COLORADO
Department of Public Health & Environment

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To: Members of the State Board of Health

From: Lorraine Dixon-Jones, Policy Analyst, Health Facilities and Emergency Medical Services Division

Through: Randy Kuykendall, MLS, Division Director, Health Facilities and Emergency Medical Services Division, DRK

Date: July 19, 2017

Subject: Proposed Amendments to 6 CCR 1011-1, Standards for Hospitals and Health Facilities, Chapter 22, Birth Centers, for the Rulemaking Hearing on July 19, 2017

The Department is proposing comprehensive amendments to its regulations regarding birth centers to ensure that standards reflect current practice. Important components of the birth center model of care that are addressed in the proposed regulations include:

- Services are for low risk pregnancies that do not require extensive medical interventions such as those available in a hospital.
- Clients are oriented to the level of services available at the center, which include prenatal, intrapartum and postpartum care. Clients are made aware of the types of services that birth centers do not provide, including anesthesia other than local anesthesia.
- Twenty-four hour, seven day access to a care provider.
- Facilities must provide their clients with continuous risk assessment during the course of the pregnancy and during labor and delivery. Client needs outside of scope of the birth center practice will be addressed through consultation by the clinical staff with other providers, referral of clients to other providers, or transfer of the clients to a hospital.
- Intrapartum care by clinical staff during labor and delivery.
- Discharge process that involves provision of or counseling about state mandated newborn screening.

Division personnel and stakeholders met monthly from September through March to arrive at consensus regarding these proposed rule amendments. The stakeholder group included representation from birth centers, the Colorado Hospital Association, the Department of Regulatory Agencies, and the Department of Health Care Policy and Financing. In addition to the amendments being based on stakeholder comment, they are also informed by research on regulations in other states and standards established by the American Association of Birth Centers and the Commission for the Accreditation of Birth Centers.

During the request for hearing meeting, the Board posed several questions, some of which were in the context of a recently released ProPublica Report that indicated that the United

States has a high rate of maternal deaths. Subsequently, the department met with stakeholders to address the board's questions, which have been responded to below.

1. What is the number of maternal deaths in Colorado? How many maternal deaths occurred or are related to birth centers?

   In 2016 there were 16 maternal deaths associated with pregnancy, child birth and puerperium (about six weeks after childbirth), according to data collected by the department from Colorado death certificates. None of these deaths appear to be attributable to delivery at a birth center. According to birth center stakeholders, there have been no maternal deaths in or related to birth centers since 2006, when the first birth center opened in Colorado.

2. How many total births take place in birth centers?

   Since 2006, when the first birth center opened in Colorado, to May 2017, there have been 3,111 births in Colorado's birth centers.

3. What is the ownership model for birth centers in Colorado? Nationwide?

   There are 5 birth centers in the state; 4 are locally owned and operated, 1 is part of a national chain. Nationwide, there are more than 300 birth centers and ownership type varies. Less than 10 percent are owned by or affiliated with hospitals.

4. Should the regulations contain a maximum distance from a hospital that a birth center can be located?

   Birth centers represent part of the continuum of maternal care options that includes home births as well as hospital births. Birth centers focus exclusively on low risk pregnancies. They are required to continuously screen for high risk factors as well as to have an extensive informed consent process which includes information about the facility's distance to the closest hospital (see section 9.2 of the proposed regulations). Establishing a distance requirement from a hospital may limit consumer choice and be unduly restrictive since the department is unaware of data that suggests that a maximum distance requirement would enhance client safety.

5. There is a Governing Body section but no definition regarding Governing Body. Should one be added?

   Neither the stakeholders nor the department believe that a definition is needed because the role and duties of the governing body are outlined in Section 4. Since the membership of the governing body may vary depending on the needs of the facility, new language was added on page 12, line 99 that reads: THE FACILITY SHALL DELINEATE THE STRUCTURE AND MEMBERSHIP OF THE GOVERNING BODY IN WRITTEN POLICY.

6. Section 6: Clarify the role of the clinical director versus the delegated committee of the clinical staff and consider adding language to clarify that a clinical director is to be a practitioner and not an administrative role.

To clarify that the clinical director is a practitioner as well as the role of the director vis-à-vis the delegated committee of the clinical staff, language was added on page 13, line 176, as follows: Clinical services shall be under the supervision of a clinical director, WHO SHALL BE A MEMBER OF THE CLINICAL STAFF. THE CLINICAL DIRECTOR SHALL BE THE FORMAL LIAISON WITH THE GOVERNING BODY.

7. Page 24, line 570: Should there be more guidelines as to when a newborn's jaundice makes it necessary to transfer?

   Further standards were not included because such guidelines would be considered scope of practice standards. Clinical scope of practice standards are established for the various regulated professions by the Department of Regulatory Agencies and by professional associations. These practice standards are subject to change in response to the evolution of medical care. As such, memorializing professional practice in health care facility regulations runs the risk of quickly becoming obsolete.

8. Page 24, line 574: Does the term "significant" provide enough clarity to birth centers regarding when to transfer a newborn with a significant congenital anomaly to a higher level of care?

   Birth center stakeholders responded to this question by stating that the term "significant" provides sufficient clarity and allows for the use of clinical judgment when determining the need for transfer. For example, while transfer would be initiated for a congenital anomaly that is or is likely to be life threatening, it would not be appropriate if the anomaly is best addressed by a referral to a specialist in a non-emergency setting. The stakeholders indicated that an example of a congenital anomaly where transfer is unnecessary is syndactyly (two or more digits are fused together). The rationale for using the word "significant" or a similar term is that since the nature of congenital anomalies may vary widely, the regulations should allow sufficient flexibility for the use of clinical judgment to determine when transfers are warranted.

