

RULES AND REGULATIONS
FOR LICENSING
BIRTH CENTERS
(R23-17-BC)

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS



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INTRODUCTION

These rules and regulations are promulgated pursuant to the authority set forth in section 23-17-10 of the General Laws of Rhode Island, as amended, 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 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.

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 the Licensing of Hospitals (R23-17-HOSP)* and shall operate under the hospital license.

Pursuant to the provisions of section 42-35-3(c) of the General Laws of Rhode Island, as amended, the following issues have been given consideration in arriving at the regulations in the best interest of the health, safety and welfare of the public; (1) alternative approaches to the regulations; (b) duplication or overlap with other state regulations; and (c) significant economic impact on small business as defined in Chapter 42-35 of the General Laws, which could result from these regulations. No known overlap or duplication, no alternative approach nor any significant economic impact were identified.

These rules and regulations shall supersede any previous rules and regulations related to the licensing of birth centers promulgated by the Rhode Island Department of Health and filed with the Rhode Island Secretary of State.

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PART I *LICENSING PROCEDURES AND DEFINITIONS*

Section 1.0 *Definitions*

Wherever used in these rules and regulations the following terms shall be construed to mean:

- 1.1 **"Birth Center"**, hereinafter referred to as 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 mother (as defined in section 1.8 herein, during pregnancy, labor, birth and puerperium.
- 1.2 **"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.

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 subsections (a) through (d) herein.

- 1.3 **"Change in owner"** means:
- (1) 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;
 - (2) in the case of a birth center which is an unincorporated solo proprietorship, the transfer of the title and property to another person;
 - (3) in the case of a birth center which is a corporation;
 - (a) a sale, lease, exchange or other disposition of all, or substantially all of the property and assets of the corporation; or
 - (b) a merger of the corporation into another corporation; or
 - (c) the consolidation of two or more corporations, resulting in the creation of a new corporation; or
 - (d) 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

- (e) 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.

- 1.4 **"Director"** means the Director of the Rhode Island Department of Health.
- 1.5 **"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.
- 1.6 **"Licensed capacity"** means the number of birthing rooms a center is licensed to operate.
- 1.7 **"Licensing agency"** means the Rhode Island Department of Health.
- 1.8 **"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 Appendix A) which preclude admission to the Center for childbirth.
- 1.9 **"Midwife"** means an individual licensed to practice midwifery in this state pursuant to the provisions of section 23-13-9 of the General Laws of Rhode Island, as amended, and the rules and regulations thereof.
- 1.10 **"Mother"** or **"women"** or **"client"**, as used herein, refers to a pregnant woman, or a mother-to-be or a mother as the case may be.
- 1.11 **"Obstetrical physician"** means an individual licensed pursuant to the provisions of Chapters 5-36 or 5-37 of the General Laws of Rhode Island, as amended, to practice medicine and with current admitting obstetrical privileges in a licensed hospital nearby the admitting center.
- 1.12 **"Person"** means any individual, trust or estate, partnership, corporation (including associations, joint stock companies) state, or political subdivision or instrumentality of a state.
- 1.13 **"Practice of midwifery"** refers to section 9.1 of the *Rules and Regulations for Licensing of Midwives*, Rhode Island Department of Health, which authorize 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.

Section 2.0 **General Requirements for Licensure**

- 2.1 No person acting severally or jointly with any other person shall establish, conduct, maintain or operate a birth center in this state without a license in accordance with the requirements of section 23-17-4 of reference 2 and the rules and regulations herein.

- 2.1.1 No person or facility shall represent itself as a "Birth Center" or use the term "Birth Center" as its title, advertising, publications or other form of communication unless licensed as a birth center in accordance with the provisions herein, except for hospital birth centers in accordance with the *Rules and Regulations for Licensing of Hospitals*.
- 2.2 Each license shall specify the licensed capacity of the center.
- 2.3 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.
- 2.4 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 reference 14.
- 2.5 Proposed changes in birth room capacity shall be submitted in writing to the licensing agency and shall be subject to the approval of the licensing agency.

