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**Aspen State Regulation Set: B 2.02 BIRTH CENTERS**

**ST - B0000 - INITIAL COMMENTS**

**Title** INITIAL COMMENTS

**Statute or Rule**

**Type** Memo Tag

**Regulation Definition**

**Interpretive Guideline**

These guidelines are meant solely to provide guidance to surveyors in the survey process.

Birth Center Citations are not classed.

**ST - B0001 - Definitions**

**Title** Definitions

**Statute or Rule** 59A-11.002 FAC; 383.302 FS

**Type** Memo Tag

**Regulation Definition**

**Interpretive Guideline**

59A-11.002 Definitions.

- (1) " AAAHC " means the Accreditation Association for Ambulatory Health Care.
- (2) " Adjacent " means nearby and easily accessible.
- (3) " Agency " means the Agency for Health Care Administration.
- (4) " CABC " means the Commission for the Accreditation of Birth Centers.
- (6) " 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.

383.302 Definitions of terms used in ss. 383.30-383.335.-As used in ss. 383.30-383.335, the term:

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- (1) " Agency " means the Agency for Health Care Administration.
- (2) " Birth center " means any facility, institution, or place, which is not an ambulatory surgical center or a hospital or in a hospital, in which births are planned to occur away from the mother ' s usual residence following a normal, uncomplicated, low-risk pregnancy.
- (3) " Clinical staff " means individuals employed full time or part time by a birth center who are licensed or certified to provide care at childbirth.
- (4) " Consultant " means a physician licensed pursuant to chapter 458 or chapter 459 who agrees to provide advice and services to a birth center and who either:
  - (a) Is certified or eligible for certification by the American Board of Obstetrics and Gynecology, or
  - (b) Has hospital obstetrical privileges.
- (5) " Governing body " means any individual, group, corporation, or institution which is responsible for the overall operation and maintenance of a birth center.
- (6) " Governmental unit " means the state or any county, municipality, or other political subdivision or any department, division, board, or other agency of any of the foregoing.
- (7) " Licensed facility " means a facility licensed in accordance with s. 383.305.
- (8) " Low-risk pregnancy " means a pregnancy which is expected to result in an uncomplicated birth, as determined through risk criteria developed by rule of the department, and which is accompanied by adequate prenatal care.
- (9) " Person " means any individual, firm, partnership, corporation, company, association, institution, or joint stock association and means any legal successor of any of the foregoing.
- (10) " Premises " means those buildings, beds, and facilities located at the main address of the licensee and all other buildings, beds, and facilities for the provision of maternity

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care located in such reasonable proximity to the main address of the licensee as to appear to the public to be under the dominion and control of the licensee.

**ST - B0010 - Licensure**

**Title** Licensure

**Statute or Rule** 383.305(2) FS; 59A-11.003(1-2)

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

383.305(2)

Each applicant for licensure and each licensee must comply with the requirements of this chapter and part II of chapter 408

59A-11.003(1-2)

(1) All persons contemplating the operation of a birth center under the provision of Chapter 383, F.S., shall make application to the Agency on the Health Care Licensing Application, Birth Center AHCA Form 3130-3001, July 2014, which is incorporated by reference, and shall receive a standard or provisional license prior to the acceptance of clients. The form is available at <https://www.flrules.org/Gateway/reference.asp?No=Ref-04594> and available from the Agency for Health Care Administration, 2727 Mahan Drive, Mail Stop 31, Tallahassee, Florida 32308, or at the web address at:

<http://ahca.myflorida.com/HQAlicensureforms>.

(2) Each birth center applying for a license shall be designated by a distinctive name and the name shall not be changed without first notifying the Agency and receiving approval in writing. Duplication of an existing birth center 's name is prohibited in new birth centers. The birth center 's occupancy permit and in the case of persons applying for a license prior to purchase, where the birth center is licensed under other

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ownership, a signed agreement to correct physical deficiencies listed in the most recent licensure inspection and the most recent life safety inspection, unless otherwise modified herein, shall accompany the initial application.

**ST - B0014 - Governing Body (GB)**

**Title** Governing Body (GB)

**Statute or Rule** 59A-11.005(1), F.A.C.; 383.307(1a)

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

59A-11.005

(1) A governing body organized under and have written bylaws, rules and regulations, which it reviews at least every two years, denotes dates to indicate time of last review, and revises as necessary and enforces. The governing body bylaws shall state the role and purpose of the birth center, including an organizational chart defining the lines of authority.

383.307

(1) Each birth center shall have a governing body which is responsible for the overall operation and maintenance of the birth center.

(a) The governing body shall develop and display a table of organization which shows the structure of the birth center and identifies the governing body, the birth center director, the clinical director, the clinical staff, and the medical consultant.

**ST - B0016 - CEO Position Established**

**Title** CEO Position Established

**Statute or Rule** 59A-11.005(2), F.A.C.

**Type** Rule

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**Regulation Definition**

A chief executive officer or other similarly titled official to whom the governing body delegates the full-time authority for the operation of the birth center in accordance with the established policy of the governing body;

**Interpretive Guideline**

**ST - B0017 - Organized Clinical Staff - Responsibilities**

**Title** Organized Clinical Staff - Responsibilities

**Statute or Rule** 59A-11.005(3)a, F.A.C.

**Type** Rule

**Regulation Definition**

- (3) An organized clinical staff to which the governing body delegates responsibility for maintaining proper standards of medical and other health care, which responsibilities include:
- (a) The clinical staff of the birth center shall be responsible for maintaining quality of care provided to the patients by:
1. Having at least one clinical staff member available for every two clients in labor;
  2. Having a clinical staff member or qualified personnel available on site during the entire time the client is in the birth center. Services during labor and delivery shall be provided by physicians or by certified nurse midwives or licensed midwives, assisted by at least one other staff member, under protocols developed by the clinical staff and approved by the governing body in accordance with accepted standards of care;
  3. Ensuring all qualified personnel and clinical staff of the birth center shall be trained in infant and adult resuscitation. Clinical staff or qualified personnel who have demonstrated ability to perform neonatal resuscitation procedures shall be present during each birth;
  4. Maintenance of clinical records describing the history, conditions, treatment and progress of the patient in sufficient

**Interpretive Guideline**

- Sample a variety of cases to include clients:
- With & without complications
  - discharges due to no longer meeting Birth Center criteria
  - transfers
  - type of birth (traditional, water..)
  - live births
  - still births

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completeness and accuracy to assure transferable comprehension of the case at any time;

5. Clinical record reviews to evaluate the quality of clinical care on the basis of documented evidence;
6. Review of admissions with respect to eligibility, course of pregnancy and outcome, evaluation of services, condition of mother and newborn on discharge, or transfer to other providers; and
7. Surveillance of infection risk and cases and the promotion of a preventive and corrective program designed to minimize these hazards.

**ST - B0023 - Governing Body Approves Bylaws**

**Title** Governing Body Approves Bylaws

**Statute or Rule** 383.307(1)(b), F.S.

**Type** Rule

**Regulation Definition**

The governing body reviews and approves the bylaws, rules and regulations of the clinical staff members and consultants. The governing body develops and makes available to clinical staff members, consultants, and licensing authorities a policy and procedures manual including protocols and description of the roles and responsibilities of all personnel.

**Interpretive Guideline**

**ST - B0031 - Consultant Physician**

**Title** Consultant Physician

**Statute or Rule** 59A-11.005(3)(b),

**Type** Rule

**Regulation Definition**

59A-11.005(3)(b)

**Interpretive Guideline**

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Services of a consultant physician are required in those birth centers which do not have a physician on the clinical staff who is certified or eligible for certification by the American Board of Obstetrics and Gynecology, the American Board of Osteopathic Obstetricians and Gynecologists or has hospital obstetrical privileges.