9. Page 28, line 697: Consider classifying which staff can establish and provide intravenous access and fluids. (Who is certified to use the equipment?)

   Clinical scope of practice standards are established for the various regulated professions by the Department of Regulatory Agencies (DORA) and by professional associations. Repeating these standards in the proposed regulations means that the department requirements will become obsolete when they are changed by DORA and other bodies. Instead of specifying which staff can establish and provide intravenous access and fluids, the department suggests an amendment to page 20, line 395 that reads: NURSES AND OTHER PERSONNEL SHALL PERFORM THEIR DUTIES IN ACCORDANCE WITH THEIR SCOPE OF PRACTICE.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
6 CCR 1011-1, Standards for Hospitals and Health Facilities,
Chapter 22 – Birth Centers

Basis and Purpose.

Birth centers are facilities that serve clients with low risk pregnancies, i.e., pregnancies for which the client's medical history demonstrates an expected normal and uncomplicated course of pregnancy and labor. The entire regulatory chapter for birth centers has been revised to enhance the safety and well-being of clients. While most of the revisions clarify and enhance existing requirements, some amendments delete obsolete provisions and others establish new requirements. Examples of changes are shown below.

Examples of Deleted Provisions

- The requirement that certified nurse midwives (CNMs) have "a backup agreement with a physician who will accept calls and referrals" has been deleted. This provision became obsolete when the Nurse Practice Act was changed to allow CNMs to practice independently.
- Currently, the regulations specify high risk factors that preclude eligibility to birth center care, such as certain levels of hypertension. Since these specifications can become outdated when medical standards change, they are being deleted and replaced with provisions that require facilities to establish risk factors based on national standards of birth center care. This allows facility practices to evolve with changes in professional practices.

Examples Enhanced Provisions

- Existing regulations require the facilities to have agreements with emergency medical services providers. The amendments broaden this standard to require facilities to have a plan for both emergency and non-emergency transfers.
- Existing provisions require either a clinical director or a delegated committee to be responsible for the quality of care. The amendments specify that clinical services must be under the supervision of a clinical director (rather than a delegated committee) – since stakeholders indicated that this is current practice. In addition, the clinical director will be responsible for the coordination of all professional medical consultants to the facility.

Examples of New Provisions

Birth centers will be required to:
- Establish an emergency preparedness plan for events such as fire or loss of utilities.
- Have individualized discharge plans that include follow up visits.

In addition, the entire chapter has been reformatted to more closely align with the regulatory chapters of other facility types, such as ambulatory surgical centers.

These rules are promulgated pursuant to the following statutes: Section 25-1.5-103, C.R.S., (2016) and Section 25-3-101, C.R.S. (2016).

Is this rulemaking due to a change in state statute?

_____ Yes, the bill number is _____. Rules are ___ authorized ___ required.
___X__ No

Is this rulemaking due to a federal statutory or regulatory change?

_____ Yes
___X__ No

Does this rulemaking incorporate materials by reference?

__X___ Yes
_____ No

If "Yes," the rule needs to provide the URL of where the material is available on the internet (CDPHE website recommended) or the Division needs to provide one print or electronic copy of the incorporated material to the State Publications Library. § 24-4-103(12.5)(c), C.R.S.

Does this rulemaking create or modify fines or fees?

_____ Yes
___X__ No

REGULATORY ANALYSIS
for Amendments to
6 CCR 1011-1, Standards for Hospitals and Health Facilities,
Chapter 22 – Birth Centers

1. A description of the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

   Birth centers and the clients served will be affected. Facilities will bear the costs of the proposed rule, as will clients, if costs are passed on to them. The facilities will benefit from the removal of obsolete provisions and the updating of the requirements to reflect current standards of practice.

2. To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

   The quantitative effects are expected to vary, dependent on the extent that birth centers must change their current operating procedures. Clients will benefit from enhanced safety requirements.

3. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

   The Department will have to amend its inspection processes to reflect the new provisions; however it is expected that costs will be absorbed within the existing budget. There are no anticipated effects on state revenues.

4. A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

   There have been several narrowly focused revisions to Chapter 22 within the past 5 years prompted by the need to conform to changes in statute. However the last time that portions of practice standards were updated to reflect current practice was in 1996. As such, the proposed rule represents a comprehensive revision of all of the requirements. Unclear, obsolete as well as outdated provisions create undue burden to facilities. In addition, new requirements are designed to more comprehensively safeguard the well-being of clients.

5. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

   No less costly or intrusive methods were encountered during the stakeholder process or through policy research.

6. Alternative Rules or Alternatives to Rulemaking Considered and Why Rejected.

   During the stakeholder process, various amendments were discussed and rejected either due to lack of consensus or insufficient statutory authority to address them. For example, some stakeholders wanted to include direct entry midwives as part of the clinical staff. Direct entry midwives (DEMs) are regulated through a registration process by the Department of Regulatory Affairs (DORA). Both the authorizing statute and the DORA rules

for these service providers refer to DEM services as being provided in the "home," as shown below.

> **Statute: Section 12-37-102(3) C.R.S.** "Direct-entry midwifery" or "practice of direct-entry midwifery" means the advising, attending, or assisting of a woman during pregnancy, labor and natural childbirth at home, and during the postpartum period in accordance with this article.
>
> **Regulation: 4 CCR 739-1(5)(E)**At least one home visit shall be made during the third trimester to assure that environmental conditions are appropriate, supplies are procured, and birth participants are prepared for the home birth.