Section 3.0 ***Application for License, Initial License or Changes in Owner, Operator, or Lessee***

- 3.1 Application for a license to conduct, maintain or operate a birth center shall be made to the licensing agency upon forms provided by it, and shall contain such information as the licensing agency reasonably requires, including but not limited to evidence of ability to comply with the provisions of reference 2 and the rules and regulations herein.
- 3.2 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.
- 3.3 Application for initial licensure or changes in the owner, operator, or lessee of a center shall be made on forms provided by the licensing agency and shall contain but not be limited to information pertinent to the statutory purpose expressed in section 23-17-3 of Chapter 23-17 or to the considerations enumerated in section 4.5 herein. Twenty-five (25) copies of such applications are required to be provided.
 - 3.3.1 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*.

Section 4.0 ***Issuance and Renewal of License***

- 4.1 Upon receipt of an application for license, the licensing agency shall issue a license or renewal thereof for a period of no more than one (1) year if the applicant meets the requirements of

reference 2 and the rules and regulations herein. 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 licensing agency.

- 4.2 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.

4.2.1 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 licensing agency as provided in sections 4.4 and 4.5, or for expedited review conducted pursuant to sections 4.8 and 4.9 herein, as a condition precedent to the transfer, assignment or issuance of a new license.

- 4.3 A license issued hereunder shall be the property of the state loaned to such licensee and it shall be kept posted in a conspicuous place on the licensed premises.

- 4.4 Except for expedited review conducted pursuant to sections 4.8 and 4.9 herein, reviews of applications for initial licensure or for changes in owner, operator, or lessee of licensed center shall be conducted according to the following procedures:

- a) Within ten (10) working days of receipt, in acceptable form, of an application for initial licensure or for a license in connection with a change in the owner, operator or lessee of an existing center, the licensing agency will notify and afford the public thirty (30) days to comment on such application.
- b) The decision of the licensing agency will be rendered within ninety (90) days from acceptance of the application.
- c) The decision of the licensing agency shall be based upon the findings and recommendations of the Health Services Council unless the licensing agency shall afford written justification for variance therefrom.
- d) All applications reviewed by the licensing agency and all written materials pertinent to licensing agency minutes of all Health Services Council meetings, shall be accessible to the public upon request.

- 4.5 Except as otherwise provided in Chapter 23-17 of the General Laws of Rhode Island, as amended, a review by the Health Services Council of an application for an initial license or for a license in the case of a proposed change in the owner, operator, or lessee of a licensed center may not be made subject to any criterion unless the criterion directly relates to the statutory purpose expressed in section 23-17.3 of the General Laws of Rhode Island, as amended. 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:

4.5.1 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 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):

- (i) in providing safe and adequate treatment to the individuals receiving the health care facility's services;
 - (ii) in encouraging, promoting and effecting quality improvement in all aspects of health care facility services; and
 - (iii) 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.

4.5.2 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;
- (i) The proposed amount and sources of owner's equity to be provided by the applicant;
 - (ii) 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;
 - (iii) The relative availability of funds for capital and operating needs;
 - (iv) The applicant's demonstrated financial capability;
 - (v) Such other financial indicators as may be requested by the state agency;

4.5.3 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;

4.5.4 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 under served 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.
- 4.5.5 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.
- 4.5.6 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.
- 4.6 Subsequent to reviews conducted under sections 4.4, 4.5, 4.7 and 4.8 of these regulations, the issuance of a license by the licensing agency may be made subject to any condition, provided that no condition may be made unless it directly relates to the statutory purpose expressed in section 23-17-3 of the General Laws of Rhode Island, as amended, or to the review criteria set forth in section 4.5 herein. This shall not limit the authority of the licensing agency 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 licensing agency.
- 4.7 Applicants for initial licensure may, at the sole discretion of the licensing agency, be reviewed under expedited review procedures established in section 4.8 if the licensing agency determines (a) 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 Chapter 23-17 whose records of compliance with licensure standards and requirements are deemed by the licensing agency to demonstrate the legal entity's ability and commitment to provide quality health services; and (b) that the licensure application demonstrates complete and satisfactory compliance with the review criteria set forth in section 4.5 herein.
- 4.8 Expedited reviews of applications for initial licensure of birth centers shall be conducted according to the following procedures:
 - a) Within ten (10) working days of receipt, in acceptable form, of an application for initial licensure the licensing agency will determine if such application will be granted expedited review and the licensing agency will notify the public of the licensing agency's initial assessment of the application materials with respect to the review criteria in section 4.5 as well as the licensing agency's intent to afford the application expedited review. At the same time the licensing agency will afford the public a

