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# TITLE 216 - DEPARTMENT OF HEALTH

## CHAPTER 40 – PROFESSIONAL LICENSING AND FACILITY REGULATION

## SUBCHAPTER 10 – FACILITIES REGULATION

PART 8 – Birth Centers

## 8.1 Authority

A. These regulations are promulgated pursuant to the authority set forth in R.I. Gen. Laws § 23-17-10, and are established for the purpose of adopting minimum standards for Birth Centers which are consistent with acceptable standards of practice and which ensure that, while providing pregnant women with a maternity care alternative, the Birth Centers will provide services in such a manner as to safeguard the health, safety, and welfare of mothers and newborns.

B. A hospital birth center service, maintained and operated by a hospital on its licensed premises shall be subject to the standards for birth center services as set forth in the rules and regulations for Licensing of Hospitals (Part 4 of this Subchapter) and shall operate under the hospital license.

## 8.2 Incorporated Materials

A. These regulations hereby adopt and incorporate the Facility Guidelines Institute's "Guidelines for Design and Construction of Hospital and Outpatient Facilities" (2014) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.

B. These regulations hereby adopt and incorporate the U.S. Department of Health & Human Services, Office of Minority Health's "National Standards on Culturally and Linguistically Appropriate Services (CLAS)" (2013) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.

## 8.3 Definitions

A. Wherever used in this Part the following terms shall be construed as follows:

1. "Act" means R.I. Gen. Laws Chapter 23-17, entitled "Licensing of Health Care Facilities."

2. "Birth center", or “Center,” means any public or private establishment, place or facility, geographically distinct and separate from a hospital or the mother's residence, staffed, equipped and operated to provide services to low-risk mothers as defined in § 8.3(A)(9) of this Part during pregnancy, labor, birth and puerperium.

3. "Change of operator" means a transfer by the governing body or operator of a Birth Center to any other person (excluding delegations of authority to the medical or administrative staff of the facility) of the governing body's authority to:

    a. Hire or fire the chief executive officer of the Center;

    b. Maintain and control the books and records of the Center;

    c. Dispose of assets and incur liabilities on behalf of the Center;

    d. Adopt and enforce policies regarding operation of the Center.

    e. This definition is not applicable to circumstances wherein the governing body of a Birth Center retains the immediate authority and jurisdiction over the activities enumerated in §§ 8.3(A)(3)(a) through (d) of this Part.

4. "Change in owner" means:

    a. In the case of a Birth Center which is a partnership, the removal, addition or substitution of a partner which results in a new partner acquiring a controlling interest in such partnership;

    b. In the case of a Birth Center which is an unincorporated sole proprietorship, the transfer of the title and property to another person;

    c. In the case of a Birth Center which is a corporation;

        (1) A sale, lease, exchange or other disposition of all, or substantially all of the property and assets of the corporation; or

        (2) A merger of the corporation into another corporation; or

        (3) The consolidation of two or more corporations, resulting in the creation of a new corporation; or

(4) In the case of a Birth Center which is a business corporation, any transfer of corporate stock which results in a new person acquiring a controlling interest in such corporation; or

(5) In the case of a Birth Center which is a non-business corporation, any change in membership which results in a new person acquiring a controlling vote in such corporation.

5. “Department” means the Rhode Island Department of Health. The Department is also the “licensing agency” designated pursuant to R.I. Gen. Laws Chapter 23-17.

6. "Director" means the Director of the Rhode Island Department of Health.

7. “Equity” means non-debt funds contributed towards the capital costs related to an initial licensure or change in owner or change in operator of a Birth Center which funds are free and clear of any repayment or liens against the assets of the proposed owner and/or licensee and that result in a like reduction in the portion of the capital cost that is required to be financed or mortgaged.

8. "Licensed capacity" means the number of birthing rooms a Center is licensed to operate.

9. "Low-risk" means expected normal, uncomplicated prenatal course assisted by adequate prenatal care and prospects for a normal uncomplicated birth based on continual screening for prenatal high-risk factors (see § 8.10 of this Part) which preclude admission to the Center for childbirth.

10. "Midwife" means an individual licensed to practice midwifery in Rhode Island pursuant to the provisions of R.I. Gen. Laws § 23-13-9 and the rules and regulations for Midwives (Subchapter 05 Part 23 of this Chapter).

11. "Mother" or "women" or "client", means a pregnant individual, or a mother-to-be, or a mother, as the case may be.

12. "Obstetrical physician" means an individual licensed pursuant to the provisions of R.I. Gen. Laws Chapter 5-37 to practice medicine and with current admitting obstetrical privileges in a licensed hospital nearby the admitting Center.

13. "Person" means any individual, trust or estate, partnership, corporation (including associations, joint stock companies), limited liability company, state, or political subdivision or instrumentality of the state.

14. "Practice of midwifery" means the authorization provided by rules and regulations for Midwives (Subchapter 05 Part 23 of this Chapter), which allow a licensed midwife to attend cases of normal childbirth, to provide prenatal, intrapartum and post-partum care including immediate care of the newborn, in continual collaboration with a physician (as defined therein) and in accordance with acceptable standards of practice.

## 8.4 Licensing Procedures

### 8.4.1 General Requirements for Licensure

A. No person or governmental unit acting severally or jointly with any other person or governmental unit shall establish, conduct, maintain or operate or hold itself out as a Birth Center in Rhode Island without a license in accordance with the requirements of R.I. Gen. Laws § 23-17-4 and this Part.

B. Each license shall specify the licensed capacity of the Center.

C. The number of women in active labor, admitted to birth rooms at any given point in time shall be no greater than the number of birth rooms in the Center.

D. Centers shall be limited to those practices normally accomplished in uncomplicated childbirth, including simple episiotomies and repairs. Any other surgical procedures such as tubal ligation, termination of pregnancy or such other would require the Center to be specifically licensed as a Freestanding Ambulatory Surgical Center in accordance with the rules and regulations for Licensing of Freestanding Ambulatory Surgical Centers (Part 5 of this Subchapter).

E. Proposed changes in birth room capacity shall be submitted in writing to the Department and shall be subject to the approval of the Department.

F. Any Birth Center that utilizes latex gloves shall do so in accordance with the provisions of Use of Latex Gloves by Health Care Workers, in Licensed Health Care Facilities, and by Other Persons, Firms, or Corporations Licensed or Registered by the Department (Part 20-15-3 of this Title).

G. Each Birth Center shall establish and maintain a health care facility specific electronic mail address (i.e., e-mail address) to be provided to the Department for the purposes of contacting the Birth Center with both routine communications and emergency notices. The Birth Center shall be responsible for providing

notice to the Department at any time that the Birth Center's specific electronic mail address is changed or updated.