The department advised the stakeholders to seek a statutory and/or a regulatory change clarifying the authority of these providers to serve in locales other than the "home." Since, to date, changes have not been made to either the statute or DORA rules, this stakeholder recommendation has not been incorporated in these licensure rules.

7. To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.

There are 5 birth centers in the state with the labor and delivery capacity ranging from 3 to 4 beds. To be licensed as a birth center the center must be a free standing facility that is not a hospital, attached to a hospital or in a hospital. Birth centers provide an alternative along the continuum of care for low risk pregnancies. The table below lists the birth centers in the state and provides the date that the facility opened, its location, and total births.

	Date opened	Location	Total births
Mountain Midwifery Center	September 2006	Englewood	3,111
Bloomin Babies Birth Center	October 2013	Grand Junction	112
Birth Center of Boulder	July 2014	Boulder	272
Baby+Company	May 2015	Wheatridge	155
Denver Center for Birth and Wellness	March 2016	Littleton	24

STAKEHOLDER COMMENTS
for Amendments to
6 CCR 1011-1, Standards for Hospitals and Health Facilities,
Chapter 22 – Birth Centers

State law requires agencies to establish a representative group of participants when considering to adopt or modify new and existing rules. This is commonly referred to as a stakeholder group.

Early Stakeholder Engagement:
The following individuals and/or entities were invited to provide input and included in the development of these proposed rules:

- Representatives from all the licensed birth centers of the state
- Colorado Chapter of American College of Nurse Midwives
- Colorado Midwives Association
- The Colorado Medical Society
- Elephant Circle
- Prospective birth centers
- Architects working with prospective birth centers
- Colorado Chapter of American Colorado of Obstetricians and Gynecologists
- Prevention Services Division, CDPHE
- Hazardous Materials and Waste Management Division, CDPHE
- Department of Regulatory Agencies
- Department of Health Care Policy and Financing
- Colorado Hospital Association

Stakeholder Group Notification
The stakeholder group was provided notice of the rulemaking hearing and provided a copy of the proposed rules or the internet location where the rules may be viewed. Notice was provided prior to the date the notice of rulemaking was published in the Colorado Register (typically, the 10th of the month following the Request for Rulemaking).

____ Not applicable. This is a Request for Rulemaking Packet. Notification will occur if the Board of Health sets this matter for rulemaking.

__X___ Yes.

Summarize Major Factual and Policy Issues Encountered and the Stakeholder Feedback Received. If there is a lack of consensus regarding the proposed rule, please also identify the Department's efforts to address stakeholder feedback or why the Department was unable to accommodate the request.

The stakeholders achieved consensus on the model of care for birth centers -which is distinct from the services provided in hospitals-as well as the revisions, since they conform with this model.

Please identify health equity and environmental justice (HEEJ) impacts. Does this proposal impact Coloradoans equally or equitably? Does this proposal provide an opportunity to advance HEEJ? Are there other factors that influenced these rules?

It is anticipated that this proposal impacts Coloradoans equitably since the proposal requires facilities to have policies and procedures for admission and client care that are culturally

competent and address the social determinants of health in accordance with national standards for midwifery care.

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities Regulation Division

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES

CHAPTER ~~XXII~~ 22- BIRTH CENTERS

6 CCR 1011-1 Chapter 22

Adopted by the Board of Health on _____2017. Effective _____, 2017.

SECTION 1 – STATUTORY AUTHORITY AND APPLICABILITY

1.1 THE STATUTORY AUTHORITY FOR THE PROMULGATION OF THESE RULES IS SET FORTH IN SECTION 25-1.5-103 AND 25-3-101, *ET SEQ.*, C.R.S.

1.2 A BIRTH CENTER, AS DEFINED HEREIN, SHALL COMPLY WITH ALL APPLICABLE FEDERAL AND STATE STATUTES AND REGULATIONS, INCLUDING, BUT NOT LIMITED TO:

(A) THIS CHAPTER 22, AND

(B) 6 CCR, 1011-1, CHAPTER 2, GENERAL LICENSURE STANDARDS, UNLESS OTHERWISE MODIFIED HEREIN.

1.3 THIS REGULATION INCORPORATES BY REFERENCE (AS INDICATED WITHIN) MATERIALS ORIGINALLY PUBLISHED ELSEWHERE. SUCH INCORPORATION DOES NOT INCLUDE LATER AMENDMENTS TO OR EDITIONS OF THE REFERENCED MATERIAL. THE DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT MAINTAINS COPIES OF THE COMPLETE TEXT OF THE INCORPORATED MATERIALS FOR PUBLIC INSPECTION DURING REGULAR BUSINESS HOURS, AND SHALL PROVIDE CERTIFIED COPIES OF THE INCORPORATED MATERIAL AT COST UPON REQUEST. INFORMATION REGARDING HOW THE INCORPORATED MATERIAL MAY BE OBTAINED OR EXAMINED IS AVAILABLE FROM:

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COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT
4300 CHERRY CREEK DRIVE SOUTH
DENVER, CO 80246
PHONE: 303-692-2800

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~~Copies of these regulations may be obtained at cost by contacting:~~

~~Division Director~~
~~Colorado Department of Public Health and Environment~~
~~Health Facilities Division~~
~~4300 Cherry Creek Drive South~~
~~Denver, Colorado 80222-1530~~
~~Main switchboard: (303) 692-2800~~

~~These chapters of regulation incorporate by reference (as indicated within) material originally published elsewhere. Such incorporation, however, excludes later amendments to or editions of the referenced material. Pursuant to 24-4-103 (12.5), C.R.S., the Health Facilities Division of the Colorado Department of~~