twenty (20) day period during which the public may review and comment on the application and the licensing agency's initial assessment of the application materials and the proposal to afford the application expedited review.

- b) 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. The licensing agency may propose a preliminary report on such application provided such proposed report incorporates findings relative to the review criteria set forth in section 4.5. 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. The Health Services Council, however, is not bound to recommend to the Director that the application be process under the provisions for expedited review as delineated in sections 4.7 and 4.8. 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. 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. If expedited review is not granted, then the comment period may be forthwith extended consistent with the time frames in section 4.4 for applications not proposed for expedited review. 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.

Section 5.0 ***Inspections***

- 5.1 The licensing agency shall make or cause to be made such inspections and investigations, as it deems necessary, in accordance with section 23-17-10 of reference 2 and the rules and regulations herein.
- 5.2 Every center shall be given prompt notice by the licensing agency of any deficiencies reported as a result of an inspection or investigation.

Section 6.0 ***Denial, Suspension, Revocation of License or Curtailment of Activities***

- 6.1 The licensing agency 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 reference 2.
 - 6.1.1 Reports of deficiencies noted in inspections conducted in accordance with section 5.0 herein shall be maintained on file in the licensing agency, and shall be considered by the licensing agency in rendering determinations to deny, suspend or revoke the license or to curtail activities of a center.

- 6.2 Whenever an action shall be proposed to deny, suspend or revoke the license of or to curtail the activities of a center, the licensing agency 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 section 23-17-8 of reference 2 and section 42-35-9 of reference 5 and in accordance with the provisions of section 36.0 herein.
- 6.2.1 However, if the licensing agency finds that public health, safety or welfare imperatively requires emergency action and incorporates a finding to that effect in its order, the licensing agency may order summary suspension of license or curtailment of activities pending proceedings for revocation or other action in accordance with section 23-1-21 of reference 4 and section 42-35-14(c) of reference 5.
- 6.3 The appropriate state and federal agencies shall be notified of any action taken by the licensing agency pertaining to either denial, suspension, or revocation or license or curtailment of activities.

PART II ***ORGANIZATION AND MANAGEMENT***

Section 7.0 ***Governing Body and Management***

- 7.1 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 herein.
- 7.2 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 herein.
- 7.3 The governing body or equivalent legal authority shall appoint and assure the competence of:
 - (a) an individual responsible for the administrative operation of the center; (b) a Director of Medical Affairs, responsible for professional practices and services and for the achievement and maintenance of quality care services; and (c) a Director of the Birth Center responsible for the day to day management of the clinical services.
- 7.3.1 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 these rules and regulations.
- 7.4 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:
 - a) a statement of qualifications and responsibilities of the Director of Medical Affairs and the Director of the Center;
 - b) a statement of the governing body's responsibility for the quality care and services;
 - c) 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 these rules and regulations;
 - d) a statement relating to development and implementation of long and short range plans;
 - e) a statement relating to conflict of interest on the part of the governing body and staff;
 - f) a policy statement concerning the publication of an annual report, including a certified financial statement; and
 - g) such other matters as may be relevant to the organization of the center.
- 7.5 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:

- a) modalities of health and medical services to be provided;
- b) involvement of mother and whenever possible, partner, in the development and assessment of plan of care;
- c) signed consent for the provision of services;
- d) 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 section 11.0 herein;
- e) effective review of professional practices;
- f) quality assurance for care and services; and
- g) 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 herein.

Section 8.0 ***Director of Medical Affairs***

8.1 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.

8.1.1 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 Appendices A, B, and C herein) 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.