**ST - B0032 - Consultant duties**

**Title** Consultant duties

**Statute or Rule** 59A-11.005(3)(c), F.A.C.

**Type** Rule

**Regulation Definition**

The responsibilities and functions of the consultant shall be specifically described in the policy and procedure manual and the patient care protocols.

**Interpretive Guideline**

**ST - B0033 - Consultant Agreement**

**Title** Consultant Agreement

**Statute or Rule** 59A-11.005(3)(d), F.A.C.; 383. 315

**Type** Rule

**Regulation Definition**

59A-11.005(3) (d)

The governing body shall maintain in writing a consultation agreement, signed within the current license year, with each consultant who agrees to provide advice and services to the birth center as requested.

**Interpretive Guideline**

383.315

Agreements with consultants for advice or services; maintenance. -

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- (1) A birth center shall maintain in writing a consultation agreement, signed within the current license period, with each consultant who has agreed to provide advice and services to the birth center as requested.
- (2) Consultation may be provided onsite or by telephone, as required by clinical and geographic conditions.

**ST - B0034 - Consultant Exemption**

**Title** Consultant Exemption

**Statute or Rule** 59A-11.005(3)(e), F.A.C.

**Type** Rule

**Regulation Definition**

Any facility which as of June 15, 1984, has an agreement with a consultant who is licensed pursuant to Chapter 458 or 459, F.S., but who is not practicing obstetrics, shall be exempt from the provisions of Chapter 383, F.S., requiring that the consultant be certified or eligible for certification by the American Board of Obstetrics and Gynecology, the American Board of Osteopathic Obstetricians and Gynecologists or has hospital obstetrical privileges.

**Interpretive Guideline**

Certification exemption if consultant agreement has been in place since June 15, 1984.

**ST - B0036 - Clinical Records Shall Contain**

**Title** Clinical Records Shall Contain

**Statute or Rule** 383.32(1-4a); 59A-11.005(4)(a-o), F.A.C.

**Type** Rule

**Regulation Definition**

383.32 Clinical records.-

- (1) Clinical records shall contain information prescribed by rule, including, but not limited to:
  - (a) Identifying information.

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- (b) Risk assessments.
- (c) Information relating to prenatal visits.
- (d) Information relating to the course of labor and intrapartum care.
- (e) Information relating to consultation, referral, and transport to a hospital.
- (f) Newborn assessment, APGAR score, treatments as required, and followup.
- (g) Postpartum followup.
- (2) Clinical records shall be immediately available at the birth center:
  - (a) At the time of admission.
  - (b) When transfer of care is necessary.
  - (c) For audit by licensure personnel.
- (3) Clinical records shall be kept confidential in accordance with s. 456.057 and exempt from the provisions of s. 119.07(1). A client ' s clinical records shall be open to inspection only under the following conditions:
  - (a) A consent to release information has been signed by the client; or
  - (b) The review is made by the agency for a licensure survey or complaint investigation.
- (4)(a) Clinical records shall be audited periodically, but no less frequently than every 3 months, to evaluate the process and outcome of care.

59A-11.005(4)(a-o),

The birth center shall have a defined client record system, policies and procedures which provide for identification, security, confidentiality, control, retrieval, and preservation of client care data and information. A current and complete clinical record for each patient accepted for care in the birth center shall include at a minimum, the following data:

- (a) Identifying information including client ' s name, address

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and telephone number;

(b) Initial history and physical examination including laboratory findings and dates;

(c) Obstetrical risk assessments and pre-term labor risk assessments including the dates of the assessments;

(d) The dates and topics of the educational sessions attended;

(e) The date and time of the onset of labor;

(f) The course of labor including all pertinent examinations and findings;

(g) The exact date and time of birth, the presenting part, the sex of the newborn, the numerical order of birth in the event of more than one newborn, to include filing of the birth certificate, and the Apgar score at one minute and five minutes;

(h) Time of expulsion and condition of placenta;

(i) All treatments rendered to the mother and newborn including prescribing prescriptions, the time, type, and dose of eye prophylaxis;

(j) Copy of the Metabolic screening report;

(k) Condition of the mother and newborn including any complications and action taken;

(l) All medical consultations relevant to the client specifically;

(m) Referrals for medical care and transfers to hospitals including that information germane to the circumstances;

(n) Examinations of the newborn and postpartum mother; and

(o) Instructions given to the client regarding postpartum care, family planning, care of the newborn, arrangements for metabolic testing, immunizations, and follow-up pediatric care.

1. All entries shall be dated and signed by the attending clinical staff members.

2. The clinical record is confidential and shall not be released without the written consent of the client except under the following conditions:

a. When the client is transferred to another source of care; and

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- b. For audit by the agency during licensure inspection or complaint investigation.
- 3. The clinical records shall be kept on file for a minimum of seven years from the date of last entry.
- 4. The clinical record shall be immediately available at the time of the client ' s admission to the birth center in labor and to the practitioner or hospital when the client is transferred.

**ST - B0040 - All Patients Under Care of Clinical Staff**

**Title** All Patients Under Care of Clinical Staff

**Statute or Rule** 59A-11.005(5), F.A.C.

**Type** Rule

**Regulation Definition**

A policy requiring that all patients be accepted on the authority of and under the care of a member of the organized clinical staff;

**Interpretive Guideline**

Sample records of patients who were transferred or who received emergency care.

**ST - B0041 - Care And Transfer In Emergency**

**Title** Care And Transfer In Emergency

**Statute or Rule** 59A-11.005(6), F.A.C.

**Type** Rule

**Regulation Definition**

- (6) A procedure for providing care and transfer in an emergency;
- (a) The birth center shall have a written protocol which shall include at a minimum:
  - 1. The name, address, telephone numbers and contact persons of the licensed ambulance service, the hospital licensed to provide emergency obstetrical and neonatal services, and other hospitals in the vicinity;

**Interpretive Guideline**

Sample records of patients who were transferred or who received emergency care.

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2. The conditions specified in the arrangements between the birth center and the ambulance service and the hospital, including financial responsibility for services rendered; and
3. Criteria to determine risk status which require medical consultation or transfer to a hospital of the newborn or the mother for any conditions such as:
  - a. Premature labor, meaning labor occurring at less than 37 weeks gestation;
  - b. Estimated fetal weight less than 2,500 grams or greater than 4,000 grams;
  - c. Hypertension;
  - d. Pre-eclampsia;
  - e. Failure to progress in labor;
  - f. Evidence of an infectious process;
  - g. Premature rupture of the membranes, meaning rupture occurring more than 12 hours before onset of active labor;
  - h. Suspected placenta praevia or abruptio;
  - i. Non-vertex presentation;
  - j. Hemorrhage of greater than 500 cc of blood;
  - k. Anemia consisting of less than 10 grams of hemoglobin per 100 milliliters of blood or 30 percent hematocrit;
1. Persistent fetal tachycardia (heart rate more than 160 beats per minute), repetitive fetal bradycardia (heart beat less than 120 beats per minute) or undiagnosed abnormalities of the fetal heart tones; and
- m. Persistent hypothermia in the newborn.
4. Criteria to determine risk status which require immediate emergency transfer to a hospital of the newborn or mother for any condition such as:
  - a. Prolapsed cord;
  - b. Uncontrolled hemorrhage;
  - c. Placenta abruptio;
  - d. Convulsions;
  - e. Major anomaly of the newborn;
  - f. Apgar score four or less at five minutes;

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- g. Fetal heart rate of 90 or less beats per minute for three minutes;
  - h. Thick meconium staining;
  - i. Respiratory distress in the newborn; and
  - j. Weight less than 2,000 grams.
5. The criteria and protocols for transfer shall be readily accessible to clinical staff members at all times.

