newborn;
- 7.6.15 Prenatal care record including at least:
  - 7.6.15.1 Hemoglobin/Hematocrit;
  - 7.6.15.2 Urine screening;
  - 7.6.15.3 Prenatal blood serology;
  - 7.6.15.4 RH factor determination;
  - 7.6.15.5 Rubella titre; and
  - 7.6.15.6 Prenatal instructions.

7.7 Newborn clinical records shall be maintained separately and shall include:

- 7.7.1 Date and hour of birth;
- 7.7.2 Birth weight;
- 7.7.3 Birth length;
- 7.7.4 Period of gestation;
- 7.7.5 Sex;
- 7.7.6 Condition of newborn on delivery, including APGAR rating and any resuscitative measures taken;
- 7.7.7 Mother's name and unique identification number;
- 7.7.8 Record of:
  - 7.7.8.1 Ophthalmic prophylaxis;
  - 7.7.8.2 Administration of RH immune globulin as appropriate;
  - 7.7.8.3 Genetic screening; and
  - 7.7.8.4 Fetal monitoring.
- 7.7.9 Birth and discharge physical examination;
- 7.7.10 Copy of birth certificate; and
- 7.7.11 Instructions for follow-up care.

7.8 All entries in the clinical record must be signed and dated by the responsible person in accordance with the facility's policies and procedures.

7.9 Computerized clinical records must be printed by the facility as requested by authorized representatives of the Department.

7.10 The facility records shall be retained in a retrievable form until destroyed.

7.10.1 Records of adults (18 years of age and older) shall be retained for a minimum of six (6) years after the last date of service before being destroyed.

7.10.2 Records of minors (less than 18 years of age) shall be retained for a minimum of six (6) years after the patient reaches eighteen (18) years of age.

7.10.3 The facility must establish procedures for the notification to patients regarding the pending destruction of clinical records.

7.10.4 All records must be disposed of by shredding, burning, or other similar protective measure in order to preserve the patients' rights of confidentiality.

7.10.5 Documentation of record destruction must be maintained by the facility.

7.11 The facility must develop acceptable policies for authentication of any computerized records.

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8.0 Physical Environment

8.1 Laundry and Linens

8.1.1 An adequate supply of clean linen or disposable materials shall be maintained.

8.1.2 Clean linen shall be stored, handled and transported to prevent contamination.

8.1.3 Linens shall be maintained in good repair.

8.1.4 Soiled linen shall be handled, transported, stored and processed in a manner to prevent leakage and the spread of infection.

8.1.5 There shall be distinct areas for the storage and handling of clean and soiled linens.

8.1.6 Soiled linen not processed on a daily basis must be stored in a separate properly ventilated storage area.

8.1.7 Soiled linen must be removed from the birth room after each procedure.

8.1.8 Carts used to transport soiled linen must be constructed of impervious materials and must be cleaned and disinfected after each use.

8.1.9 Laundry processed on-site:

8.1.9.1 The laundry processing area shall be arranged to allow for an orderly progressive flow of work from the soiled to the clean area.

8.1.9.2 The temperature of water during the washing process shall be controlled to provide a minimum temperature of 165° Fahrenheit for 25 minutes or 130° Fahrenheit if the soap/detergent supplier will verify that their products will work effectively at that lower temperature. A label indicating same shall be affixed to the laundry machine.

8.1.10 Laundry processed off-site:

8.1.10.1 The facility must have a contract with a commercial or hospital laundry.

8.1.10.2 Clean linens returned to the facility must be completely wrapped or covered to protect against contamination.

8.2 Sanitation and Housekeeping

8.2.1 The facility shall provide housekeeping services to maintain a clean, sanitary, safe environment which is free from odors.

8.2.2 Birth rooms shall be thoroughly cleaned after each use.

8.2.3 All cleaning materials, solutions, cleaning compounds and hazardous substances shall be:

8.2.3.1 Properly identified;

8.2.3.2 Stored in a safe place; and

8.2.3.3 Stored separate from care items and food.

8.2.4 Cleaning shall be performed in a manner which minimizes the spread of pathogenic organisms in the environment.

8.2.5 The facility shall be kept free of insects and rodents. A contract with a pest control agency shall be executed and available for review.

8.3 Waste Storage and Disposal

8.3.1 All rubbish and refuse containers shall be impervious, lined and clean.

8.3.2 All rubbish and refuse shall be collected, stored and disposed of in a manner designed to prevent transmission of disease.