Section 9.0 ***Birth Center Director***

- 9.1 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 section 1.8 herein, or a midwife licensed in this state.

Section 10.0 ***Personnel***

- 10.1 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.
- 10.1.1 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.
- 10.2 There shall be no staff members attending each birth; one of the two must be an obstetrical physician or a midwife, licensed in this state. The other member may be a midwife, or an obstetrical physician licensed in this state, or a nurse licensed in Rhode Island, who has training and experience in obstetrical care and resuscitation of the newborn. Furthermore;
- 10.2.1 Whenever one or more women in active labor are on the premises there shall be one staff member in excess of the number of women in labor.
- 10.2.2 Each center shall establish a mechanism to enable professional staff on the center to make immediate telephone contact with an obstetrical physician on a twenty-four (24) hour basis, seven (7) days a week. Mechanical answering services shall not be acceptable.
- 10.3 Each center shall establish a job description for each classification of position, which clearly delineates qualifications, duties, authority and responsibilities inherent in each position.
- 10.4 Records shall be maintained on the premises for all personnel which shall contain no less than;
- a) current background information pertaining to qualifications;
 - b) evidence of registration, certification or licensure as may be required by law; and
 - c) signed contracts for those employees employed on a part-time basis.
- 10.5 A health care facility shall require all persons, including students, who examine, observe, or treat a patient or resident of such facility 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.

Health Screening

- 10.6 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 (R23-17-*

HCW) promulgated by the Department of Health.

Section 11.0 ***Written Agreements***

- 11.1 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:
 - 11.1.1 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;
 - 11.1.2 "obstetrical physician(s)" as defined in section 1.11 herein 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 the provisions of the rules and regulations herein;
 - 11.1.3 a board certified pediatrician, with pediatric privileges in a hospital licensed in this state;
 - 11.1.4 an ambulance service licensed in this state to ensure the immediate transfer of mothers and/or newborns in emergencies, when appropriate;
 - 11.1.5 a clinical laboratory licensed in this state to ensure accessibility to a full range of clinical laboratory testing, as may be required; and
 - 11.1.6 such other, as may be required for the provision of supportive services (see section 24.0 herein) which are not provided directly by the center.

Section 12.0 ***Rights of Clients***

- 12.1 Each center shall observe applicable provisions of section 23-17-19.1 of reference 2 with respect to each client.
- 12.2 Each center shall display in a conspicuous place on the premises, a copy of the "Rights of Patients."

Section 13.0 ***Disaster Preparedness***

- 13.1 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.
 - a) Such a plan shall be developed and coordinated with appropriate state and local agencies and representatives concerned with emergency safety and rescue.
 - b) A copy of the plan shall be submitted to the licensing agency.
 - c) 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 licensing agency.

- 13.2 Emergency steps of action shall be clearly outlined and posted in conspicuous locations throughout the center.

Section 14.0 ***Administrative Records***

- 14.1 Each center shall maintain such administrative records as may be deemed necessary by the licensing agency. These records shall include but not be limited to:
- a) monthly statistical summary of numbers of visits, deliveries appropriately classified;
 - b) 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;
 - c) a record of all transfers to hospitals or other sources, and consultation; and
 - d) such other reports or records as may be deemed appropriate.

Section 15.0 ***Uniform Reporting System***

- 15.1 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 regulation may be met shall be prescribed from time to time in directives promulgated by the Director.
- 15.2 Each center shall report to the licensing agency 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.
- 15.3 The licensing agency is authorized to make the reported data available to any state or federal agency concerned with or exercising jurisdiction over the center.
- 15.4 The directives promulgated by the Director pursuant to these regulations 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 licensing agency.

PART III ***MANAGEMENT OF CLINICAL SERVICES***

Section 16.0 ***Selection of Clients***

16.1 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. As a minimum, mothers with problems and conditions considered to be high-risk as listed in Appendix A, must be precluded from admission to the center's services, except mothers with problems and conditions identified with an asterisk in Appendix A 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 section 8.1 herein.

16.1.1 Therefore, only those mothers who have no abnormal findings or findings declared insignificant (see section 16.1 above) and demonstrate the potential for an uncomplicated course of pregnancy and labor, may be accepted for childbirth at the center.