~~Public Health And Environment maintains copies of the incorporated texts in their entirety which shall be available for public inspection during regular business hours at:~~

~~Division Director~~
~~Colorado Department of Public Health and Environment~~
~~Health Facilities Division~~
~~4300 Cherry Creek Drive South~~
~~Denver, Colorado 80222-1530~~
~~Main switchboard: (303) 692-2800~~

~~Certified copies of material shall be provided by the division, at cost, upon request. Additionally, any material that has been incorporated by reference after July 1, 1994 may be examined in any state publications depository library. Copies of the incorporated materials have been sent to the state publications depository and distribution center, and are available for interlibrary loan.~~

SECTION 2 – DEFINITIONS

2.1 ~~Birth Center – Any public or private health facility or institution which is not licensed as a hospital or as part of a hospital and provides care during delivery and immediately after delivery for generally less than twenty-four hours.~~ "BIRTH CENTER" MEANS A FREESTANDING FACILITY LICENSED BY THE DEPARTMENT THAT IS NOT A HOSPITAL, ATTACHED TO A HOSPITAL, OR IN A HOSPITAL WHICH PROVIDES PRENATAL, LABOR, DELIVERY AND POSTPARTUM CARE TO LOW RISK PREGNANT PERSONS AND THE NEWBORNS. CARE DURING DELIVERY AND IMMEDIATELY AFTER DELIVERY SHALL BE GENERALLY LESS THAN TWENTY-FOUR HOURS.

2.2 ~~IV B. Definition~~: ~~"Certified Nurse-Midwife~~" "CERTIFIED NURSE MIDWIFE" (CNM) MEANS AN ADVANCED PRACTICE ~~- a professional~~ nurse licensed in the state of Colorado who is educated in the two disciplines of nursing and midwifery, who possesses evidence of certification according to the requirements of the American ~~College of Nurse-Midwives~~ MIDWIFERY CERTIFICATION BOARD.

2.3 "CLIENT" MEANS A PERSON RECEIVING PRENATAL, INTRAPARTUM, AND POSTPARTUM SERVICES. UNLESS THE CONTEXT DICTATES OTHERWISE, CLIENT ALSO MEANS AN INFANT RECEIVING NEWBORN CARE SERVICES FROM THE FACILITY.

2.4 "FACILITY" MEANS A BIRTH CENTER.

2.5 "INTRAPARTUM" MEANS PERTAINING TO THE PERIOD OF LABOR AND BIRTH.

2.6 "LOW RISK PREGNANCY" MEANS EXPECTED NORMAL, UNCOMPLICATED PRENATAL AND INTRAPARTUM COURSE ASSISTED BY ADEQUATE PRENATAL CARE AND PROSPECTS FOR A NORMAL UNCOMPLICATED BIRTH BASED ON CONTINUAL SCREENING FOR PRENATAL HIGH RISK FACTORS. PRENATAL HIGH RISK FACTORS SHALL PRECLUDE ELIGIBILITY FOR ADMISSIONS AS WELL AS CONTINUED SERVICES AT THE FACILITY.

2.7 "MEDICAL WASTE" MEANS WASTE THAT MAY CONTAIN DISEASE CAUSING ORGANISMS SUCH AS DISCARDED SURGICAL GLOVES, SHARPS, BLOOD, HUMAN TISSUE, PRODUCTS OF CONCEPTION; OR WASTE THAT MAY CONTAIN CHEMICALS THAT PRESENT POTENTIAL HEALTH HAZARDS SUCH AS PHARMACEUTICAL WASTE AND LABORATORY WASTE.

~~I. LICENSE~~

~~A. Birth Center shall meet all the requirements specified in chapter II and this Chapter XXII of the Colorado Department of Health Standards for Hospitals and Health Facilities.~~

SECTION 3 – RESERVED

SECTION 4 – ~~II.~~ GOVERNING BODY

4.1 ~~A. Responsibility:~~ THE GOVERNING BODY SHALL BE RESPONSIBLE FOR THE OVERALL OPERATION AND MANAGEMENT OF THE FACILITY. THE GOVERNING BODY ~~A Governing Body~~ shall provide ADEQUATE facilities, personnel and services necessary for the welfare and safety of the ~~patients~~ CLIENTS. THE FACILITY SHALL DELINEATE THE STRUCTURE AND MEMBERSHIP OF THE GOVERNING BODY IN WRITTEN POLICY.

4.2 ~~B. Duties:~~ The ~~G~~governing ~~B~~body shall:

(A) ~~1.~~ adopt ADMINISTRATIVE AND OPERATIONAL by-laws in accordance with legal requirements THAT INCLUDE THE FACILITY'S ORGANIZATIONAL STRUCTURE WITH LINES OF AUTHORITY AND RESPONSIBILITY.

(B) ~~2~~. ~~meet regularly~~ MEET AT LEAST ANNUALLY and maintain~~s~~ accurate records of such meetings. ~~;~~

(C) DEFINE THE SCOPE OF THE SERVICES PROVIDED BY THE FACILITY.

(D) ENSURE THAT THE FACILITY IS AVAILABLE FOR OCCUPANCY 24 HOURS PER DAY. ~~;~~

(E) ~~5. establish a formal means of liaison with the clinical staff:~~ APPOINT, IN WRITING, A FULL-TIME ADMINISTRATOR.