### 8.4.2 Application for License, Initial License or Changes in Owner, Operator, or Lessee

A. Application for a license to conduct, maintain or operate a Birth Center shall be made to the Department upon forms provided by it, and shall contain such information as the Department reasonably requires, including but not limited to evidence of ability to comply with the provisions of R.I. Gen. Laws § 23-17-4 and this Part.

B. A notarized listing of names and addresses of direct and indirect owners whether individual, partnership or corporation with percentages of ownership designated shall be provided with the application for licensure and shall be updated annually. The list shall include each owner (in whole or in part) of any mortgage, deed or trust, note or other obligation secured (in whole or in part) by the Center of any of the property or assets of the Center. The list shall also include all officers, directors and other persons or any subsidiary corporation owning stock, if the Center is organized as a corporation, and all partners if the Center is organized as a partnership.

C. Application for initial licensure or changes in the owner, operator, or lessee of a Center shall be made on forms provided by the Department and shall contain but not be limited to information pertinent to the statutory purpose expressed in R.I. Gen. Laws § 23-17-3 or to the considerations enumerated in § 8.4.3(D) of this Part. Three (3) paper copies and an electronic copy of such applications are required to be provided.

1. Each application filed pursuant the provisions of this section shall be accompanied by a non-returnable, non-refundable application fee as set forth in the rules and regulations pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health (Part 10-05-2 of this Title).

### 8.4.3 Issuance and Renewal of License

A. Upon receipt of an application for license, the Department shall issue a license or renewal thereof for a period of no more than one (1) year if the applicant meets the requirements of R.I. Gen. Laws § 23-17-4 and this Part. Said license, unless sooner suspended or revoked, shall expire by limitation on the 31st day of December following its issuance and may be renewed from year to year after inspection and approval by the Department.

B. A license shall be issued to a specific licensee for a specific location and shall not be transferable. The license shall be issued only for the premises and the individual owner, operator or lessee, or to the corporate entity responsible for its governance.

1. Any initial license or any change in owner, operator, or lessee of a licensed Center shall require prior review by the Health Services Council and approval of the Department as provided in §§ 8.4.3(D) and (E) of this Part or for expedited review conducted pursuant to § 8.4.3(H) of this Part, as a condition precedent to the transfer, assignment or issuance of a new license.

C. A license issued hereunder shall be the property of the State of Rhode Island loaned to such licensee and it shall be kept posted in a conspicuous place on the licensed premises.

D. Except for expedited review conducted pursuant to § 8.4.3(H) of this Part, reviews of applications for initial licensure or for changes in owner, operator, or lessee of licensed Center shall be conducted according to the procedures stated in R.I. Gen. Laws § 23-17-14.4. The Department will notify and afford the public thirty (30) days to comment on such application.

E. The limits on licensing criteria are stated in R.I. Gen. Laws § 23-17-14.3. In conducting reviews of such applications, the Health Services Council shall specifically consider and it shall be the applicant's burden of proof to demonstrate:

1. The character, commitment, competence and standing in the community of the proposed owners, operators, or directors of the Center as evidenced by:

a. In cases where the proposed owners, operators, or directors of the health care facility currently own, operate, or direct a health care facility, or in the past five (5) years owned, operated or directed a health care facility, whether within or outside Rhode Island, the demonstrated commitment and record of that (those) person(s):

(1) In providing safe and adequate treatment to the individuals receiving the health care facility's services;

(2) In encouraging, promoting and effecting quality improvement in all aspects of health care facility services; and

(3) In providing appropriate access to health care facility services;

b. A complete disclosure of all individuals and entities comprising the applicant and

c. The applicant’s proposed and demonstrated financial commitment to the health care facility.

2. The extent to which the facility will provide or will continue without material effect on its viability at the time of change of owner, operator, or lessee, to provide safe and adequate treatment for individuals receiving the facility's services as evidenced by:

   a. The immediate and long term financial feasibility of the proposed financing plan;

   b. The proposed amount and sources of owner's equity to be provided by the applicant;

   c. The proposed financial plan for operating and capital expenses and income for the period immediately prior to, during and after the implementation of the change in owner, operator or lessee of the health care facility;

   d. The relative availability of funds for capital and operating needs;

   e. The applicant's demonstrated financial capability;

   f. Such other financial indicators as may be requested by the state agency;

3. The extent to which the facility will provide or will continue to provide safe and adequate treatment for individuals receiving the facility's service and the extent to which the facility will encourage quality improvement in all aspects of the operation of the health care facility as evidenced by:

   a. The credibility and demonstrated or potential effectiveness of the applicant's proposed quality assurance programs;

4. The extent to which the facility will provide or will continue to provide appropriate access with respect to traditionally underserved populations as evidenced by:

   a. In cases where the proposed owners, operators, or directors of the health care facility currently own, operate, or direct a health care facility, or in the past five years owned, operated or directed a health care facility, both within and outside of Rhode Island, the

demonstrated record of that person(s) with respect to access of traditionally underserved populations to its health care facilities; and

b. The proposed immediate and long term plans of the applicant to ensure adequate and appropriate access to the programs and health care services to be provided by the health care facility.

5. In consideration of the proposed continuation or termination of emergency, primary care and/or other core health care services by the facility.

a. The effect(s) of such continuation or termination on the provision of access to safe and adequate treatment of individuals, including but not limited to traditionally underserved populations.

6. And in cases where the application involves a merger, consolidation or otherwise legal affiliation of two or more health care facilities, the proposed immediate and long term plans of such health care facilities with respect to the health care programs to be offered and health care services to be provided by such health care facilities as a result of the merger, consolidation or otherwise legal affiliation.

F. Subsequent to reviews conducted under §§ 8.4.3(D), (E), (G) and (H) of this Part, the issuance of a license by the Department may be made subject to any condition, provided that no condition may be made unless it directly relates to the statutory purpose expressed in R.I. Gen. laws § 23-17-3 or to the review criteria set forth in § 8.4.3(E) of this Part. This shall not limit the authority of the Department to require correction of conditions or defects which existed prior to the proposed change of owner, operator, or lessee and of which notice had been given to the facility by the Department.

G. Applicants for initial licensure may, at the sole discretion of the Department, be reviewed under expedited review procedures established in § 8.4.3(H) of this Part if the Department determines:

1. That the legal entity seeking licensure is the licensee for one or more health care facilities licensed in Rhode Island pursuant to the provisions of R.I. Gen. Laws Chapter 23-17 whose records of compliance with licensure standards and requirements are deemed by the Department to demonstrate the legal entity’s ability and commitment to provide quality health services; and

2. That the licensure application demonstrates complete and satisfactory compliance with the review criteria set forth in § 8.4.3(E) of this Part.