**ST - B0042 - Emergency Telephone Numbers Posted**

**Title** Emergency Telephone Numbers Posted

**Statute or Rule** 59A-11.005(6)(b), F.A.C.; 383.316(3)

**Type** Rule

**Regulation Definition**

59A-11.005(6) (b) The names and telephone numbers of the ambulance service, neonatal transport service, and hospital shall be clearly posted at each telephone in the birth center.

383.316(3)

A licensed facility shall identify neonatal-specific transportation services, including ground and air ambulances; list their particular qualifications; and have the telephone numbers for access to these services clearly listed and immediately available.

**Interpretive Guideline**

**ST - B0043 - Transfer Report**

**Title** Transfer Report

**Statute or Rule** 59A-11.005(6)(c), F.A.C.

**Type** Rule

**Regulation Definition**

A written report of the transfer shall be documented and

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available for quality assurance review and agency inspection.

The report shall include:

1. The client 's name;
2. The date of the event;
3. The reason for transfer;
4. The provider and mode of transportation to the hospital;
5. The exact time of the initial call, any subsequent calls;
6. Arrival of the emergency personnel;
7. Departure of the client;
8. Arrival at the hospital;
9. Name of the hospital;
10. Initiation of emergency medical services;
11. The condition of the client at the time of transfer; and
12. Any information regarding the medical care of the client and outcome.

**ST - B0044 - Eval of Transfer Report**

**Title** Eval of Transfer Report

**Statute or Rule** 59A-11.005(6)(d), F.A.C.

**Type** Rule

**Regulation Definition**

The clinical staff, consultants, and governing body shall review and evaluate the criteria, protocols, and emergency transfer reports annually. The findings of the evaluation shall be documented.

**Interpretive Guideline**

**ST - B0045 - Infection Control Committee**

**Title** Infection Control Committee

**Statute or Rule** 59A-11.005(7)(a), F.A.C.

**Type** Rule

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**Regulation Definition**

There shall be an Infection Control Committee, composed of the clinical staff and consultants, delegated responsibility for developing and maintaining current written policies and procedures for the prevention, control and investigation of infection in the birth center, and for assuring the effectiveness of current procedural techniques

**Interpretive Guideline**

**ST - B0046 - Infection Control P&P**

**Title** Infection Control P&P

**Statute or Rule** 59A-11.005(7)(b), F.A.C.

**Type** Rule

**Regulation Definition**

There shall be current written policies and procedures to assure, define, and validate infection control for any of the following subjects and areas:

1. Medical asepsis;
2. Surgical asepsis;
3. Sterilization and disinfection;
4. Housekeeping;
5. Clean and soiled utility areas;
6. Linen;
7. Traffic flow patterns;
8. Staff health status requirements;
9. Infection control inservice education for all personnel;
10. Recording and reporting of all potential infections;
11. Bacteriological testing of potential infections, recording results and reporting to Infection Control Committee;
12. Management of clients with specific or suspected infections;
13. Postpartum follow-up system; and
14. Reporting of notifiable communicable disease in an

**Interpretive Guideline**

If the birth center offers water births, ensure they have a policy on the cleaning of the tub between clients.

Check for policies on the autoclave if the facility utilizes one. How is sterilization of instruments ensured?

For Sterilization issues, review tag .

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infectious stage.

**ST - B0048 - Quality Assurance Review**

**Title** Quality Assurance Review

**Statute or Rule** 59A-11.005(8)(a-c), F.A.C.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

An ongoing program to enhance the quality of patient care and review the appropriateness of utilization of services. To ensure the program is effective, the following will be accomplished:

(a) An interdisciplinary committee shall be appointed to do periodic quality assurance review. Two members of the committee shall have clinical expertise in maternal-infant care such as a physician or registered nurse. All members of the committee will be health care providers who are involved in the care or treatment of the patients being audited.

(b) Clinical records shall be audited by the clinical staff at least every three months and a sample audited by the quality assurance committee at least every six months. The audit shall evaluate the following:

1. Initial history, physical examination, risk assessments and laboratory tests;
2. Documentation of clinical observations, examinations and treatments;
3. Evidence that appropriate actions have been taken in response to clinical findings;
4. Counseling, education, consultation, and referral activities are recorded;
5. Consent forms are signed as required by subsections 59A-11.010(2), (3), F.A.C.; and
6. All entries are legible, dated, and signed.

(c) The quality assurance committee shall analyze the incidence of maternal and perinatal morbidity and mortality, obstetrical risk assessments, pre-term labor risk assessments,

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consultants' referrals and outcomes, and transfers of care and outcomes.

**ST - B0051 - RISK STATUS CRITERIA**

**Title** RISK STATUS CRITERIA

**Statute or Rule** 59A-11.009(1), F.A.C.383.31(1)(a)

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

59A-11.009(1),  
Birth center clients 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.

383.31(1)(a)  
A birth center may accept only those patients who are expected to have normal pregnancies, labors, and deliveries.

**ST - B0052 - RISK STATUS CRITERIA**

**Title** RISK STATUS CRITERIA

**Statute or Rule** 59A-11.009(2), F.A.C.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

Each birth center shall establish a written risk assessment system which shall be a part of the policy and procedure manual. The individual risk assessment shall be included in the client ' s clinical record.

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**ST - B0053 - RISK STATUS CRITERIA**

**Title** RISK STATUS CRITERIA

**Statute or Rule** 59A-11.009(3), F.A.C.

**Type** Rule

**Regulation Definition**

The general health status and risk assessment shall be determined by a physician, certified nurse midwife, or advanced registered nurse practitioner after obtaining a detailed medical history, performing a physical examination, and taking into account family circumstances and other social and psychological factors.

**Interpretive Guideline**

Note that this rule does not include licensed midwives.

467.003 (2) " Certified nurse midwife " means a person who is licensed as an advanced registered nurse practitioner under part I of chapter 464 and who is certified to practice midwifery by the American College of Nurse Midwives.  
(7) " Midwife " means any person not less than 21 years of age, other than a licensed physician or certified nurse midwife, who is licensed under this chapter to supervise the birth of a child. (Licensed midwives are not necessarily nurses)

**ST - B0054 - RISK STATUS CRITERIA**

**Title** RISK STATUS CRITERIA

**Statute or Rule** 59A-11.009(4), 59A-11.012(4), F.A.C.

**Type** Rule

**Regulation Definition**

59A-11.009(4)

The following criteria shall be used as a minimum baseline upon which the risk status of clients shall be determined. These criteria shall be applied to all clients prior to acceptance for birth center services and throughout the pregnancy for continuation of services. Clients with any of the following risk factors shall be referred to a physician for continuing maternity care and hospital delivery:

- (a) Age limits to be determined on an individual basis.
- (b) Major medical problems including but not limited to:
  - 1. Chronic hypertension, heart disease, or pulmonary embolus;
  - 2. Congenital heart defects assessed as pathological by a

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cardiologist, placing mother and/or fetus at risk;

3. Severe renal disease;

4. Drug addiction or required use of anticonvulsant drugs;

5. Diabetes mellitus or thyroid disease which is not maintained in a euthyroid state; or

6. Bleeding disorder or hemolytic disease.

(c) Previous history of significant obstetrical complications, including, but not limited to:

1. Rh sensitization;

2. Previous uterine wall surgery including Caesarean section.

An exception to this rule is permissible for all centers which are participating in the Vaginal Birth after a Caesarean (VBAC) Section study sponsored by the National Association of Childbearing Centers. Centers planning to participate in this study should notify the State Health Office. Every VBAC candidate shall be evaluated and approved for a birth center delivery by an obstetrician or physician with hospital obstetrical privileges. This evaluation and approval shall be documented in the client ' s record;

3. Seven or more term pregnancies;

4. Previous placenta abruptio.

(d) Significant signs or symptoms of:

1. Hypertension;

2. Toxemia;

3. Poly or oligo hydramnios;

4. Abruptio placenta;

5. Chorioamnionitis;

6. Malformed fetus;

7. Multiple gestation;

8. Intrauterine growth retardation;

9. Fetal distress;

10. Alcoholism or drug addiction;

11. Thrombophlebitis; or

12. Pyelonephritis.

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59A-11.012(4)

(4) ...The assessment shall be performed during the initial visit and repeated at 28 weeks gestation.