16.2 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 section 16.1 and 16.1.1 above. 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.

16.3 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.

Section 17.0 ***Orientation and Childbirth Education***

17.1 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:

- a) the philosophy and goals of the center;
- b) services available directly at the center;
- c) services provided through consultation and referrals;
- d) policies and procedures;
- e) requirement for signed written consent for care and services, attesting to full awareness of care and services to be provided;
- f) involvement of mother (and partner whenever possible) in the development and assessment of plan of care in accordance with section 25.0 herein;
- g) charges for required care and potential additional charges;

- h) risk factors associated with possible poor outcomes which are subject to the Director of Medical Affairs's final determination; and
 - i) such other matters as may be deemed appropriate.
- 17.2 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.
- 17.2.1 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.

Section 18.0 ***Prenatal Care***

- 18.1 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:
- 18.1.1 every mother to be enrolled in the development and assessment of plan of care:
 - 18.1.2 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 care 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;
 - 18.1.3 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 Appendix A, section B of these rules and regulations. 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.

Section 19.0 ***High-Risk Factors Requiring Transfer of Mother and/or Newborn***

- 19.1 Any risk factor pertaining to labor, delivery or postpartum periods as outlined in Appendix B and Appendix C of these rules and regulations 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's final determination in accordance with section 8.1.1 herein.

19.1.1 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.

19.1.2 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.

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

Section 20.0 ***Postpartum Care***

20.1 Generally 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 Section 11.1.1 herein).

20.2 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:

20.2.1 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;

20.2.2 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

20.2.3 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, assessment of mother-child relationship including breast feeding.

Section 21.0 ***Analgesia and Anesthesia***

21.1 Inhalation or intravenous anesthesia shall not be administered at any birth center, local anesthesia for episiotomies and/or repair of lacerations may be performed in accordance with written procedures established by the Director of Medical Affairs.

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

Section 22.0 ***Food Service***

22.1 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.

- 22.2 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 Food Establishment of reference 6.

Section 23.0 ***Laboratory Services***

- 23.1 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 section 11.0 herein.

Section 24.0 ***Other Services***

- 24.1 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 section 11.1.5 herein.

Section 25.0 ***Plan of Care***

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

25.1.1 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.

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:

25.1.2 Prenatal Care

- a) personal and family history;
- b) findings of physical examination(s) and laboratory tests;
- c) continuous assessment of mother for high risk factors.

25.1.3 Labor: (documentation of progress in labor and findings of examinations);

25.1.4 Intrapartum and postpartum care:

- a) immediate postpartum care and newborn assessment;
- b) eye prophylaxis to newborn;

- c) test for appropriate use of RH immune globulin, and metabolic screening and other tests for the newborn as may be required by law;
- d) postpartum examination and family planning and follow-up care;
- e) preparation and submission of birth certificates; and
- f) such other care as may be deemed necessary.

Section 26.0 ***Clinical Records***

- 26.1 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:
 - 26.1.1 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;
 - 26.1.2 a consultant to render an opinion after examination and review of clinical record;
 - 26.1.3 another practitioner to assume the care of the mother or the newborn at any time;
 - 26.1.4 pertinent information for quality assurance assessments to be retrieved;
 - 26.1.5 the clinical staff to utilize the record to instruct mother and family.
- 26.2 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 Appendices A, B and C. Clinical records shall furthermore contain no less than:
 - a) admitting identification data, including history, physical examination and risk assessment;
 - b) signed consent;
 - c) prenatal record containing blood serology, rubella screening and RH factor, blood typing and screening for irregular antibodies;
 - d) labor and delivery records;
 - e) clinical observations during prenatal care, labor and delivery, postpartum care, including laboratory reports, medical orders, consultation reports, signed entries by professionals rendering care;
 - f) newborn record including all pertinent data of assessment and other care;
 - g) complications, transfers, referrals;

- h) report of postpartum home visits;
 - i) discharge summary; and
 - j) such other information, data and reports as may be deemed necessary.
- 26.3 All entries in the clinical records shall be signed by the responsible person in accordance with the center's policies and procedures.
- 26.4 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 section 23-3-26 of reference 15.
- 26.4.1 Records of minors shall be kept for at least five (5) years after such minor shall have reached the age of eighteen (18) years.