(F) ~~3. appoint a credentials committee, composed of clinical staff, which shall have the authority and responsibility for appointments and reappointments of clinical staff and ensure that only members of the clinical staff shall admit patients to the birth center; 4.~~ appoint and delineate, IN WRITING, clinical privileges of practitioners based upon recommendations by the clinical staff ~~and other appropriate indicators of physicians and certified nurse mid-wife competence.~~ AND COMMENSURATE WITH THE PRACTITIONER'S QUALIFICATIONS, EXPERIENCE, AND PRESENT CAPABILITIES. AN UP-TO-DATE ROSTER OF PRACTITIONERS CREDENTIALED BY THE FACILITY THAT SPECIFIES THE APPROVED PROCEDURAL PRIVILEGES OF EACH PRACTITIONER SHALL BE AVAILABLE TO THE STAFF AT ALL TIMES.

(G) ~~6. approve by-laws, rules and regulations of the clinical staff; 7. appoint committees consistent with the needs of the birth center~~. APPROVE WRITTEN POLICIES AND PROCEDURES FOR THE OPERATION OF THE FACILITY. POLICIES AND PROCEDURES SHALL BE CONSISTENT WITH CURRENT PROFESSIONAL STANDARDS, REVIEWED ANNUALLY AND REVISED AS NECESSARY.

(H) ENSURE THAT CONTRACTED SERVICES ARE DELIVERED IN ACCORDANCE WITH THE FACILITY'S POLICIES AND PROCEDURES. CONTRACTS, INCLUDING SERVICE CONTRACTS, SHALL BE REVIEWED ANNUALLY AND REVISED AS NECESSARY.

(I) DEVELOP JOB DESCRIPTIONS FOR ALL EMPLOYEE POSITIONS THAT DELINEATE FUNCTIONAL RESPONSIBILITIES AND AUTHORITY.

(J) ~~C. Quality of Care: 1. Conduct, with the active participation of the clinical staff, an ongoing, comprehensive self-assessment of the quality of care provided, including the medical necessity of procedures performed, the appropriateness of care, and the appropriateness of utilization. This information shall provide a basis for the revision of facility policies and the granting or continuation of clinical privileges~~. MAINTAIN AN EFFECTIVE QUALITY MANAGEMENT PROGRAM IN ACCORDANCE WITH 6 CCR 1011-1, CHAPTER 2, SECTION 3.1.

(K) ~~C,2. Require that the facility's Quality Assurance Program~~ ADOPT A NATIONAL STANDARD FOR INFECTION CONTROL AND ensure~~s~~ the adequate investigation, control and prevention of infections.

(L) ~~C.3. Provide that there shall be on file in the center an agreement with an ambulance service (air or ground) for emergency transfer of patients to hospital.~~ ESTABLISH A WRITTEN PLAN FOR EMERGENT AND NON EMERGENT TRANSPORT OF CLIENTS TO A HOSPITAL WITH SPECIFIC EXAMPLES THAT DENOTE EMERGENT AND NON-EMERGENT CONDITIONS. THE EFFECTIVENESS OF THE PLAN SHALL BE EVALUATED ANNUALLY. CLIENTS WITH AN EMERGENT CONDITION SHALL BE TRANSPORTED BY EMERGENCY MEDICAL SERVICES TO THE NEAREST HOSPITAL CAPABLE OF PROVIDING CARE.

(M) DEVELOP AND MAINTAIN A WRITTEN EMERGENCY PREPAREDNESS PLAN FOR THE EMERGENCY CARE OR RELOCATION OF CLIENTS IN THE EVENT OF FIRE OR OTHER PHYSICAL DAMAGE TO THE FACILITY, WEATHER EMERGENCIES ENDEMIC TO THE REGION, LOSS OF UTILITIES OR EQUIPMENT MALFUNCTION. THE PLAN SHALL BE CURRENT. EMERGENCY EVACUATION DRILLS SHALL BE CONDUCTED AT LEAST SEMIANNUALLY.

(N) ENSURE THAT STAFF PERFORM MEDICAL EMERGENCY DRILLS AT LEAST QUARTERLY.

SECTION 5 – ~~III~~ ADMINISTRATOR

5.1 ~~A. Responsibility;~~ The administrator shall HAVE AUTHORITY FOR THE DAY TO DAY OPERATION OF THE FACILITY. THE ADMINISTRATOR SHALL DESIGNATE IN WRITING A QUALIFIED EMPLOYEE TO ACT AS ADMINISTRATOR IN THE TEMPORARY ABSENCE OF THE ADMINISTRATOR. ~~be the official representative of the governing body and the chief executive officer of the birth center. The administrator shall be delegated responsibility and authority in writing by the governing body for the management of the birth center and shall provide liaison among the governing body, clinical staff and other departments of the birth center.~~

5.2 ~~B. Duties:~~ The administrator shall be responsible for the development of FACILITY ~~Birth Center~~ policies and procedures for employee and clinical staff use. All policies and procedures shall be reviewed and/or updated as necessary but at least annually.

SECTION 6 – ~~IV~~ CLINICAL STAFF

6.1 ~~A. Organization:~~ The ~~birth center~~ FACILITY shall have an organized clinical staff restricted to THE FOLLOWING PRACTITIONERS: physicians and certified ~~nurse-midwives~~ NURSE MIDWIVES. THE CLINICAL STAFF SHALL BE CURRENTLY LICENSED TO PRACTICE MEDICINE OR MIDWIFERY IN COLORADO.