**ST - B0055 - Admission criteria**

**Title** Admission criteria

**Statute or Rule** 59A-11.009(5), F.A.C.

**Type** Rule

**Regulation Definition**

With the exception of those facilities exempted under Section 383.335, F.S., 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.

**Interpretive Guideline**

Does the facility administer anesthesia?

Is the facility owned by an obstetrician been in business before June 15, 1984?

Section 383.335, F.S. exempts birth centers from this requirement who have been owned and operated by a board-certified obstetrician since June 15, 1984 (statute below)

**ST - B0056 - INFORMED CONSENT**

**Title** INFORMED CONSENT

**Statute or Rule** 59A-11.010(1-3), F.A.C.; 383.31(2)(a)

**Type** Rule

**Regulation Definition**

59A-11.010 (1)

Before admission to services, a client shall be informed of:

- (a) The qualifications of the birth center clinical staff;
- (b) The risks related to out-of-hospital childbirth;
- (c) The benefits of out-of-hospital childbirth; and
- (d) The possibility of referral or transfer if complications arise during pregnancy or labor with additional costs for services rendered.

(2) The birth center clinical staff shall obtain the client ' s

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written consent for birth center services using form Consent to Deliver in a Birth Center, AHCA Form 3130-3003 November 2013, which is incorporated herein by reference and available at

<http://www.flrules.org/Gateway/reference.asp?No=Ref-04100> and available from the Agency for Health Care Administration, 2727 Mahan Drive, Mail Stop 31, Tallahassee, Florida 32308, or at the web address at:

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

(3) The signed consent form shall be included with the client's individual clinical record.

383.31(2)(a)

A patient may not be accepted for care until the patient has signed a client informed-consent form

**ST - B0061 - PRENATAL CARE - Initial Visit**

**Title** PRENATAL CARE - Initial Visit

**Statute or Rule** 59A-11.012(1), F.A.C.

**Type** Rule

**Regulation Definition**

(1) Initial Visit:

(a) A comprehensive health history shall be completed which includes medical, emotional, dietary, and obstetrical data including a pre-term delivery risk assessment.

(b) A physical examination shall be completed by a physician, or certified nurse midwife or advanced registered nurse practitioner, or licensed midwife, which includes measurement of height and weight, vital signs including blood pressure and examination of the skin, head and neck, heart and lungs, breasts, abdomen, pelvis and neurologic reactions.

(c) The following tests are required:

1. Hemoglobin or hematocrit, urinalysis by dipstick for

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protein, sugar, and ketones; serological test for syphilis; cervical cytology, and Rh determination and blood type. Results of a cervical cytology done within one year is acceptable. The hemoglobin test and urinalysis may be performed by a clinical staff member or qualified personnel.

**ST - B0062 - PRENATAL CARE - Return Visits**

**Title** PRENATAL CARE - Return Visits

**Statute or Rule** 59A-11.012(2-3), F.A.C.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

- (2) Return visits shall include at a minimum:
- (a) Measurements of the weight, blood pressure, fundal height, and fetal heart rate when applicable;
  - (b) Urinalysis by dipstick for protein and sugar;
  - (c) Hemoglobin or hematocrit should be repeated at least twice and more often if indicated during the course of the pregnancy;
  - (d) Review of signs and symptoms of complications of pregnancy and risk status; and
  - (e) Examination to determine the estimated weeks of gestation, fetal position and presentation.
- (3) Return prenatal visits shall be scheduled at least every four weeks until the 32nd week, every two weeks until the 36th week and then every week until delivery unless the client's condition requires more frequent visits.

**ST - B0065 - Prenatal Education**

**Title** Prenatal Education

**Statute or Rule** 59A-11.012(5), F.A.C.

**Type** Rule

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**Regulation Definition**

All patients receive specific instruction regarding preterm labor including the potential hazards, preventive measures, symptoms, detection and timing of contractions, and the need for prompt notification of the health provider.

**Interpretive Guideline**

**ST - B0067 - Prenatal Screening Instrument**

**Title** Prenatal Screening Instrument

**Statute or Rule** 59A-11.012(7), F.A.C.

**Type** Rule

**Regulation Definition**

The Healthy Start Prenatal Screening Instrument, as described in Rule 64C-7.009, F.A.C., must be offered as specified to each pregnant woman at the first prenatal contact.

**Interpretive Guideline**

Review patient chart for a copy of the screening instrument.

64C-7.009, F.A.C states: (c) The health care provider shall assure that at the initial visit the pregnant woman receives an explanation of Healthy Start services and is informed of her risk status as determined by the prenatal risk screening instrument.

The Healthy Start Prenatal Screening Instrument is available from DOH in 3 languages, English, Creole and Spanish. It is called " Prenatal Risk Screen ", DOH Form 3134, 01/15

**ST - B0068 - INTRAPARTUM CARE**

**Title** INTRAPARTUM CARE

**Statute or Rule** 59A-11.013(1-4), F.A.C.

**Type** Rule

**Regulation Definition**

- (1) A clinical staff member shall be present or available to the client at all times throughout her stay in the birth center.
- (2) The clinical staff shall monitor the progress of labor and

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condition of the mother and fetus at intervals sufficiently frequent to identify abnormalities or complications at the earliest possible time.

(3) The client shall be transferred to a hospital if complications occur requiring medical or surgical intervention pursuant to the criteria listed in subsections of this chapter.

(4) The family or support persons shall be instructed as needed to assist the client during labor and delivery.

**ST - B0072 - SURGICAL SERVICES**

**Title** SURGICAL SERVICES

**Statute or Rule** 59A-11.014, F.A.C.; 383.313(2)

**Type** Rule

**Regulation Definition**

59A-11.014  
No surgical procedures shall be performed except episiotomy, repair of episiotomy or laceration, or circumcision except in those birth centers exempted pursuant to Section 383.335, F.S.

383.313(2)  
SURGICAL SERVICES.-Surgical procedures shall be limited to those normally performed during uncomplicated childbirths, such as episiotomies and repairs and shall not include operative obstetrics or caesarean sections.

**Interpretive Guideline**

Section 383.335, F.S. exempts birth centers from this requirement who have been owned and operated by a board-certified obstetrician since June 15, 1984 (statute below)

**ST - B0073 - Postpartum evaluation**

**Title** Postpartum evaluation

**Statute or Rule** 383.318(3), FS

**Type** Rule

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**Regulation Definition**

**Interpretive Guideline**

(3) Postpartum evaluation and followup care shall be provided, which shall include:

- (a) Physical examination of the infant.
- (b) Metabolic screening tests required by s. 383.14.
- (c) Referral to sources for pediatric care.
- (d) Maternal postpartum assessment.
- (e) Instruction in child care, including immunization, breastfeeding, safe sleep practices, and possible causes of Sudden Unexpected Infant Death.
- (f) Family planning services.
- (g) Referral to secondary or tertiary care, as indicated.