PART IV ***ENVIRONMENTAL MANAGEMENT***

Section 27.0 ***Housekeeping***

- 27.1 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.
- 27.2 Written policies and procedures shall be established pertaining to environmental controls to assure comfortable, safe and sanitary environment with well-lighted space.
- 27.3 Equipment and supplies shall be provided for cleaning of all surfaces. Such equipment shall be maintained in a safe and sanitary condition.
- 27.4 Hazardous, cleaning solution, compounds, and substances shall be labeled, stored in a safe place and kept in an enclosed section separated from other cleaning materials.
- 27.5 Cleaning shall be performed in a manner which minimizes the spread of pathogenic organisms in the atmosphere.
- 27.6 Birth rooms shall be thoroughly cleaned after each delivery.
- 27.7 Smoking shall be permitted only in restricted areas in accordance with reference 13.

Section 28.0 ***Laundry Service***

- 28.1 Each center shall make provisions for the cleaning of all linens and other washable goods provided either on the premises or per contractual arrangement.
- 28.2 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 reference 12.
- 28.3 There shall be distinct areas for the separate storage and handling of clean and soiled linens.
- 28.4 All soiled linen shall be placed in closed containers prior to transporting to laundry.

PART V ***PHYSICAL PLANT AND EQUIPMENT***

Section 29.0 ***New Construction***

- 29.1 All new construction shall be subject to the provisions of references 4, 6, 7, 8, 9 and 12.
- 29.2 In addition, any other applicable state and local laws, codes and regulations shall apply. Where there is a difference between codes, the code having the higher standard shall apply.

Section 30.0 ***General Provisions for Physical Facility (Including Existing Facilities)***

- 30.1 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.
- 30.2 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.
- 30.3 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.
- 30.3.1 Hallways and doors providing access and entry into the birth room shall be of adequate width to accommodate ambulance stretchers and wheelchairs.
- 30.3.2 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.
- 30.4 Acceptable toilet facilities shall be available to each laboring mother and adequate shower facilities shall also be available to accommodate mothers.
- 30.5 *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.
- 30.6 *Medication and storage* areas shall be provided and equipped with locks to ensure the safekeeping of drugs and biologicals.

- 30.7 *Heating and ventilation* systems shall be capable of maintaining comfortable temperatures.
- 30.8 *Lighting and electrical services:* Each center shall be adequately lighted with appropriate lighting for examination in the birth room(s).
- 30.8.1 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.
- 30.8.2 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.
- 30.9 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.

Section 31.0 ***Equipment***

- 31.1 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:
- a) Oxygen and positive pressure masks;
 - b) DeLee trap suction and infant laryngoscope and airways;
 - c) IV equipment;
 - d) Blood expanders;
 - e) Medications identified in protocols for emergency needs;
 - f) Infant transport equipment and infant warmers.
- 31.1.1 In addition the center shall be equipped with standard equipment which includes no less than:
- a) equipment for standard screening;
 - b) laboratory tests; and
 - c) sterilization of instruments.

Section 32.0 ***Plumbing***

- 32.1 All plumbing material and plumbing systems or parts thereof installed shall meet the minimum requirements of reference 8.

Section 33.0 ***Water Supply***

- 33.1 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 reference 8.

Section 34.0 ***Waste Disposal***

34.1 Waste disposal methods shall be provided acceptable to the licensing agency.

PART VI ***PRACTICES AND PROCEDURES, CONFIDENTIALITY AND SEVERABILITY***

Section 35.0 ***Variance Procedure***

- 35.1 The licensing agency 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.
- 35.2 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.
- 35.2.1 Upon the filing of each request for variance with the licensing agency, and within thirty (30) days thereafter, the licensing agency 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 section 36.0 herein.