H. Expedited reviews of applications for initial licensure of Birth Centers shall be conducted according to the following procedures:

1. Within ten (10) working days of receipt, in acceptable form, of an application for initial licensure the Department will determine if such application will be granted expedited review and the Department will notify the public of the Department's initial assessment of the application materials with respect to the review criteria in § 8.4.3(E) as well as the Department's intent to afford the application expedited review. At the same time the Department will afford the public a twenty (20) day period during which the public may review and comment on the application and the Department's initial assessment of the application materials and the proposal to afford the application expedited review.

2. Written objections from affected parties directed to the processing under the expedited procedures and/or the satisfaction of the review criteria shall be accepted during the twenty (20) day comment period. Objections must provide clear, substantial and unequivocal rationale as to why the application does not satisfy the review criteria and/or why the application ought not to be processed under the expedited review mechanism.

3. The Department may propose a preliminary report on such application provided such proposed report incorporates findings relative to the review criteria set forth in § 8.4.3(E) of this Part.

4. The Health Services Council may consider such proposed report and may provide its advisory to the Director of Health by adopting such report in amended or unamended form.

    a. The Health Services Council, however, is not bound to recommend to the Director that the application be processed under the provisions for expedited review as delineated in §§ 8.4.3(G) and (H) of this Part.

5. The Health Services Council shall take under advisement all objections both to the merits of the application and to the proposed expedited processing of the proposed application and shall make a recommendation to the Director regarding each.

6. Should the Health Services Council not recommend to the Director that the application be processed under expedited review procedures as initially proposed, such application may continue to be processed consistent with the time frames and procedures for applications not recommended for expedited review.

7. If expedited review is not granted, then the comment period may be forthwith extended consistent with the time frames in § 8.4.3(D) for applications not proposed for expedited review.

8. The Director, with the advice of the Health Services Council, shall make the final decision either to grant or to deny expedited review and shall make the final decision to grant or to deny the application on the merits within the expedited review mechanism and time frames.

### 8.4.4 Inspections

A. The Department shall make or cause to be made such inspections and investigations, as it deems necessary, in accordance with R.I. Gen. Laws § 23-17-10 and this Part.

B. Every Center shall be given notice within fifteen (15) business days by the Department of any deficiencies reported as a result of an inspection or investigation.

C. A duly authorized representative of the Department shall have the right to enter at any time without prior notice to inspect the entire premises and services, including all records of any Center for which an application has been received or for which a license has been issued. Any application shall constitute permission for and willingness to comply with such inspections.

D. Refusal to permit inspections shall constitute a valid ground for license revocation.

### 8.4.5 Denial, Suspension, Revocation of License or Curtailment of Activities

A. The Department is authorized to deny, suspend or revoke the license of or to curtail the activities of any Center which:

1. Has failed to comply with the rules and regulations pertaining to the licensing of Birth Centers; and

2. Has failed to comply with the provisions of R.I. Gen. Laws Chapter 23-17.

3. Reports of deficiencies noted in inspections conducted in accordance with § 8.4.4 of this Part shall be maintained on file in the Department, and shall be considered by the Department in rendering determinations to deny, suspend or revoke the license or to curtail activities of a Center.

B. Whenever an action shall be proposed to deny, suspend or revoke the license of or to curtail the activities of a Center, the Department shall notify the Center by

certified mail, setting forth reasons for the proposed action, and the applicant or licensee shall be given an opportunity for a prompt and fair hearing in accordance with R.I. Gen. Laws §§ 23-17-8 and 42-35-9 and in accordance with the provisions of § 8.9.2 of this Part.

1. However, if the Department finds that public health, safety, or welfare imperatively requires emergency action and incorporates a finding to that effect in its order, the Department may order summary suspension of license or curtailment of activities pending proceedings for revocation or other action in accordance with R.I. Gen. Laws §§ 23-1-21 and 42-35-14(c).

C. The appropriate state and federal agencies shall be notified of any action taken by the Department pertaining to denial, suspension, revocation of license, or curtailment of activities.

## 8.5 Organization and Management

### 8.5.1 Governing Body and Management

A. Each Center shall have an organized governing body or equivalent legal authority ultimately responsible for:

1. The management and control of the operation;

2. The assurance of quality care and services;

3. Compliance with all federal, state and local laws and regulations; and

4. Other relevant health and safety requirements, including the rules and regulations of this Part.

B. The governing body or equivalent legal authority shall be responsible to provide a sufficient number of appropriately qualified personnel, physical resources and equipment, supplies and services for the provision of safe, effective and efficient delivery of care services for normal uncomplicated pregnancies to low-risk mothers as defined in this Part.

C. The governing body or equivalent legal authority shall appoint and assure the competence of:

1. An individual responsible for the administrative operation of the Center;

2. A Director of Medical Affairs, responsible for professional practices and services and for the achievement and maintenance of quality care services; and

3. A Director of the Birth Center responsible for the day to day management of the clinical services.

4. The governing body or equivalent legal authority shall furthermore be responsible to establish a mechanism through the organization's by-laws and/or policies to assure that the Director of Medical Affairs, the Director of the Birth Center and other clinical staff are duly qualified by education, training and experience and meet the requirements of this Part.

D. The governing body or equivalent legal authority shall adopt and maintain by-laws defining responsibilities for the operation and performance of the organization, identifying purposes and means of fulfilling such, and in addition the by-laws shall include but not be limited to:

1. A statement of qualifications and responsibilities of the Director of Medical Affairs and the Director of the Center;

2. A statement of the governing body's responsibility for the quality care and services;

3. A statement of policy pertaining to the criteria for the selection, admission and transfer or referral of mothers and/or newborns in accordance with the requirements of this Part;

4. A statement relating to development and implementation of long and short range plans;

5. A statement relating to conflict of interest on the part of the governing body and staff;

6. A policy statement concerning the publication of an annual report, including a certified financial statement; and

7. Such other matters as may be relevant to the organization of the Center.

E. Furthermore, the governing body or equivalent legal authority in consultation with the Director of Medical Affairs shall be ultimately responsible to develop policies governing no less than the following:

1. Modalities of health and medical services to be provided;

2. Involvement of mother and whenever possible, partner, in the development and assessment of plan of care;

3. Signed consent for the provision of services;

4. Referrals and written agreements with other health care facilities, community agencies and medical personnel to insure back-up services and continuity of care in accordance with § 8.5.5 of this Part;

5. Effective review of professional practices;

6. Quality assurance for care and services; and

7. Such other matters as may be relevant to the organization and operation of the Center, the delivery of services and as may be required under the rules and regulations of this Part.