~~B. Definition: Certified Nurse-Midwife (CNM) - a professional nurse licensed in the state of Colorado who is educated in the two disciplines of nursing and midwifery, who possesses evidence of certification according to the requirements of the American College of Nurse-Midwives.~~

6.2 ~~B.~~ CLINICAL SERVICES SHALL BE UNDER THE SUPERVISION OF A CLINICAL DIRECTOR, WHO SHALL BE A MEMBER OF THE CLINICAL STAFF. THE CLINICAL DIRECTOR SHALL BE THE FORMAL CLINICAL LIAISON WITH THE GOVERNING BODY. THE CLINICAL DIRECTOR SHALL BE RESPONSIBLE FOR IMPLEMENTING, COORDINATING AND ASSURING THE QUALITY OF CLIENT CARE SERVICES. THE CLINICAL DIRECTOR SHALL ALSO BE RESPONSIBLE FOR THE COORDINATION OF ALL THE PROFESSIONAL MEDICAL CONSULTANTS TO THE FACILITY.

6.3 ~~C. Duties~~: The clinical DIRECTOR ~~staff~~ or a delegated committee OF THE CLINICAL STAFF shall:

~~1. be responsible for the quality of all medical care provided patients in the facility;~~

(A) ~~2. bold meetings regularly~~ MEET AT LEAST ANNUALLY and maintain accurate records of such meetings.~~;~~

(B) ~~3.~~ formulate, adopt and enforce by-laws, rules, regulations and policies for the proper conduct of its members.~~;~~

(C) ~~4.~~ recommend CLINICAL staff privileges to the governing body.~~;~~

~~5. establish formal liaison with the governing body.;~~

(D) ~~6.~~ participate ~~actively~~ in the quality ~~assurance~~ MANAGEMENT program.~~;~~

(E) ~~7.~~ recommend ~~admission and procedure~~ policies and procedures FOR ADMISSION AND CLIENT CARE to the governing body. SUCH POLICIES AND PROCEDURES SHALL ADDRESS CULTURAL COMPETENCY AND THE SOCIAL DETERMINANTS OF HEALTH, IN ACCORDANCE WITH NATIONAL STANDARDS FOR MIDWIFERY CARE.

~~D. Clinical Staff Requirements;~~

~~1. Each staff physician shall be licensed to practice medicine in the state of Colorado and provide proof.~~

~~2. Each certified nurse-midwife shall be licensed as a professional nurse and show proof.~~

~~3. Any physician applying for privileges at the birthing center must demonstrate hospital admitting privileges for patients who develop complications~~.

~~4. Any certified nurse-midwife applying for privileges must provide proof of a back-up agreement with a physician who will accept consultation calls and referrals from the CNM 24 hours a day. Proof of hospital admitting privileges of the back-up physicians must be submitted.~~

~~5. A physician or certified nurse mid-wife shall be present at each birth and until the woman and newborn are stable postpartum. A second person in addition to the above, who is a registered nurse with adult and infant resuscitation skills, shall be present during the delivery.~~

~~6. A certified nurse-midwife or registered nurse with adult and infant resuscitation skills shall be present at the birthing center at all times when a patient is present. Additional and sufficient personnel shall be provided when more than one woman is in active labor~~.

6.4 PRACTITIONER CONSULTATIVE SERVICES BY INDIVIDUALS SUCH AS ADVANCED PRACTICE NURSES, FAMILY MEDICINE PRACTITIONERS, OBSTETRICIANS, AND PEDIATRICIANS SHALL BE AVAILABLE TO CLINICAL STAFF COMMENSURATE WITH THE SCOPE OF SERVICES PROVIDED BY THE FACILITY. AN UP-TO-DATE ROSTER OF PROFESSIONAL MEDICAL CONSULTANTS SHALL BE AVAILABLE TO THE STAFF AT ALL TIMES.

SECTION 7 – ~~V.~~ ~~MEDICAL RECORDS~~ HEALTH INFORMATION MANAGEMENT

7.1 ~~A. Facilities:~~ The ~~center~~ FACILITY shall provide sufficient space and equipment for the processing and the safe storage OF HEALTH INFORMATION records. RECORDS SHALL BE MAINTAINED AND STORED OUT OF DIRECT ACCESS OF WATER, FIRE, AND OTHER HAZARDS TO PROTECT THEM FROM DAMAGE AND LOSS. A RECORDS RECOVERY OR BACKUP SYSTEM SHALL BE UTILIZED TO ENSURE THAT THERE IS NO LOSS OF HEALTH INFORMATION RECORDS.

7.2 ~~B. Personnel:~~ A person knowledgeable in HEALTH INFORMATION ~~the~~ management ~~of Medical Records~~ shall be responsible for the proper administration and ~~functioning of the medical records section~~ PROTECTION OF HEALTH INFORMATION.

7.3 ~~C. Security: Medical records shall be protected from loss, damage and unauthorized use~~. THE FACILITY SHALL STORE HEALTH INFORMATION IN A MANNER THAT PROTECTS CLIENT PRIVACY AND CONFIDENTIALITY AND ALLOWS FOR RETRIEVAL OF RECORDS IN A TIMELY MANNER.

7.4 ~~D. Preservation:~~ RETENTION

(A) With the exception of HEALTH INFORMATION ~~medical~~ records of minors (individuals under the age of 18 years) ~~medical~~ records shall be preserved as original records, ~~or~~ on microfilm, OR ELECTRONIC FORMAT for no less than ~~ten~~ SEVEN years after the most recent ~~patient~~ CLIENT care ~~usage~~ ENCOUNTER, after which time records may be destroyed at the discretion of the facility.

(B) ~~1. Medical~~ HEALTH INFORMATION records of minors shall be preserved for the period of minority plus 10 years.