Section 36.0 ***Deficiencies and Plans of Correction***

- 36.1 The licensing agency 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 Section 23-1-21 of the General Laws of Rhode Island, as amended.
- 36.2 A facility which received a notice of deficiencies must submit a plan of correction to the licensing agency 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.
- 36.3 The licensing agency will be required to approve or reject the plan of correction submitted by a facility in accordance with Section 36.2 above within fifteen (15) days of receipt of the plan of correction.
- 36.4 If the licensing agency rejects the plan of correction, or if the facility does not provide a plan of correction within the fifteen (15) day period stipulated in Section 36.3 above, or if a facility whose plan of correction has been approved by the licensing agency fails to execute its plan within a reasonable time, the licensing agency may invoke the sanctions enumerated in Section 6.0 herein. If the facility is aggrieved by the sanctions of the licensing agency, the facility may appeal the decision and request a hearing in accordance with reference 5.

- 36.6 The notice of the hearing to be given by the Department of Health shall comply in all respects with the provisions of Chapter 42-35 of the Rhode Island General Laws. The hearing in all respects shall comply with all provisions therein.

Section 37.0 *Rules Governing Practices and Procedures*

- 37.1 All hearings and reviews required under the provisions of Chapter 23-17 of the General Laws of Rhode Island, as amended, shall be held in accordance with the provisions of the rules and regulations promulgated by the Rhode Island Department of Health entitled *Rules and Regulations of the Rhode Island Department of Health Regarding Practices and Procedures Before the Department of Health and Access to Public Records of the Department of Health (R42-35-PP)* of reference 10.

Section 38.0 *Confidentiality*

- 38.1 Disclosure of any health care information relating to individuals shall be subject to the provisions of the Confidentiality Act of reference 11 and other relevant statutory and federal requirements.

Section 39.0 *Severability*

- 39.1 If any provision of the rules and regulations herein or the applicant thereof to any facility or circumstances shall be held invalid, such invalidity shall not affect the provisions or application of the rules and regulations which can be given effect, and to this end the provisions of the rule and regulations are declared to be severable.

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Friday, 14 September 2012

PART VII **REFERENCES**

1. *Rules and Regulations for Licensing of Midwives (R23-13-MID)*, Rhode Island Department of Health, November 2001 and subsequent amendments thereto.
2. "Licensing of Health Care Facilities", Chapter 23-17 of the General Laws of Rhode Island, as amended.
3. *Rules and Regulations for Determination of Need for New Health Care Equipment and New Institutional Health Services (R23-15-CON)*, Rhode Island Department of Health, January 2000 and subsequent amendments thereto.
4. "Department of Health", Chapter 23-1 of the General Laws of Rhode Island, as amended.
5. "Administrative Procedures Act", Chapter 42-35 of the General Laws of Rhode Island, as amended.
6. *Food Code (R23-1, 21-27-FOOD)*, Rhode Island Department of Health, Office of Food Protection, July, 1994.
7. "Rhode Island Fire Safety Code", Chapter 23-28.1 of the General Laws of Rhode Island, as amended.
8. "Rhode Island State Building Code", Chapter 23-27.3 of the General Laws of Rhode Island, as amended.
9. "The American National Standard-Specifications for Making Buildings and Facilities Accessible to and Usable by the Physically Handicapped", American National Standards Institute, Inc., 1430 Broadway, New York, New York 10013.
10. *Rules and Regulations of the Rhode Island Department of Health Regarding Practices and Procedures Before the Department of Health and Access to Public Records of the Department of Health*, Rhode Island Department of Health, April 2004 and subsequent amendments thereto.
11. "Confidentiality of Health Care Information Act", Chapter 5-37.3 of the General Laws of Rhode Island, as amended.
12. *Rules and Regulations Establishing Minimum Standards Relating to Location, Design, Construction and Maintenance of Individual Sewage Disposal System*, Rhode Island Department of Environmental Management.
13. "Smoking in Public Places", Chapter 23-20.6 of the General Laws of Rhode Island, as amended.
14. *Rules and Regulations for Licensing of Freestanding Ambulatory Surgical Centers (R23-17-FASC)*, Rhode Island Department of Health, July 2002 and subsequent amendments thereto.
15. "Vital Statistics", Section 23-3-26 of the General Laws of Rhode Island, as amended.
16. *Rules and Regulations Pertaining to Immunization, Testing, and Health Screening for*

Health Care Workers (R23-17-HCW), Rhode Island Department of Health.