8.3.3 All contaminated dressings, pathological or similar waste shall be properly disposed of.

8.3.4 All personnel must wash their hands immediately after handling rubbish or refuse.

8.4 Maintenance

8.4.1 The facility shall establish and implement a written program of preventive maintenance to ensure that all essential mechanical, electrical and patient care equipment is in safe operating condition.

8.4.2 Stairwells and corridors shall be kept free from obstruction at all times.

8.5 Safety

8.5.1 Fire safety:

8.5.1.1 The facility shall comply with the rules and regulations of the State Fire Prevention Commission.

8.5.1.2 The facility must be inspected annually by the fire marshal having jurisdiction and all applications for license (new and renewal) must include a letter certifying compliance by the fire marshal having jurisdiction.

8.5.1.3 Notification of non-compliance with the rules and regulations of the State Fire Prevention Commission shall be grounds for licensure action.

8.5.1.4 A simulated fire drill shall be performed every quarter on each work shift.

8.5.1.4.1 A written record of each fire drill shall be kept on file at the facility.

8.5.1.4.2 The written record must include the following:

8.5.1.4.2.1 Date and time of the drill;

8.5.1.4.2.2 Description of the simulated emergency fire condition;

8.5.1.4.2.3 Signatures and titles of those participating in the drill;

8.5.1.4.2.4 Duration of the drill; and,

8.5.1.4.2.5 Evaluation of the drill.

8.5.2 Facility safety:

8.5.2.1 The facility shall make provisions for the reporting and investigation of and corrective action for accidental events regarding patients, visitors and personnel.

8.5.2.2 Needles and syringes shall be disposed of appropriately.

8.5.2.3 Every bathroom door lock shall be designed to permit the opening of the locked door from the outside in an emergency.

8.5.2.4 Each birthing room shall have a nurse call system.

8.5.2.5 Each toilet and bathing area shall have grab bars and a nurse call system.

8.5.2.6 The temperature of the water supply to shower, bathing and handwashing facilities shall be automatically regulated not to exceed 110° Fahrenheit.

8.5.2.7 Emergency numbers shall be located near the telephone.

8.5.2.8 There shall be a written evacuation plan for the removal of patients in the event of an emergency.

8.5.2.8.1 The evacuation plan shall be posted in a conspicuous place on each floor of the building.

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9.0 Physical Plant

9.1 Minimum construction requirements are set forth herein.

9.2 All construction, new/renovations/remodeling, must conform to the design and construction standards recognized by the Department.

9.3 In the event that there is a conflict between the design and construction standard utilized by the Department and the minimum standard set forth herein, the higher standard or requirement shall prevail.

9.4 When a facility is classified under this law or regulation and plans to construct, extensively remodel or convert any building, one (1) copy of properly prepared plans and specifications for the entire facility shall be presented to the Department.

9.4.1 An approval, in writing, shall be obtained from the Department before construction/renovation/remodeling work is begun.

9.4.2 Upon completion of construction/renovation/remodeling, in accordance with the plans and specifications, the Department will inspect and approve the site prior to occupancy/use by the facility.

9.5 All facilities shall either be at grade level or shall be equipped with ramps or elevators to allow easy access for persons with disabilities.

9.6 The facility shall comply with all local and state building codes and ordinances as pertain to this occupancy.

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10.0 Equipment and Supplies

10.1 The facility shall be equipped with those items needed to provide low risk maternity care and shall include equipment to initiate emergency procedures in life-threatening events to mother and newborn.

10.2 Equipment shall include but not be limited to:

10.2.1 Furnishings suitable for labor, delivery and recovery;

10.2.2 Oxygen with flow meters and masks or equivalent;

10.2.3 Mechanical and bulb suction;

10.2.4 Resuscitation equipment for the mother and newborn;

10.2.5 Emergency medications, intravenous fluids and related supplies and equipment for both the mother and newborn;

10.2.6 Fetal monitoring equipment;

10.2.7 A means for monitoring and maintaining the optimum body temperature of the newborn;

10.2.8 An infant scale;

10.2.9 A clock with a sweep second hand;

10.2.10 Sterile suturing equipment and supplies; and

10.2.11 An adjustable examination light.

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11.0 Patient Rights

11.1 The facility shall establish and implement policies and procedures regarding the rights of patients.

11.2 The facility must provide the patient with a written notice of the patient's rights during the initial assessment visit or before admission for services.