~~2. Facilities shall establish procedures for the notification to patients whose records are to be destroyed prior to the destruction of such records.~~

~~3. The sole responsibility for the destruction of all medical records.shall be in the facility involved.~~

~~4. Nothing in this section shall be construed to affect the requirements for the destruction of public records as set out in Part 1 of Article 80 of Title 24, C.R.S.~~

~~E. Content: The medical records shall contain sufficient accurate information to justify the diagnosis and warrant the treatment and end results including, but not limited to:~~

~~1. complete patient identification and a unique identification number;~~

~~2. admission and discharge dates;~~

~~3. chief complaint and admission diagnosis;~~

~~4. medical history and physical examination completed prior to birth;~~

~~5. diagnostic tests, laboratory and x-ray reports when appropriate;~~

~~6. progress notes if appropriate;~~

~~7. properly executed informed consent which shall be obtained prior to the onset of labor and shall include evidence of an explanation by personnel of the birth services offered and the potential risks;~~

~~8. patient's s condition on discharge, final diagnosis and instructions given patient for follow-up care of patient and child;~~

~~9. obstetrical records shall include in addition to the requirements for medical records the following:~~

~~a. prenatal care record containing at least a hemoglobin or hematocrit, urine screening, prenatal blood serology, RH factor determination, rubella titre, past obstetrical history and physical examination;~~

~~b. labor and delivery record, including reasons for induction and operative procedures if any;~~

~~c. records of anesthesia and analgesia and medication given in the course of labor, delivery and postpartum.~~

7.5 GENERAL CONTENT

(A) COMPLETE HEALTH INFORMATION RECORDS SHALL BE MAINTAINED ON EVERY CLIENT FROM THE TIME OF REGISTRATION FOR SERVICES THROUGH DISCHARGE. ALL ENTRIES INTO THE RECORD SHALL BE DATED, TIMED, AND SIGNED BY THE APPROPRIATE PERSONNEL.

(B) ALL ORDERS FOR DIAGNOSTIC PROCEDURES, TREATMENTS AND MEDICATIONS SHALL BE SIGNED BY THE CLINICAL STAFF OR OTHER AUTHORIZED LICENSED PRACTITIONERS SUBMITTING THEM AND ENTERED IN THE RECORD IN INK OR TYPE, AS A FACSIMILE, OR BY ELECTRONIC MEANS. THE PROMPT COMPLETION OF THE HEALTH INFORMATION RECORD SHALL BE THE RESPONSIBILITY OF THE CLINICAL STAFF. AUTHENTICATION MAY BE BY WRITTEN SIGNATURE, IDENTIFIABLE INITIALS OR COMPUTER KEY.

(C) THE RECORD SHALL CONTAIN ACCURATE DOCUMENTATION OF SIGNIFICANT CLINICAL INFORMATION PERTAINING TO THE CLIENT AND NEWBORN SUFFICIENTLY DETAILED AND ORGANIZED IN SUCH A MANNER TO ENABLE:

(1) ANOTHER PRACTITIONER TO ASSUME CARE OF THE CLIENT OR NEWBORN AT ANY TIME.

(2) EVALUATION OF THE QUALITY OF CLIENT CARE BY THE QUALITY MANAGEMENT PROGRAM.

(3) THE CLINICAL STAFF TO UTILIZE THE RECORD TO INSTRUCT THE CLIENT AND FAMILY MEMBERS.

(4) THE CLINICAL STAFF TO DETERMINE HIGH RISK FACTORS THROUGHOUT THE PREGNANCY, LABOR, DELIVERY AND POSTPARTUM PERIOD.

7.6 CONTENT OF ADULT CLIENT RECORD

(A) THE RECORDS OF ADULT CLIENTS SHALL CONTAIN, BUT NOT BE LIMITED TO:

(1) IDENTIFICATION DATA INCLUDING HISTORY, PHYSICAL EXAMINATION, AND RISK ASSESSMENTS, INCLUDING PSYCHOSOCIAL INFORMATION. EACH CLIENT SHALL HAVE A UNIQUE MEDICAL RECORD IDENTIFICATION NUMBER.

(2) EXECUTED INFORMED CONSENT(S) WHICH SHALL BE OBTAINED PRIOR TO THE ONSET OF LABOR.

(3) ALL LABORATORY TESTING RESULTS, INCLUDING BUT NOT LIMITED TO, TEST RESULTS FOR RUBELLA SCREENING AND RH FACTOR.

(4) CLINICAL OBSERVATIONS, INTERVENTIONS, AND MEDICATIONS ADMINISTERED DURING PRENATAL CARE, LABOR AND DELIVERY, AND IMMEDIATE POSTPARTUM CARE.

(5) MEDICAL ORDERS AND, IF APPLICABLE, CONSULTATIVE REPORTS.

(6) COMPLICATIONS, REFERRALS, AND TRANSFERS.

(7) DISCHARGE SUMMARY.

(8) POSTPARTUM VISITS.

(9) THE FAMILY MEMBER OR SUPPORT PERSON DESIGNATED BY THE CLIENT, WHO WILL CARE FOR THE NEWBORN IN THE EVENT THAT THE ADULT CLIENT IS SEPARATED FROM THE NEWBORN.

7.7 CONTENT OF NEWBORN RECORD

(A) ~~10.~~ Records of newborns ~~infants~~ shall be maintained as separate records ~~and shall include in addition to the requirements for medical records, the following information~~. THE CLINICAL RECORDS OF THE NEWBORN SHALL CONTAIN:

(1) ~~a.~~ date and ~~hour~~ TIME of birth, birth weight and length, period of gestation, sex and condition of infant on delivery (including Apgar and any resuscitative measures taken).~~;~~

(2) ~~c.~~ record of ophthalmic prophylaxis.~~;~~

(3) ~~d.~~ record of administration of Rh immune globulin if any.~~;~~

(4) ~~e. appropriate~~ physical examination at birth and at discharge.~~;~~

(5) ~~f.~~ genetic screening, PKU or other metabolic disorders report.~~;~~

(6) ~~g.~~ fetal monitoring record.~~;~~

(7) ~~h.~~ copy of birth certificate WORKSHEET.~~;~~

(8) ANY COMPLICATIONS, REFERRALS AND TRANSFERS.