### 8.5.2 Director of Medical Affairs

A. The Director of Medical Affairs shall be appointed by and responsible to the governing body or equivalent legal authority, and shall be a board-certified obstetrician/ gynecologist, with full obstetrical privileges in a licensed hospital nearby the Center. The Director of Medical Affairs may also be designated as the Director of the Birth Centers and may also be designated as the individual responsible for the administrative operation of the Center. Furthermore, the Director of Medical Affairs shall be responsible for:

1. Advising and consulting with the staff of the Center on all matters related to medical management of pregnancy, birth, postpartum, newborn and gynecologic health care and infection control;

2. The approval of written policies and procedures and protocols for midwifery care management where appropriate or applicable;

3. The coordination of all professional medical consultants to the Center (i.e., consulting obstetrical physicians, pediatricians, family practice physicians, etc.); and

4. Such other functions as may be deemed appropriate.

5. In addition, it shall be the responsibility of the Director of Medical Affairs to determine if a mother and/or newborn found to have clinically significant risk factors (see §§ 8.10, 8.11, and 8.12 of this Part) should be admitted to the Center, or whether or not the Center should continue to provide care to the mother and/or newborn during the puerperium period.

### 8.5.3 Birth Center Director

The Birth Center Director, who may also be the designated individual responsible for the administrative operation of the Center, shall be either an obstetrical physician as defined in this Part, or a midwife licensed in Rhode Island.

### 8.5.4 Personnel

A. Each Center shall be staffed with an appropriate number of professional and ancillary personnel whose education, training and experience is commensurate with assigned duties and responsibilities.

1. There shall be on the premises at all times when a woman is in labor, a staff person who hold a current certificate in cardiopulmonary resuscitation from a recognized program such as the American Heart Association or the American Red Cross.

B. There shall be at least two (2) staff members attending each birth; one of the two must be an obstetrical physician or a midwife, licensed in Rhode Island. The other member may be a midwife, or an obstetrical physician licensed in Rhode Island, or a nurse, nurse practitioner, or physician assistant licensed in Rhode Island, who has training and experience in obstetrical care and resuscitation of the newborn. Furthermore:

1. Whenever one or more women in active labor are on the premises there shall be at least one staff member on the premises in excess of the number of women in labor.

2. Each Center shall establish a mechanism to enable professional staff of the Center to make immediate telephone contact with an obstetrical physician and a pediatrician on a twenty-four (24) hour basis, seven (7) days a week. Mechanical answering services shall not be acceptable.

3. Each Center must ensure all qualified personnel and clinical staff shall be trained in infant and adult resuscitation. Clinical staff or qualified personnel who have demonstrated the ability to perform neonatal resuscitation procedures must be present during each birth.

C. Each Center shall establish a job description for each classification of position, which clearly delineates qualifications, duties, authority and responsibilities inherent in each position.

D. Records shall be maintained on the premises for all personnel which shall contain no less than:

1. Current background information pertaining to qualifications, including evidence of national criminal background checks for Center personnel whose employment involves routine contact with a patient;

2. Evidence of registration, certification or licensure as may be required by law; and

3. Signed contracts for those employees employed on a part-time basis.

4. Each Center shall require all persons, including students, who examine, observe, or treat a patient to wear a photo identification badge which states, in a reasonably legible manner, the first name, licensure/ registration status, if any, and staff position of such person.

E. Upon hire and prior to delivering services, a pre-employment health screening shall be required for each individual who has or may have direct contact with a patient in the birth Center. Such health screening shall be conducted in accordance with the rules and regulations pertaining to Immunization, Testing, and Health Screening for Health Care Workers (Part 20-15-7 of this Title) .

**8.5.5 Written Agreements**

A. Each Center shall enter into signed written agreements to ensure accessibility to supportive services, and such agreement must clearly delineate the mutual responsibilities of the undersigned parties to ensure the provision of services as agreed upon. Such agreements shall be entered into with no less than:

1. A hospital licensed in Rhode Island which is nearby the Center and which has an obstetrical service, in order to provide emergency back-up services to a mother and/or infant in need of emergency obstetrical and/or pediatric hospital services;

2. "Obstetrical physician(s)" as defined in this Part to ensure availability to the staff and mothers at the Center, twenty-four (24) hours a day, seven (7) days a week, in accordance with agency policies and this Part;

3. A board certified pediatrician, with pediatric privileges in a hospital licensed in Rhode Island;

4. An ambulance service licensed in Rhode Island to ensure the immediate transfer of mothers and/or newborns in emergencies, when appropriate;

5. A clinical laboratory licensed in Rhode Island to ensure accessibility to a full range of clinical laboratory testing, as may be required;

6. A radiological service agreement with a provider licensed in Rhode Island to ensure accessibility to a full range of radiological services, as may be required; and

7. Such other, as may be required for the provision of supportive services (see § 8.6.9 of this Part) which are not provided directly by the Center.

### 8.5.6 Rights of Clients

A. Each Center shall observe applicable provisions of R.I. Gen. Laws § 23-17-19.1 with respect to each client.

B. In accordance with R.I. Gen. Laws § 23-17-19.2, each Center shall display in a conspicuous place on the premises, a copy of the "Rights of Patients" as defined in R.I. Gen. Laws § 23-17-19.1.

### 8.5.7 Disaster Preparedness

A. Each Center shall develop and maintain a written disaster preparedness plan which shall include specific provisions and procedures for the emergency care of mothers and infants in the event of fire, natural disaster or functional failure of equipment.

1. Such a plan shall be developed and coordinated with appropriate state and local agencies and representatives concerned with emergency safety and rescue.

2. A copy of the plan shall be submitted to the Department.

3. Simulated drills testing the effectiveness of the plan shall be conducted at least semi-annually. Written reports and evaluation of all drills shall be maintained by the Center and available for review by the Department.