**ST - B0074 - Newborn Cord Blood Sample**

**Title** Newborn Cord Blood Sample

**Statute or Rule** 59A-11.016(1), F.A.C.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

A cord blood sample shall be secured for laboratory testing for type, Rh determination, and direct Coombs test when the mother is Rh negative

**ST - B0075 - Newborn Care**

**Title** Newborn Care

**Statute or Rule** 59A-11.016(2), F.A.C.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

The newborn shall be weighed, measured, inspected for abnormalities and examined for complications. An

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identification tape shall be placed on the newborn if more than one newborn is at the center at the same time.

**ST - B0076 - Newborn Care**

**Title** Newborn Care

**Statute or Rule** 59A-11.016(3), F.A.C.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

(3) One half milligram of Vitamin K shall be administered to the newborn within 24 hours after birth. If no one on the birth center staff is licensed to administer this medication, the parents shall be instructed to take the infant to a private physician or clinic for the injection.

**ST - B0077 - Newborn Care, Complications**

**Title** Newborn Care, Complications

**Statute or Rule** 59A-11.016(4), F.A.C.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

(4) The newborn shall be referred to physician or hospital care if the following conditions occur:

- (a) Low birthweight (under 2500 grams);
- (b) Apgar score of six or less at five minutes;
- (c) Signs of pre or post maturity;
- (d) Jaundice;
- (e) Persistent hypothermia consisting of a body temperature of less than 97 degrees Fahrenheit for more than two hours after birth;
- (f) Respiratory difficulties;
- (g) Major congenital anomalies;

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- (h) Exaggerated tremors; and
- (i) Any other condition requiring medical care.

**ST - B0078 - POSTPARTUM CARE**

**Title** POSTPARTUM CARE

**Statute or Rule** 59A-11.016(5), F.A.C.

**Type** Rule

**Regulation Definition**

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

**Interpretive Guideline**

**ST - B0079 - Discharge within 24 hours**

**Title** Discharge within 24 hours

**Statute or Rule** 59A-11.016(6-7), F.A.C.; 383.318(1), FS

**Type** Rule

**Regulation Definition**

59A-11.016(6-7)

- (6) The mother and infant shall be discharged from the birth center within 24 hours after the birth occurs except under the following conditions:
- (a) The mother is in a deep sleep when the 24 hour period is completed. In this case the mother shall be discharged as soon after waking as feasible; or
  - (b) The 24 hour period is completed during the middle of the night.
- (7) If the mother, or infant, is retained at the birth center longer than 24 hours after birth, except as identified in paragraphs 59A-11.016(6)(a) and (b), F.A.C., a report shall be filed with the local county public health unit within 48 hours

**Interpretive Guideline**

Mother shall be discharged in 24 hours unless a listed exception applies.

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after the birth describing the circumstances and reasons for the decision.

383.318(1)

(1) A mother and her infant shall be dismissed from the birth center within 24 hours after the birth of the infant, except in unusual circumstances as defined by rule of the agency. If a mother or infant is retained at the birth center for more than 24 hours after the birth, a report shall be filed with the agency within 48 hours of the birth describing the circumstances and the reasons for the decision.

**ST - B0081 - Postpartum Exam**

**Title** Postpartum Exam

**Statute or Rule** 59A-11.016(8), F.A.C.

**Type** Rule

**Regulation Definition**

(8) A postpartum examination shall be performed within 72 hours after delivery and at approximately four to six weeks after delivery.

(a) The examination within 72 hours shall include at a minimum:

1. Interval history;
2. Blood pressure measurement; and
3. Observation of the breasts, perineum and abdomen.

(b) The examination at four to six weeks shall include all of the above and also:

1. Weight;
2. Hemoglobin or hematocrit; and
3. Bi-manual pelvic examination.

**Interpretive Guideline**

A bi-manual pelvic is an exam where the gynecologist inserts two fingers into the vagina and places the other hand on top of the lower abdomen and palpates for abnormalities.

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**ST - B0082 - Postpartum Education**

**Title** Postpartum Education

**Statute or Rule** 59A-11.016(9), F.A.C.

**Type** Rule

**Regulation Definition**

The mother shall be counseled regarding breast feeding, perineal care, family planning, signs of common complications, activities and exercises, sex relations, care and feeding of the newborn, and changing family relationships.

**Interpretive Guideline**

**ST - B0084 - Postpartum Care - pediatrician**

**Title** Postpartum Care - pediatrician

**Statute or Rule** 59A-11.016(11), F.A.C.

**Type** Rule

**Regulation Definition**

The parents shall be referred to providers of pediatric care and instructed about immunization.

**Interpretive Guideline**

**ST - B0085 - POSTPARTUM CARE - complications**

**Title** POSTPARTUM CARE - complications

**Statute or Rule** 59A-11.016(12), F.A.C.

**Type** Rule

**Regulation Definition**

If complications in the mother or newborn occur during the postpartum period, a consultation or referral shall be made to

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the appropriate source of secondary or tertiary care.

**ST - B0086 - Postpartum Care - Eye prophylaxis**

**Title** Postpartum Care - Eye prophylaxis

**Statute or Rule** 59A-11.016(13), F.A.C.; 383.318(2); 383.

**Type** Rule

**Regulation Definition**

59A-11.016(13)

If the mother refuses to permit eye prophylaxis on account of religious beliefs contrary to the use of drugs, Vitamin K injection, or metabolic screening test, a waiver indicating this decision shall be signed by the mother, witnessed by a clinical staff member, and filed with the clinical record.

383.318(2)

A prophylactic shall be instilled in the eyes of each newborn in accordance with s. 383.04.

383.04 Prophylactic required for eyes of infants.-Every physician, midwife, or other person in attendance at the birth of a child in the state is required to instill or have instilled into the eyes of the baby within 1 hour after birth an effective prophylactic recommended by the Committee on Infectious Diseases of the American Academy of Pediatrics for the prevention of neonatal ophthalmia. This section does not apply to cases where the parents file with the physician, midwife, or other person in attendance at the birth of a child written objections on account of religious beliefs contrary to the use of drugs. In such case the physician, midwife, or other person in attendance shall maintain a record that such measures were or were not employed and attach thereto any written objection.

**Interpretive Guideline**

In 2012 the above committee recommended: 2 drops of 1% silver nitrate or a 1 cm ribbon of antibiotic ointment (either erythromycin 0.5% or tetracycline 1%) placed into the lower conjunctival sac. Erythromycin ointment is considered the best regimen for prophylaxis against neonatal conjunctivitis because of its efficacy against gonococcal, and nongonococcal nonchlamydial pathogens, and due to its low incidence of causing a chemical conjunctivitis.

Ask the practitioner about any refusals, and ensure written documentation was obtained.

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**ST - B0087 - Postnatal Screening**

**Title** Postnatal Screening

**Statute or Rule** 59A-11.016(14), F.A.C.

**Type** Rule

**Regulation Definition**

The Healthy Start Postnatal Screening Instrument, shall be offered as specified in Rule 64C-7.008, F.A.C..

**Interpretive Guideline**

64C-7.008(1) The health care provider shall request any pregnant woman who objects to prenatal risk screening, after the purpose of the screening has been fully explained, to indicate her objection in writing on the screening instrument, and to sign the instrument. The screening instrument to be used is the Prenatal Risk Screen, DOH Form 3134.

**ST - B0088 - REPORTS - Birth Certificates**

**Title** REPORTS - Birth Certificates

**Statute or Rule** 383.327(1), F.S.

**Type** Rule

**Regulation Definition**

A completed certificate of birth shall be filed with the local registrar within 5 days of each birth in accordance with chapter 382.