11.3 Each patient shall have the right to:

11.3.1 Be treated with courtesy, consideration, respect and dignity;

11.3.2 Self-determination and choice, including the opportunity to participate in developing one's plan for care;

11.3.3 Privacy and confidentiality;

11.3.4 Be protected from abuse, neglect, mistreatment, financial exploitation, solicitation and harassment;

11.3.5 Voice grievances without discrimination or reprisal;

11.3.6 Be fully informed, as evidenced by the patient's written acknowledgment of these rights, of all rules and regulations regarding patient conduct and responsibilities;

11.3.7 Be fully informed, at the time of admission, of services and activities available and related charges;

11.3.8 Be served by individuals who are properly trained and competent to perform their duties;

11.3.9 Refuse services and to be informed of possible negative consequences of her refusal;

11.3.10 To refuse to participate in experimental research;

11.3.11 Receive all the information needed to give informed consent for any proposed procedure or treatment. This information shall include the possible risks and benefits of the procedure or treatment; and,

11.3.12 Request transfer from the facility to another health care facility.

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12.0 Disaster Preparedness

12.1 The facility shall have a current internal emergency plan(s) that provides for fires, bomb threats, severe weather, utility service failures and other disasters such as earthquakes, flooding, chemical spills and toxic fumes.

12.2 The disaster preparedness plan(s) must include provisions for relocation of persons within the building and/or partial or total evacuation.

12.3 All facility staff must be oriented to the disaster preparedness plan(s).

12.3.1 Records of staff attendance must be maintained in the employee file.

12.4 A copy of the disaster preparedness plan(s) shall be available to all staff.

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13.0 Quality Improvement

13.1 Each facility shall develop and implement a documented ongoing quality improvement program. The program shall include at a minimum:

13.1.1 An internal monitoring process that tracks performance measures;

13.1.2 A review of the program's goals and objectives at least annually;

13.1.3 A review of the grievance/complaint process;

13.1.4 A review of all major adverse incidents;

13.1.5 A review of actions taken to address identified issues; and

13.1.6 A process to monitor the satisfaction of the patients with the services of the facility.

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14.0 Infection Prevention and Control Program

14.1 The birthing center shall establish and implement an infection prevention and control program which shall be based upon Centers for Disease Control and Prevention and other nationally recognized infection prevention and control guidelines.

14.1.1 The infection prevention and control program must cover all services and each particular area of the birthing center, including provision of the appropriate personal protective equipment for all patients, staff and visitors.

14.2 The individual designated to lead the birthing center's infection prevention and control program must develop and implement a comprehensive plan that includes actions to prevent, identify, and manage infections and communicable diseases. The plan must include mechanisms that result in immediate action to take preventive or corrective measures that improve the birthing center's infection control outcomes.

14.3 All birthing center staff shall receive orientation at the time of employment and annual in-service education regarding the infection prevention and control program.

14.4 Specific Requirements for COVID-19

14.4.1 Before their start date, all new staff, vendors and volunteers must be tested for COVID-19 in accordance with Division of Public Health guidance.

14.4.2 All staff, vendors and volunteers must be tested for COVID-19 in a manner consistent with Division of Public Health guidance.

14.4.3 The birthing center must follow recommendations of the Centers for Disease Control and Prevention and the Division of Public Health regarding the provision of care or services to patients by staff, vendor or volunteer found to be positive for COVID-19 in an infectious stage.

14.5 The birthing center shall amend their policies and procedures to include:

14.5.1 Work exclusion and return to work protocols for staff tested positive for COVID-19;

14.5.2 Staff refusals to participate in COVID-19 testing;

14.5.3 Staff refusals to authorize release of testing results or vaccination status to the birthing center;

14.5.4 Procedures to obtain staff authorizations for release of laboratory test results to the birthing center to inform infection control and prevention strategies; and

14.5.5 Plans to address staffing shortages and the birthing center demands should a COVID-19 outbreak occur.

~~14.0~~ 15.0Severability

~~14.1~~ In the event any particular clause or section of these regulations should be declared invalid or unconstitutional by any court of competent jurisdiction, the remaining portions shall remain in full force and effect.

12 DE Reg. 235 (08/01/08)

25 DE Reg. 777 (02/01/22) (Final)