B. Emergency steps of action shall be clearly outlined and posted in conspicuous locations throughout the Center.

### 8.5.8 Administrative Records

A. Each Center shall maintain such administrative records as may be deemed necessary by the Department. These records shall include but not be limited to:

1. Monthly statistical summary of numbers of visits, deliveries appropriately classified;

2. An administrative record, log book or appointment book maintained in chronological sequence of admissions, which shall include pertinent

information such as mother's name, age, address, parity, expected delivery date, date of each visit, reason for appointment, complications, date of admission, date of discharge or transfer, morbidity and mortality data, and such other data as may be relevant;

3. A record of all transfers to hospitals or other sources, and consultation; and

4. Such other reports or records as may be deemed appropriate.

### 8.5.9 Uniform Reporting System

A. Each Center shall establish and maintain records and data in such a manner as to make uniform the system of periodic reporting. The manner in which the requirements of this Part may be met shall be prescribed from time to time in directives promulgated by the Director.

B. Each Center shall report to the Department detailed statistical data pertaining to its operation, services and facility. Such reports and data shall be made at such intervals and by such dates as determined by the Director.

C. The Department is authorized to make the reported data available to any state or federal agency concerned with or exercising jurisdiction over the Center.

D. The directives promulgated by the Director pursuant to this Part shall be sent to each Center to which they apply. Such directives shall prescribe the form and manner in which the statistical data required shall be furnished to the Department.

## 8.6 Management of Clinical Services

### 8.6.1 Selection of Clients

A. Each Center shall clearly delineate in its policy and procedure manual the medical and social risk factors which exclude women from the low-risk intrapartum group. At a minimum, mothers with problems and conditions considered to be high-risk as listed in § 8.10 of this Part, must be precluded from admission to the Center's services, except mothers with problems and conditions identified with an asterisk in § 8.10 of this Part shall require in each particular case for the Director of Medical Affairs to make a determination as to whether or not the mother may be admitted to the Center for services in accordance with § 8.5.2 of this Part.

B. Therefore, only those mothers who have no abnormal findings or findings declared insignificant (see § 8.6.1(A) of this Part) and demonstrate the potential

for an uncomplicated course of pregnancy and labor, may be accepted for childbirth at the Center.

C. An initial assessment shall be made of every woman seeking Birth Center services. Such assessment shall be made by a professional staff member (obstetrician and/or midwife) to determine eligibility of the women for admission to the Center in accordance with the provisions of § 8.6.1(A) of this Part. All findings of the assessment shall be recorded into the clinical record, signed by the responsible person and countersigned by the Director of Medical Affairs.

D. Women who fail to register with the Center before the end of first trimester shall be excluded from admission unless a written, signed exception is made by the Director of Medical Affairs on an individual basis.

### 8.6.2 Orientation and Childbirth Education

A. Each Center shall assure that each woman and family registering for care at the Center shall be given an orientation to the Center which includes information pertaining to no less than:

1. The philosophy and goals of the Center;

2. Services available directly at the Center;

3. Services provided through consultation and referrals;

4. Policies and procedures;

5. Requirement for signed written consent for care and services, attesting to full awareness of care and services to be provided;

6. Involvement of mother (and partner whenever possible) in the development and assessment of plan of care in accordance with § 8.6.10 of this Part;

7. Charges for required care and potential additional charges;

8. Risk factors associated with possible poor outcomes which are subject to the Director of Medical Affairs' final determination; and

9. Such other matters as may be deemed appropriate.

B. A childbirth education program shall be provided or made available by each Center. The program shall consist of a course of instruction to expectant mothers pertaining to prenatal care and its outcome, care of the newborn, and to provide

an understanding of labor and delivery, self-care and preparation for their participation in the childbirth process.

1. All women who have not previously attended a basic childbirth education program must attend a program of childbirth education and preferably with a support person.

### 8.6.3 Prenatal Care

A. The Center shall ensure that mothers have adequate prenatal care in accordance with the Center's written policies and procedures and acceptable standards of practice. The policies shall require:

1. Every mother to be enrolled in the development and assessment of plan of care.

2. Every mother to be evaluated within two (2) weeks of the initial request for care in order to establish a data base of risk assessment, identification of problems and needs, and to develop a protocol of car which must include:

a. Data from history, physical examination;

b. Laboratory findings, (results of gestational diabetes test at appropriate time - 26 weeks);

c. Social, nutritional and health assessments; and

d. Frequency of prenatal visits.

3. Every mother accepted for care at the Center shall be evaluated on a regular basis for the presence of any high-risk factor listed in § 8.10.2 of this Part. Mothers who develop problems or conditions considered to be high-risk shall require in each particular case that the Director of Medical Affairs makes a determination as to whether or not the Center may continue to provide care to the mother. Findings shall be entered in the clinical record and signed by the Director of Medical Affairs.

### 8.6.4 High-Risk Factors Requiring Transfer of Mother and/or Newborn

A. Any risk factor pertaining to labor, delivery or postpartum periods as outlined in §§ 8.11 and 8.12 of this Part shall be cause to preclude continuation of care of the mother and/or newborn at the Center with the exception of those risk factors identified with an asterisk which shall be subject to the Director of Medical Affairs' final determination in accordance with § 8.5.2 of this Part.

1. If a clinical complication occurs in the course of labor, delivery or postpartum, it is the responsibility of the obstetrical physician or midwife to have the mother and/or newborn transferred promptly to a licensed hospital obstetrical service and notify the Director of Medical Affairs. When indicated, a physician, nurse, nurse practitioner, or physician assistant, or midwife shall accompany the patient.

2. Consultation with the Board Certified OB/GYN and/or Pediatrician as the case may indicate shall be required in doubtful cases to ascertain referral and/or transfer to the hospital obstetrical and/or newborn service and/or other.

3. Appropriate records shall accompany a mother and/or newborn upon transfer.

### 8.6.5 Postpartum Care

A. In general, mothers and newborns shall be discharged within twenty-four (24) hours after birth in accordance with written policies and procedures established by the Center. If a mother or newborn is not in satisfactory condition for discharge within twenty-four (24) hours following birth, the mother and/or newborn shall be transferred to a hospital licensed in Rhode Island which has an obstetrical and nursery service. (See § 8.5.5(A)(1) of this Part).

B. Furthermore, the written policies and procedures established by the Director of Medical Affairs for a follow-up program of care and postpartum evaluation after discharge from the Center shall include no less than:

1. The Center's physician, midwife or nurse must be accessible by telephone, twenty-four (24) hours a day to mothers, to assist mothers in case of need during the postpartum period;

2. A home visit within twenty-four (24) to forty-eight (48) hours of discharge by the Center's professional staff personnel to insure continuity of care, and assessment of mother and newborn; and

3. The Center's postpartum program must include provisions for the assessment of mother and infant, including physical examination, laboratory screening tests at appropriate times, maternal postpartum status, instructions in child care, including immunization, referral to sources of pediatric care, provisions for family planning services, and assessment of mother-child relationship including breast feeding.