**Interpretive Guideline**

382.013, Birth registration: A certificate for each live birth that occurs in this state shall be filed within 5 days after such birth with the local registrar of the district in which the birth occurred ...

(a) If a birth occurs in a hospital, birth center, or other health care facility, or en route thereto, the person in charge of the facility shall be responsible for preparing the certificate, certifying the facts of the birth, and filing the certificate with the local registrar. Within 48 hours after the birth, the physician, midwife, or person in attendance during or immediately after the delivery shall provide the facility with the medical information required by the birth certificate.

(b) If a birth occurs outside a facility and a physician licensed in this state, a certified nurse midwife, a midwife licensed in this state, or a public health nurse employed by the department was in attendance during or immediately after the delivery, that person shall prepare and file the certificate.

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**ST - B0089 - REPORTS - Death**

**Title** REPORTS - Death

**Statute or Rule** 383.327(2), F.S.

**Type** Rule

**Regulation Definition**

Each maternal death, newborn death, and stillbirth shall be reported immediately to the medical examiner.

**Interpretive Guideline**

**ST - B0090 - REPORTS - eye Discharge**

**Title** REPORTS - eye Discharge

**Statute or Rule** 59A-11.019(1), F.A.C.

**Type** Rule

**Regulation Definition**

If inflammation or unnatural discharge in the eyes of the newborn is observed within two weeks after birth, it shall be reported to the local health officer or licensed physician within six hours of discovery.

**Interpretive Guideline**

**ST - B0091 - REPORTS - Lab**

**Title** REPORTS - Lab

**Statute or Rule** 59A-11.019(2), F.A.C.

**Type** Rule

**Regulation Definition**

The laboratory reports on the serological test shall be reported in accordance with Chapter 381, F.S. It shall be noted on the

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form that this was a pregnancy test.

**ST - B0092 - REPORTS - Metabolic screening tests**

**Title** REPORTS - Metabolic screening tests

**Statute or Rule** 59A-11.019(3), 59A-11.016(10)F.A.C.

**Type** Rule

**Regulation Definition**

59A-11.019(3)  
Metabolic screening tests shall be reported to the Department of Health, Office of Vital Statistics, pursuant to Section 383.14, F.S., and rules promulgated thereunder.

59A-11.016(10),  
The metabolic screening test shall be performed on the newborn in accordance with Section 383.14, F.S

**Interpretive Guideline**

Newborn metabolic screening tests are collected on a specimen slip, DOH Form DH 677, and submitted to DOH pursuant to 383.14, F.S. and 64C-7.002, F.A.C.

**ST - B0093 - REPORTS - Annual Report**

**Title** REPORTS - Annual Report

**Statute or Rule** 59A-11.019(4), F.A.C.

**Type** Rule

**Regulation Definition**

A report on AHCA Form 3130-3004-JUN 94, " Birth Center Annual Report " , which is available from the Agency and is herein incorporated by reference, shall be submitted annually to the AHCA, Office of Health Facility Regulation, Tallahassee, FL for the period from July 1 to June 30 of the current year. The report shall be due July 30th each year.

**Interpretive Guideline**

AHCA Form 3130-3004-JUN 94, " Birth Center Annual Report " can be found on the Birth Center page at [ahca.myflorida.com](http://ahca.myflorida.com) under Health Facility Regulation, Hospital and Outpatient.

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

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**ST - B0108 - Laundry and Bedding**

**Title** Laundry and Bedding

**Statute or Rule** 59A-11.023(2-3), F.A.C.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

(2) Laundry.

(a) Where laundry facilities are provided, clean clothing, bed linens, and towels shall be available for the patients.

(b) Carts used for transporting dirty clothes, linens, and towels shall not be used for transporting clean articles unless they have been thoroughly cleaned.

(c) If laundry facilities are not available, sheets and blankets shall be cleaned by commercial laundries.

(3) Bedding. Beds and beddings shall be kept in good repair, cleaned and sanitized whenever soiled. Mattresses and pillows shall have cleanable covers which shall be cleaned and sanitized between use by different clients. Clean sheets shall be used for each client. Blankets shall be washed or dry cleaned whenever soiled. Sheets, blankets, and clean clothing shall be stored in a clean, dry place between laundering and use.

**ST - B0113 - Poisonous or Toxic Substances**

**Title** Poisonous or Toxic Substances

**Statute or Rule** 59A-11.023(16), F.A.C.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

Poisonous or toxic compounds are to be stored apart from food and other areas that would constitute a hazard to the

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residents.

**ST - B0114 - Water Supply, Sewage and Waste Disposal**

**Title** Water Supply, Sewage and Waste Disposal

**Statute or Rule** 59A-11.023(6-8), F.A.C.; 383.308(3)

**Type** Rule

**Regulation Definition**

(6) Water Supply. Water supplies shall be adequate to serve the demands of the facility and shall be constructed, operated and maintained as required by Chapter 62-555 or 64E-8, F.A.C.

(7) Sewage Disposal.

(a) All sewage and liquid waste shall be disposed of in manners as required by Chapter 62-600 or 64E-6, F.A.C.

(8) Waste Disposal.

(a) All garbage, trash and rubbish from residential areas shall be collected daily and taken to storage facilities. Garbage shall be removed from storage frequently enough to prevent a potential hazard or at least twice per week. Wet garbage shall be collected and stored in impervious, leak proof, fly tight containers pending disposal. All containers, storage areas and surrounding premises shall be kept clean and free of vermin.

(b) If public or contract garbage collection service is available, the facility shall subscribe to these services unless the volume makes on-site disposal feasible. If garbage and trash are disposed of on premises, the method of disposal shall be operated in a manner as required by Chapter 62-701, F.A.C.

383.308(3)

A birth center shall meet codes for ordinary construction and for water supply and sewage disposal. Solid waste shall be disposed of in accordance with the provisions of chapter 403 and rules promulgated thereunder.

**Interpretive Guideline**

Chapter 62-555 = Permitting, Construction, Operation, And Maintenance Of Public Water Systems

Chapter 64E-8 = Drinking Water Systems

Chapter 62-600 = Domestic Wastewater Facilities

Chapter 64E-6 = Standards For Onsite Sewage Treatment And Disposal Systems

Chapter 62-701 = Solid Waste Management Facilities

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**ST - B0119 - FOOD SERVICE**

**Title** FOOD SERVICE

**Statute or Rule** 59A-11.024(1-5), F.A.C.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

In birth centers where food is provided to the clients:

(1) All food service areas shall comply with Chapter 64E-11, F.A.C.

In birth centers where food is provided to the clients:

(2) Birth centers with three or less birthing rooms shall have facilities and equipment that is consistent with those found in single family dwelling units.

In birth centers where food is provided to the clients:

(3) Birth centers, with four or more birthing rooms, and in which food is provided to the clients shall comply with the prescribed equipment pursuant to Chapter 64E-11, F.A.C.

In birth centers where food is provided to the clients:

(4) If food is catered from outside sources, those sources must comply with Chapter 64E-11, F.A.C.

In birth centers where food is provided to the clients:

(5) If the birth center policy limits the food service to light snacks supplied by the client or support persons there shall be an adequate refrigerator capable of maintaining a temperature of 45 degrees Fahrenheit or lower.