APPENDIX A

PRENATAL HIGH-RISK FACTORS

A. REPRODUCTIVE HISTORY:

(1) MATERNAL CHARACTERISTICS

- Age < 16 and > 40
- * Height < 60"
- * Weight < 100 lbs. and > 200 lbs.
- Parity four (4) or more

(2) PAST OBSTETRICAL HISTORY

*Habitual Abortion -more than two (2) consecutive spontaneous or two (2) or more induced abortions
Post Partum Hemorrhage or 3rd Stage problem(s), e.g., severe lacerations, inverted uterus, retained placenta, etc.

*Pre-Eclampsia

Hypertension - all hypertensive disorders of pregnancy

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

Previous Delivery:

- (1) other than spontaneous or low forceps; and
- (2) Caesarian Section

Baby:*Prematurity -37 weeks or less than 2500 grams
> 4500 grams

- * Signifies that the risk factor could be clinically significant and, therefore, subject to the Director of Medical Affairs final determination.
- * Respiratory Distress
- * Congenital abnormality
- * Known genetic disorders
- * Any Neonatal death
- * Fetal death
- * Significant birth injury

(3) ASSOCIATED CONDITIONS

Scarred uterus - vaginal plastic surgery - * Urinary tract surgery

Adrenal disease

Cardiovascular disease except for mild asymptomatic Class I without hemodynamic abnormality

Collagen disease

Renal disease (albuminuria; hematuria, casts)

Chronic or acute liver disease

Diabetes Mellitus

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

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

Genetic Disorder

Hematologic disease

Hypertension

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

* Pulmonary disease, requiring treatment

- * Signifies that the risk factor could be clinically significant and, therefore, subject to the Director of Medical Affairs' final determination.
- * Psychiatric
- Neurologic disorder
- Hyperthyroidism
- Venereal and Related diseases
- * Thrombophlebitis
- * Alcohol abuse
- * Drug abuse
- * Smoking - (> 1 pkg. a day)

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

B. PRENATAL COURSE OF CURRENT PREGNANCY

Late Registration (see section 16.3 herein)

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

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

Uterine Bleeding (except for threatened abortion in first trimester)

Any presentations except vertex position at 37 weeks or beyond

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

Pre-Eclampsia

Hypertension - resting BP 140/90 or an increase of 30 systolic or fifteen (15) diastolic over the patient's base line pressure

Known Multiple gestation

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

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

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

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.

Prolonged Pregnancy - (at 42 completed weeks or more)

Polyhydramnios

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

Development of any condition listed above under section A (3) entitled "Associated Conditions"

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

APPENDIX B

HIGH RISK FACTORS REQUIRING TRANSFER OF MOTHER FROM THE CENTER

LABOR - DELIVERY - POST PARTUM

Abnormal Bleeding

Cord Prolapse

Dystocia Labor (at term)

Prolonged latent phase with ruptured membranes

(20 hrs. nulliparous)

(14 hrs. multiparous)

Protraction or arrest in the active stage

Prolonged second stage greater than two (2) hours

Secondary arrest

Extensive perineal or cervical laceration

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

Fetal Distress -

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

Meconium (stain of the amniotic fluid)

Hypertension or Hypotension

Maternal Tachycardia

More than 24 hours in active labor unless delivery is imminent

Presentation (any other than vertex)

Retained placenta (greater than one hour)

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

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

APPENDIX C

CRITERIA REQUIRING TRANSFER OF NEWBORN

Apgar score of: a) five (5) or less at one (1) min.; or b) seven (7) or less at five (5) min.

Exaggerated tremors

Failure to take feeding

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

Jaundice

Major congenital anomaly

Neonatal sepsis or infection

Respiratory distress

* Signs of pre or post maturity

Shock or asphyxia

* Weight (<2500 grams)

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

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