### 8.6.6 Analgesia and Anesthesia

A. Inhalation or intravenous anesthesia shall not be administered at any Birth Center.

B. Local anesthesia for episiotomies and/or repair of lacerations may be performed in accordance with written procedures established by the Director of Medical Affairs.

C. Systemic non-narcotic analgesia may be administered but pain control should depend primarily on emotional support and adequate preparation for the birth experience.

### 8.6.7 Food Service

A. Each Center shall have the capacity to provide mothers and families with appropriate nourishment and light snacks. The minimum equipment shall include refrigerator, stove, sink, cupboard and counter space or equivalent.

B. Food may be prepared by the family or prepared in the Center. When meals are prepared and served by the Center, the Center will be subject to the Rhode Island Food Code (Part 50-10-1 of this Title).

### 8.6.8 Laboratory Services

Each Center must have assurance of accessibility to a full range of clinical laboratory tests in accordance with the provisions of written agreements as required in § 8.5.5 of this Part.

### 8.6.9 Other Services

Each Center shall have assurance of access to a full range of diagnostic services including laboratory, sonography, radiology, electronic monitoring, intensive care and emergency transportation in accordance with the requirements of § 8.5.5(A)(5) of this Part.

### 8.6.10 Plan of Care

A. A written plan of care shall be established by professional staff for each mother accepted for care at the Center, including the newborn.

1. After assessment and discussion of the mother's needs, the plan of care shall be developed with the participation of the mother, and partner whenever possible. A plan which is mutually acceptable to staff and mother, shall include those provisions required by law and shall clearly identify parental choices for those care services available at the Center, such as: local anesthesia for episiotomies or for repair of laceration, breast

feeding, circumcision of newborn male, need for postpartum supportive services.

2. Furthermore, the mother shall be involved in the continuous assessment and revision as may be required of the plan of care. In addition to the above, the plan of care shall include provisions pertaining to the following:

    a. Prenatal Care.

        (1) Personal and family history;

        (2) Findings of physical examination(s) and laboratory tests; and

        (3) Continuous assessment of mother for high-risk factors.

    b. Labor.

        (1) Documentation of progress in labor and findings of examinations; and

        (2) Ensuring that clinical staff or qualified personnel who have demonstrated the ability to perform neonatal resuscitation procedures are present, pursuant to § 8.5.4(B)(3) of this Part.

    c. Intrapartum and postpartum care.

        (1) Immediate postpartum care and newborn assessment;

        (2) Eye prophylaxis to newborn;

        (3) Test for appropriate use of RH immune globulin, and metabolic screening and other tests for the newborn as may be required by law;

        (4) Postpartum examination and family planning and follow-up care;

        (5) Preparation and submission of birth certificates; and

        (6) Such other care as may be deemed necessary and appropriate.

**8.6.11 Clinical Records**

A. The Center shall maintain a clinical record for every mother and newborn serviced at the Center. Such record shall contain accurate documentation of significant clinical information pertaining to the mother and newborn sufficiently detailed and organized in such a manner to enable:

1. The responsible practitioners to provide effective continuing care to determine retrospectively the condition of the mother and newborn infant and to review procedures performed and individual's responses to the care;

2. A consultant to render an opinion after examination and review of clinical record;

3. Another practitioner to assume the care of the mother or the newborn at any time;

4. Pertinent information for quality assurance assessments to be retrieved;

5. The clinical staff to utilize the record to instruct mother and family.

B. The clinical records shall contain significant documented data to assist the clinical staff in their determinations of high-risk factors throughout the course of the mother's pregnancy, labor and delivery including the newborn in accordance with the risk-factors identified in §§ 8.10, 8.11, and 8.12 of this Part. Clinical records shall furthermore contain no less than:

1. Admitting identification data, including history, physical examination and risk assessment;

2. Signed consent;

3. Prenatal record containing blood serology, rubella screening and RH factor, blood typing and screening for irregular antibodies;

4. Labor and delivery records;

5. Clinical observations during prenatal care, labor and delivery, postpartum care, including laboratory reports, medical orders, consultation reports, signed entries by professionals rendering care;

6. Newborn record including all pertinent data of assessment and other care;

7. Complications, transfers, referrals;

8. Report of postpartum home visits;

9. Discharge summary; and

10. Such other information, data and reports as may be deemed necessary.

C. All entries in the clinical records shall be signed by the responsible person in accordance with the Center's policies and procedures.

D. All clinical records either original or accurate reproductions shall be preserved for a minimum of five (5) years following discharge of the mother and/or newborn in accordance with R.I. Gen. Laws § 23-3-26.

1. Records of minors shall be kept for at least five (5) years after such minor shall have reached the age of eighteen (18) years.

### 8.6.12 Infection Control

A. A mechanism shall be established by the Director of Medical Affairs for the development of infection control policies which shall pertain to no less than:

1. Infection surveillance activities;

2. Sanitation and asepsis;

3. Handling and disposal of waste and contaminants;

4. Sterilization, disinfection and laundry;

5. Reporting, recording and evaluation of occurrences of infections; and

6. Documentation of infection rate.

B. The Center shall report promptly to the Department infectious diseases which may present a potential hazard to patients, personnel and the public. Included are reportable diseases and the occurrences of other diseases in outbreak form.

## 8.7 Environmental Management

### 8.7.1 Housekeeping

A. The Center shall be maintained and equipped to provide functional, sanitary, safe and comfortable environment, with all furnishings in good repair, and the premises shall be kept free of hazards.

B. Written policies and procedures shall be established pertaining to environmental controls to assure comfortable, safe and sanitary environment with well-lighted space.

C. Equipment and supplies shall be provided for cleaning of all surfaces. Such equipment shall be maintained in a safe and sanitary condition.

D. Hazardous cleaning solutions, compounds, and substances shall be labeled, stored in a safe place and kept in an enclosed section separated from other cleaning materials.

E. Cleaning shall be performed in a manner which minimizes the spread of pathogenic organisms in the atmosphere.

F. Birth rooms shall be thoroughly cleaned after each delivery in accordance with the Center's infection control policies.

G. Smoking shall be permitted only in areas designated pursuant to R.I. Gen. Laws Chapter 23-20.10.

### 8.7.2 Laundry Service

A. Each Center shall make provisions for the cleaning of all linens and other washable goods provided either on the premises or per contractual arrangement.

B. A Center having laundry service on the premises shall have adequate space and equipment for the safe and effective operation of a laundry service, and in unsewered areas shall obtain approval of the sewage system to ensure adequacy in accordance with the "Rules Establishing Minimum Standards Relating to Location, Design, Construction and Maintenance of Onsite Wastewater Treatment Systems."