The Department of Health has authority over Chapter 64E-11

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**ST - B0127 - EQUIPMENT AND SUPPLIES**

**Title** EQUIPMENT AND SUPPLIES

**Statute or Rule** 59A-11.028(2), F.A.C.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

- (1) Equipment shall be clean and free from safety hazards and in sufficient supply to meet the needs of the clients and staff.
- (2) Equipment shall include at a minimum:
  - (a) Examining table and stool;
  - (b) Examination light;
  - (c) Sphygmomanometer and stethoscope;
  - (d) Clinical thermometer;
  - (e) Fetoscope or doppler unit;
  - (f) Adult beam scale;
  - (g) Infant scale;
  - (h) Sweep second hand clock;
  - (i) Mechanical suction or bulb suction;
  - (j) Oxygen with flow meter and mask or equivalent;
  - (k) Resuscitation equipment to include resuscitation bags and oral airways; laryngoscopes and endotracheal tubes appropriate for the newborn;
  - (l) Emergency medications and intravenous fluids with supplies and equipment appropriate for administration;
  - (m) Sterile suturing equipment and supplies;
  - (n) Bassinet; and
  - (o) A firm surface suitable for resuscitation.

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**ST - B0128 - Emergency equipment**

**Title** Emergency equipment

**Statute or Rule** 59A-11.028(3), F.A.C.

**Type** Rule

**Regulation Definition**

Emergency equipment shall be readily available to the birth rooms; and other equipment and supplies shall be stored in a convenient and suitable place.

**Interpretive Guideline**

**ST - B0132 - PHARMACEUTICALS AND ANESTHETICS**

**Title** PHARMACEUTICALS AND ANESTHETICS

**Statute or Rule** 59A-11.030(1), F.A.C.

**Type** Rule

**Regulation Definition**

(1) There shall be written prescriptions or protocols signed by a practitioner legally authorized to prescribe for all drugs administered to clients within the birth center. Systemic analgesics and local anesthetics may be administered under the following conditions:

- (a) The clinical staff member who administers the systemic analgesic or local anesthetic is legally authorized to do so and shall be present in the birth center during the use of intravenous analgesics;
- (b) The dosage and drugs are specifically noted in the protocols for clinical services; and
- (c) The use of such drugs is in conformance with the policies and procedures of the birth center.

**Interpretive Guideline**

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**ST - B0133 - ANESTHETICS**

**Title** ANESTHETICS

**Statute or Rule** 59A-11.030(5), F.A.C.

**Type** Rule

**Regulation Definition**

Anesthetic agents other than systemic analgesics and local anesthetics for pudendal blocks shall not be used.

**Interpretive Guideline**

**ST - B0134 - ANESTHETICS**

**Title** ANESTHETICS

**Statute or Rule** 59A-11.030(2), F.A.C.; 383.313(3) FS

**Type** Rule

**Regulation Definition**

59A-11.030  
(2) General and conduction anesthesia shall not be administered at birth centers except in those birth centers exempted from restrictions pursuant to Section 383.335, F.S., and only when the following conditions are met:  
(a) The anesthesia service shall have written policies and procedures that are approved by the governing body and clinical staff, are reviewed annually, signed and dated at the time of review, revised and enforced as necessary;  
(b) A qualified anesthesiologist or certified registered nurse anesthetist designated by the governing body shall be responsible for coordinating the functions, equipment, and supplies of the service;  
(c) All general anesthesia shall be administered by an anesthesiologist or certified registered nurse anesthetist;  
(d) A physician shall be present in the birth center during the

**Interpretive Guideline**

Section 383.335, F.S. exempts birth centers from this requirement who have been owned and operated by a board-certified obstetrician since June 15, 1984 (statute below)

Section 383.335, F.S states that facilities that were " providing obstetrical and gynecological surgical services and was owned and operated by a board-certified obstetrician on June 15, 1984, and that would otherwise be subject to licensure under ss. 383.30-383.335 as a birth center, is exempt from the provisions of ss. 383.30-383.335 and part II of chapter 408 which restrict the provision of surgical services and outlet forceps delivery and the administration of anesthesia at birth centers. "

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anesthesia and post-anesthesia recovery period until the client is fully alert;

(e) Prior to the administration of anesthesia, the patient's condition shall be assessed;

(f) The responsibilities and qualifications of all anesthesia personnel, including physician, nurse anesthetists and all other trainees, must be defined in a policy statement, job description, or other appropriate document; and

(g) Anesthetic safety regulations shall be developed, posted and enforced. Such regulations shall include at least the following requirements:

1. All operating room electrical and anesthesia equipment shall be inspected on no less than a quarterly basis, and a written record of the results and corrective actions shall be maintained;
2. Flammable anesthetic agents shall not be employed in birth centers;
3. Each anesthetizing location shall be identified by a prominently posted permanent sign that clearly states that the anesthetizing location is not approved for flammable anesthetic agents;
4. Electrical equipment in anesthetizing areas shall be on an audiovisual line isolation monitor, with the exception of radiological equipment and fixed lighting more than five feet above the floor;
5. Each anesthetic gas machine shall have a pin-index system, a fail-safe mechanism, a minimum oxygen flow safety device which will prevent administration of less than 25 percent oxygen and less than 300 milliliters per minute oxygen flow, and an in-line oxygen monitor; and
6. All reusable anesthesia equipment in direct contact with the patient shall be cleaned or sterilized as appropriate after each use;
7. At a minimum, the following monitors shall be applied to all patients receiving conduction or general anesthesia:

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- a. Precordial or esophageal stethoscope;
- b. Blood pressure cuff;
- c. Electrocardiogram;
- d. Continuous temperature device; and
- e. Inspired oxygen concentration.

383.313

**(3) ADMINISTRATION OF ANALGESIA AND**

**ANESTHESIA.**-General and conduction anesthesia may not be administered at a birth center. Systemic analgesia may be administered, and local anesthesia for pudendal block and episiotomy repair may be performed if procedures are outlined by the clinical staff and performed by personnel with statutory authority to do so.

**ST - B0135 - Drug Policy and Procedure**

**Title** Drug Policy and Procedure

**Statute or Rule** 59A-11.030(3-4), F.A.C.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

(3) There shall be policies and procedures addressing the receiving, transcribing, and implementing of orders for administration of drugs.

(4) Written policies shall be established addressing the type and intended use of any drug to be used by patients within the facility

**ST - B0138 - Drugs Administered**

**Title** Drugs Administered

**Statute or Rule** 59A-11.030(6), F.A.C.

**Type** Rule

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**Regulation Definition**

Drugs shall be administered only by personnel or clinical staff licensed to administer drugs.

**Interpretive Guideline**

**ST - B0139 - Pharmaceuticals & Chemicals**

**Title** Pharmaceuticals & Chemicals

**Statute or Rule** 59A-11.030(7), F.A.C.

**Type** Rule

**Regulation Definition**

(7) Drugs, medications, and chemicals kept anywhere in the center shall be handled pursuant to Chapters 465 and 499, F.S., and rules promulgated thereunder.

(8) Drugs, chemicals, and medications shall be stored and secured in specifically designated cabinets, closets, drawers, or storerooms and made accessible only to authorized persons pursuant to the provisions in Chapters 465 and 499, F.S., and rules promulgated thereunder.

(9) Poisonous chemicals, caustic materials, or drugs shall show appropriate warning or poison labels and shall be stored separately from other drugs. Drugs for external use shall be separated from drugs for internal use.

**Interpretive Guideline**

Chapter 465 = Pharmacy

Chapter 499 = Florida Drug And Cosmetic Act

**ST - B0142 - Oxygen Supplies**

**Title** Oxygen Supplies

**Statute or Rule** 59A-11.028(4)

**Type** Rule

**Regulation Definition**

Oxygen shall be stored in a clean dry place with no flammable materials or machinery capable of producing sparks in the

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immediate vicinity. Oxygen supplies shall be purchased from a licensed dealer.

**ST - B0143 - Adequate Number of Staff**

**Title** Adequate Number of Staff

**Statute or Rule** 383.307(2-4) F.S.

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

(2) There shall be an adequate number of licensed personnel to provide clinical services needed by mothers and newborns and a sufficient number of qualified personnel to provide services for families and to maintain the birth center.