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

D. All soiled linen shall be placed in closed containers prior to transporting to laundry.

## 8.8 Physical Plant and Equipment

### 8.8.1 Physical Facility

A. All construction shall be subject to the laws, rules, regulations and codes of R.I. Gen. Laws Chapters 23-17 and 23-28.1, and "Guidelines for Design and Construction of Hospital and Outpatient Facilities" incorporated above at § 8.2(A) of this Part, and all other appropriate state and local laws, codes, regulations and ordinances. Where there is a difference between codes, the code having the more stringent standard shall apply.

B. All plans for new construction or the renovation, alteration, extension, modification or conversion of an existing Birth Center that may affect compliance with "Guidelines for Design and Construction of Hospital and Outpatient Facilities" incorporated above at § 8.2(A) of this Part shall be reviewed by a licensed architect, acceptable to the Director. Said architect shall certify that the plans conform to the construction requirements of "Guidelines for Design and Construction of Hospital and Outpatient Facilities" incorporated above at § 8.2(A) of this Part, prior to construction. The Birth Center shall maintain a copy of the plans reviewed and the architect's signed certification, for review by the Department upon request.

1. In the event of non-conformance for which the Birth Center seeks a variance, the general procedures outlined in § 8.9.1 of this Part shall be followed. Variance requests shall include a written description of the entire project, details of the non-conformance for which the variance is sought and alternate provisions made, as well as detailing the basis upon which the request is made. The Department may request additional information while evaluating variance requests.

2. If variances are granted, a licensed architect shall certify that the plans conform to all construction requirements of "Guidelines for Design and Construction of Hospital and Outpatient Facilities" incorporated above at § 8.2(A) of this Part, except those for which variances were granted, prior to construction. The Birth Center shall maintain a copy of the plans reviewed, the variance(s) granted and the architect's signed certification, for review by the Department upon request.

C. Upon completion of construction, the Birth Center shall provide written notification to the Department, describing the project, and a copy of the architect's certification. The Birth Center shall obtain authorization from the Department prior to occupying/re-occupying the area. At the discretion of the Department, an on-site visit may be required.

### 8.8.2 General Provisions for Physical Facility (Including Existing Facilities)

A. Each Center shall be constructed, designed, planned, equipped and maintained to protect the health and safety of mothers, newborns, personnel and the public, and to facilitate emergency exit of mothers and/or newborns in the event of emergency.

B. Reception areas, examination rooms, birth rooms, family rooms and other supportive areas shall be designed and equipped to provide good and safe care as well as to provide privacy and comfort to mothers and their families.

C. The birth room(s) shall be located to provide unimpeded, rapid access to an exit of the building where emergency transportation vehicles may be accommodated.

1. Hallways and doors providing access and entry into the birth room shall be of adequate width to accommodate ambulance stretchers and wheelchairs.

2. The birth room shall be spacious enough to accommodate staff to move freely and to include at least:

a. A large bed or double bed;

b. Chairs - lounge and straight-back;

c. Bedside/procedure tables;

d. A bassinet;

e. Space for birth room supplies and equipment and for family belongings; and

f. Access to a sink with hot and cold running water with elbow-wrist controls.

D. Acceptable toilet facilities shall be available to each laboring mother and adequate shower facilities shall also be available to accommodate mothers.

E. Utility, storage and laundry areas shall be designed and equipped for washing, sterilizing and storage of equipment, linens and medical supplies in a manner which insures segregation of clean linen and sterile supplies and equipment from those that are soiled and/or contaminated.

F. Medication and storage areas shall be provided and equipped with locks to ensure the safekeeping of drugs and biologicals.

G. Heating and ventilation systems shall be capable of maintaining comfortable temperatures.

H. Lighting and electrical services: Each Center shall be adequately lighted with appropriate lighting for examination in the birth room(s).

1. An emergency source of electrical light shall be available for the protection of mothers and families in the event the normal electrical power is interrupted.

2. All electrical and other equipment used in the Center shall be maintained free of defects which could be a potential hazard to mother/newborns, their families and staff.

I. An elevator shall be provided where care is provided at different floor levels. The cab size of the elevator shall be large enough to accommodate a stretcher, an attendant and such equipment as may be needed.

### 8.8.3 Equipment

A. Each Center 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. Such equipment shall include no less than:

1. Oxygen and positive pressure masks;

2. DeLee trap suction and infant laryngoscope and airways;

3. IV equipment;

4. Blood expanders;

5. Medications identified in protocols for emergency needs;

6. Infant transport equipment and infant warmers.

B. In addition, the Center shall be equipped with standard equipment which includes no less than:

1. Equipment for standard screening;

2. Laboratory tests; and

3. Sterilization of instruments.

### 8.8.4 Plumbing

All plumbing material and plumbing systems or parts thereof installed shall meet the minimum requirements of R.I. Gen. Laws Chapter 23-27.3.

### 8.8.5 Water Supply

Water shall be obtained from an approved water system and shall be distributed to conveniently located taps and fixtures throughout the facility and shall be

adequate in volume and pressure for all Center purposes, including fire safety in accordance with R.I. Gen. Laws Chapter 23-27.3.

### 8.8.6 Waste Disposal

Waste disposal methods shall be provided that are acceptable to the Department.

## 8.9 Practices and Procedures, Confidentiality

### 8.9.1 Variance Procedure

A. The Department may grant a variance either upon its own motion or upon request of the applicant from the provisions of any rule or regulation in a specific case, if it finds that a literal enforcement of such provision will result in unnecessary hardship to the applicant and that such a variance will not be contrary to the public interest, public health and/or health and safety of patients.

B. A request for a variance shall be filed by any applicant in writing, setting forth in detail the basis upon which the request is made.

1. Upon the filing of each request for variance with the Department, and within thirty (30) days thereafter, the Department shall notify the applicant by certified mail of its approval or in the case of a denial, a hearing date, time and place may be scheduled if the facility appeals the denial and in accordance with the provisions of § 8.9.2 of this Part.

### 8.9.2 Deficiencies and Plans of Correction

A. The Department shall notify the governing body or other legal authority of a facility of violations of individual standards through a notice of deficiencies which shall be forwarded to the facility within fifteen (15) days of inspection of the facility unless the director determines that immediate action is necessary to protect the health, welfare, or safety of the public or any member thereof through the issuance of an immediate compliance order in accordance with R.I. Gen. Laws § 23-1-21.

B. A facility which received a notice of deficiencies must submit a plan of correction to the Department within fifteen (15) days of the date of the notice of deficiencies. The plan of correction shall detail any requests for variances as well as document the reasons therefore.

C. The Department will be required to approve or reject the plan of correction submitted by a facility in accordance with § 8.9.2(B) of this Part within fifteen (15) days of receipt of the plan of correction.

D. If the Department rejects the plan of correction, or if the facility does not provide a plan of correction within the fifteen (15) day period stipulated in § 8.9.2(C) of this Part, or if a facility whose plan of correction has been approved by the Department fails to execute its plan within a reasonable time, the Department may invoke the sanctions enumerated in § 8.4.5 of this Part. If the facility is aggrieved by the sanctions of the Department, the facility may appeal the decision and request a hearing in accordance with R.I. Gen. Laws Chapter 42-35.

E. The notice of the hearing to be given by the Department of Health shall comply in all respects with the provisions of R.I. Gen. Laws Chapter 42-35. The hearing in all respects shall comply with all provisions therein.

### 8.9.3 Rules Governing Practices and Procedures

All hearings and reviews required under the provisions of R.I. Gen. Laws Chapter 23-17, shall be held in accordance with the provisions of Part 10-05-4 of this Title [Practices and Procedures Before the Department of Health].

### 8.9.4 Confidentiality

Disclosure of any health care information relating to individuals shall be subject to the provisions of R.I. Gen. Laws Chapter 5-37.3 and other relevant statutory and federal requirements.

## 8.10 Prenatal High-Risk Factors

### 8.10.1 Reproductive History

A. * Signifies that the risk factor could be clinically significant and, therefore, subject to the Director of Medical Affairs' final determination.

B. Maternal Characteristics.

1. Age: <16 and >40 years

2. *Height: <60 inches

3. *Weight: <100 lbs. and >200 lbs.

4. Parity: Four (4) or more

C. Past Obstetrical History.

1. *Habitual Abortion: more than two (2) consecutive spontaneous or two (2) or more induced abortions

2. Post Partum Hemorrhage or 3rd Stage problem(s), e.g., severe lacerations, inverted uterus, retained placenta, etc.

3. *Pre-Eclampsia

4. Hypertension - all hypertensive disorders of pregnancy

5. *Previous Second Stage Labor greater than two (2) hours

6. Previous Delivery:

    a. Other than spontaneous or low forceps; and

    b. Caesarian Section

7. Baby:

    a. *Prematurity <37 weeks or <2500 grams or >4500 grams

    b. *Respiratory Distress

    c. *Congenital abnormality

    d. *Known genetic disorders

    e. *Any Neonatal death

    f. *Fetal death

    g. *Significant birth injury

D. Associated Conditions.

1. Scarred uterus - vaginal plastic surgery - * Urinary tract surgery

2. Adrenal disease

3. Cardiovascular disease except for mild asymptomatic Class I without hemodynamic abnormality

4. Collagen disease

5. Renal disease (albuminuria, hematuria, casts)

6. Chronic or acute liver disease

7. Diabetes Mellitus

8. Gestational diabetes - (blood or plasma screening test or abnormal glucose tolerance test or equivalent)

9. *Gastrointestinal disorders, e.g., regional ileitis, ulcerative colitis, etc.

10. Genetic Disorder

11. Hematologic disease

12. Hypertension

13. *Pulmonary disease, (not requiring treatment) e.g., asthma, chronic bronchitis, etc.

14. *Pulmonary disease, requiring treatment

15. *Psychiatric

16. Neurologic disorder

17. Hyperthyroidism

18. Venereal and Related diseases

19. *Thrombophlebitis

20. *Alcohol abuse

21. *Drug abuse

22. *Smoking - (> 1 pkg. a day)

23. Such other medial/obstetrical/or surgical problem or condition as determined to be significant risk to the mother or fetus.

**8.10.2 Prenatal Course of Current Pregnancy**

A. Late Registration (see § 8.6.1(D) of this Part)

B. Anemia (less than ten (10) gm Hgb concentration and not responding to therapy)

C. Uterine Bleeding (except for threatened abortion in first trimester)

D. Any presentations except vertex position at 37 weeks or beyond

E. Intra-uterine fetal growth retardation or fetus small for gestational age

F. Pre-Eclampsia

G. Hypertension - resting BP140/90 or an increase of 30 systolic or fifteen (15) diastolic over the patient's base line pressure

H. Known Multiple gestation

I. Premature Labor at less than thirty-seven (37) weeks

J. Premature rupture of membranes under thirty-seven (37) weeks

K. Prolonged rupture of membranes:

1. For fourteen (14) hours without regular contractions; or

2. For twenty-four (24) hours with contractions unless delivery is imminent.

L. Prolonged Pregnancy - (at 42 completed weeks or more)

M. Polyhydramnios

N. Significant isoimmunization against RH or other antigen which may affect the fetus

O. Development of any condition listed above under § 8.10.1 of this Part

## 8.11 High-Risk Factors Requiring Transfer of Mother from the Center

### 8.11.1 Labor – Delivery – Post Partum

A. Abnormal Bleeding

B. Cord Prolapse

C. Dystocia Labor (at term)

D. Prolonged latent phase with ruptured membranes

1. (20 hrs. nulliparous)

2. (14 hrs. multiparous)

E. Protraction or arrest in the active stage

F. Prolonged second stage greater than two (2) hours

G. Secondary arrest

H. Extensive perineal or cervical laceration

I. Fever above 100.4 F on two (2) occasions four (4) hours apart

J. Fetal Distress -

1. Fetal heart rate < 100 or > 180 or any audible decelerations of heart beat

K. Meconium (stain of the amniotic fluid)

L. Hypertension or Hypotension Maternal Tachycardia

M. More than 24 hours in active labor unless delivery is imminent

N. Presentation (any other than vertex)

O. Retained placenta (greater than one hour)

P. Any other condition requiring more than twelve (12) hours observation post delivery

## 8.12 Criteria Requiring Transfer of Newborn

A. * Signifies that the risk factor could be clinically significant and, therefore, subject to the Director of Medical Affairs' final determination.

B. Apgar score of:

1. Five (5) or less at one (1) min.; or

2. Seven (7) or less at five (5) min.

C. Exaggerated tremors

D. Failure to take feeding

E. Instability of vital signs which includes T.P.R.

F. Jaundice

G. Major congenital anomaly

H. Neonatal sepsis or infection

I. Respiratory distress

J. *Signs of pre or post maturity

K. Shock or asphyxia

L. *Weight (<2500 grams)

M. Any other condition requiring more than twelve (12) hours observation post delivery