(3) All clinical staff members and consultants shall hold current licenses from this state to practice their respective disciplines.

(4) Clinical staff members and consultants shall adopt bylaws which are subject to the approval of the governing body and which shall include recommendations for clinical staff or consultation appointments, delineation of clinical privileges, and the organization of the clinical staff.

**ST - B0144 - Annual Assessments**

**Title** Annual Assessments

**Statute or Rule** 383.316(4)

**Type** Rule

**Regulation Definition**

**Interpretive Guideline**

Annual assessments of the transportation services and transfer protocols shall be made and documented.

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**ST - B0145 - Morbidity and Mortality**

**Title** Morbidity and Mortality

**Statute or Rule** 383.32(4)(b)

**Type** Rule

**Regulation Definition**

Statistics on maternal and perinatal morbidity and mortality, maternal risk, consultant referrals, and transfers of care shall be analyzed at least semiannually.

**Interpretive Guideline**

**ST - B0146 - Room Requirements**

**Title** Room Requirements

**Statute or Rule** 383.308 (1)

**Type** Rule

**Regulation Definition**

A birth center shall be so designed to assure adequate provision for birthing rooms, bath and toilet facilities, storage areas for supplies and equipment, examination areas, and reception or family areas. Handwashing facilities shall be in, or immediately adjacent to, all examining areas and birthing rooms.

**Interpretive Guideline**

**ST - B0147 - Facility Provisions**

**Title** Facility Provisions

**Statute or Rule** 383.308 (2)(b)

**Type** Rule

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**Regulation Definition**

Provision shall be made, on or off the premises, for Laundry, sterilization of supplies and equipment, Laboratory examinations, and Light snacks. If a food service is provided, special requirements shall be met as defined in rules promulgated pursuant to chapter 381.

**Interpretive Guideline**

For specific concerns:

Laundry - see tag 0108

Sterilization - tag 0046

Food - tag 0119

**ST - B0148 - Maintenance**

**Title** Maintenance

**Statute or Rule** 383.308 (4)(a)

**Type** Rule

**Regulation Definition**

A birth center shall be maintained in a safe, clean, and orderly manner.

**Interpretive Guideline**

**ST - B0149 - Adoption**

**Title** Adoption

**Statute or Rule** 383.3105

**Type** Rule

**Regulation Definition**

Patients consenting to adoptions; protocols.-

(1) Each licensed facility shall adopt a protocol that at a minimum provides for facility staff to

be knowledgeable of the waiting periods, revocation and the contents of the consent to adoption as contained ins.

63.082(4), and describes the supportive and unbiased manner in which facility staff will interact with birth parents and

**Interpretive Guideline**

63.082(4) gives detailed guidance as to the content of the consent.

63.082(4)(b): A consent to the adoption of a minor who is to be placed for adoption may be executed by the birth mother 48 hours after the minor 's birth or the day the birth mother is notified in writing, either on her patient chart or in release paperwork, that she is fit to be released from the licensed hospital or birth center, whichever is earlier.

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prospective adoptive parents regarding the adoption, in particular during the waiting period required ins. 63.082(4)(b) before consenting to an adoption.

(2) The protocol shall be in writing and be provided upon request to any birth parent or prospective adoptive parent of a child born in the facility.

**ST - B0150 - Client Education**

**Title** Client Education

**Statute or Rule** 383.311

**Type** Rule

**Regulation Definition**

Education and orientation for birth center clients and their families.-

(1) The clients and their families shall be fully informed of the policies and procedures of the birth center, including, but not limited to, policies and procedures on:

- (a) The selection of clients.
- (b) The expectation of self-help and family/client relationships.
- (c) The qualifications of the clinical staff.
- (d) The transfer to secondary or tertiary care.
- (e) The philosophy of childbirth care and the scope of services.

(f) The customary length of stay after delivery.

(2) The clients shall be prepared for childbirth and childbearing by education in:

- (a) The course of pregnancy and normal changes occurring during pregnancy.
- (b) The need for prenatal care.
- (c) Nutrition, including encouragement of breastfeeding.
- (d) The effects of smoking and substance abuse.
- (e) Labor and delivery.

**Interpretive Guideline**

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(f) The care of the newborn to include safe sleep practices and the possible causes of Sudden Unexpected Infant Death.

**ST - B0151 - INTRAPARTAL USE OF CHEMICAL AGENTS.**

**Title** INTRAPARTAL USE OF CHEMICAL AGENTS.

**Statute or Rule** 383.313(4)

**Type** Rule

**Regulation Definition**

INTRAPARTAL USE OF CHEMICAL AGENTS.-Labor may not be inhibited, stimulated, or augmented with chemical agents during the first or second stage of labor unless prescribed by personnel with statutory authority to do so and unless in connection with and prior to emergency transport.

**Interpretive Guideline**

' Intrapartal ' is the period from the onset of labor to its termination, marked by delivery of the placenta.

Inquire if any clients received labor inducing or stimulating medications. Add 1 or more to sample.

**ST - B0152 - Audits and Analyses**

**Title** Audits and Analyses

**Statute or Rule** 383.32(4)(c)

**Type** Rule

**Regulation Definition**

The governing body shall examine the results of the record audits and statistical analyses and shall make such reports available for inspection by the public and licensing authorities.

**Interpretive Guideline**

**ST - B0153 - Public Information**

**Title** Public Information

**Statute or Rule** 383.325(1)

**Type** Rule

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**Regulation Definition**

Each licensed facility shall maintain as public information, available upon request, records of all inspection reports pertaining to that facility which have been filed with, or issued by, any governmental agency. Copies of such reports shall be retained in the records of the facility for no less than 5 years from the date the reports are filed and issued.

**Interpretive Guideline**

**ST - B0154 - CHOW & closure**

**Title** CHOW & closure

**Statute or Rule** 59A-11.003 (5-6)

**Type** Rule

**Regulation Definition**

(5) Each license shall be returned to the Agency by the licensee immediately upon change in ownership or classification, suspension, revocation, or voluntary cessation of operations.

(6) A licensee shall notify the Agency of impending voluntary closure of a birth center not less than 30 days prior to such closure. The birth center shall be responsible for advising the licensing agency as to the placement of patients and disposition of medical records.

**Interpretive Guideline**

**ST - B0155 - Disaster Plan**

**Title** Disaster Plan

**Statute or Rule** 59A-11.027

**Type** Rule

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**Regulation Definition**

Each birth center shall develop a written disaster plan which shall be rehearsed by personnel at least twice a year and shall cover internal casualty producing incidents. The plan shall include provisions for complete evacuation of the facility during an actual disaster.

**Interpretive Guideline**

Were disaster drills conducted twice a year?

**ST - B0156 - Transfer and Transport to Hospital**

**Title** Transfer and Transport to Hospital

**Statute or Rule** 383.316(1-2)

**Type** Rule

**Regulation Definition**

(1) If unforeseen complications arise during labor, the client shall be transferred to a hospital.  
(2) Each licensed facility shall make arrangements with a local ambulance service licensed under chapter 401 for the transport of emergency patients to a hospital. Such arrangements shall be documented in the policy and procedures manual of the facility if the birth center does not own or operate a licensed ambulance. The policy and procedures manual shall also contain specific protocols for the transfer of any patient to a licensed hospital.

**Interpretive Guideline**

- Review the center policy and procedures regarding transfers.
- Review contract with ambulance service.
- Request a list of all transfers since last survey.
- Review a sample of transferred patients.
- Did the center follow their procedures?
- If no policies or contract, may also consider governing body (B014).
- If transfer records incomplete, may also consider clinical records (B036).