(9) DISCHARGE SUMMARY.

7.8 ~~F. Nursing Records: Standard nursing practice and procedure shall be followed in the~~ PROGRESS NOTES. THE FACILITY SHALL ESTABLISH A STANDARD METHODOLOGY FOR recording ~~of~~ CLIENT EDUCATION, medications, ~~and~~ treatments AND PROCEDURES. ~~including operative and post-operative notes~~. ~~Nursing notes~~ DOCUMENTATION shall include notation of the instructions given ~~patients~~ TO CLIENTS ~~pre-operatively and~~ at the time of discharge. All recordings shall be ~~in ink and properly~~ signed, including name and identifying title.

~~G. Entries: All orders for diagnostic procedures, treatments and medications will conform to the requirements of Chapter IV, section 4.4, of Standards for Hospitals and Health Facilities~~.

7.9 CENTRAL LOG. THERE SHALL BE A LOG FOR REGISTERING BIRTHS, WITH INFORMATION ABOUT THE ADULT CLIENT AND THE NEWBORN.

(A) ADULT CLIENT. THE LOG SHALL CONTAIN THE FOLLOWING INFORMATION FOR THE ADULT CLIENT:

(1) NAME.

(2) DATE OF DELIVERY.

(3) TIME OF DELIVERY.

(4) TYPE OF DELIVERY.

(5) TRANSFER INFORMATION, IF APPLICABLE:

(a) MODE OF TRANSFER, I.E, EMS OR OTHER.

(b) REASON FOR TRANSFER.

(c) OUTCOME AFTER TRANSFER.

(B) NEWBORN. THE LOG SHALL CONTAIN THE FOLLOWING INFORMATION FOR THE NEWBORN:

(1) NAME, IF AVAILABLE.

(2) SEX.

(3) WEIGHT.

(4) GESTATIONAL AGE.

(5) APGAR SCORE.

(6) TRANSFER INFORMATION, IF APPLICABLE:

(a) MODE OF TRANSFER, I.E, EMS OR OTHER.

(b) REASON FOR TRANSFER.

(c) OUTCOME AFTER TRANSFER.

~~IX. Equipment and Supplies 15. A. There shall be appropriate equipment and supplies maintained for the mother and newborn, to include, but not be limited to: log book, for registration of birth which shall contain at least the following:~~

~~a. mother's name~~

~~b. mother's facility number~~

~~c. date of delivery~~

~~d. time of delivery~~

~~e. mother's age~~

~~f. Gravida, Para,~~

~~g. newborn weight~~

~~h. newborn sex~~

~~i. gestational age~~

~~j. transport:~~

~~(1) mother~~

~~(2) baby~~

~~(3) where~~

~~(4) when~~

~~(5) by whom~~

~~k. indication for hospital delivery~~

~~l. maternal outcome after transfer~~

~~m. indication for newborn transfer n. newborn outcome after transfer o. death:~~

~~(1) neonatal~~

~~(2) maternal~~

~~(3) stillbirth~~

~~p. type of delivery~~

~~q. condition of newborn at delivery/congenital anomalies~~

~~r. delivering person~~

~~s. Apgar~~

~~t. any required resuscitation.~~

SECTION 8 – ~~VII .~~ NURSING AND OTHER PERSONNEL

~~A. Orientation; The purpose and objectives of the birth center shall be explained to all personnel as part of an overall orientation program.~~

~~B. Policies: There shall be appropriate written personnel policies, rules and regulations governing the conditions of employment, the management of employees and the types of functions to be performed.~~

8.1 STAFFING

(A) EACH FACILITY SHALL BE STAFFED WITH AN APPROPRIATE NUMBER OF PROFESSIONAL AND ANCILLARY PERSONNEL WHOSE EDUCATION, TRAINING AND EXPERIENCE IS COMMENSURATE WITH ASSIGNED DUTIES AND RESPONSIBILITIES.

(B) ~~VI. NURSING SERVICES A. Nursing Personnel;~~ There shall be sufficient ~~Registered Professional Nurses~~ REGISTERED NURSES and auxiliary nursing personnel on duty to meet the total nursing needs of the ~~patients~~ CLIENTS.

(C) NURSES AND OTHER PERSONNEL SHALL PERFORM THEIR DUTIES IN ACCORDANCE WITH THEIR SCOPE OF PRACTICE.

8.2 PERSONNEL FILES SHALL BE MAINTAINED ON THE PREMISES FOR ALL PERSONNEL WHICH CONTAIN AT MINIMUM:

(A) EVIDENCE OF CURRENT LICENSURE OR CERTIFICATION.

(B) SIGNED CONTRACTS FOR CONTRACTED EMPLOYEES.

8.3 THE FACILITY SHALL DEVELOP AND IMPLEMENT WRITTEN POLICIES AND PROCEDURES REGARDING:

(A) THE CONDITIONS OF EMPLOYMENT, ORIENTATION AND MANAGEMENT OF EMPLOYEES.

(B) EVALUATION OF SKILLS FOR NON-CREDENTIALED STAFF.

(C) EMPLOYEE HEALTH TO PROTECT CLIENTS FROM BEING EXPOSED TO COMMUNICABLE DISEASE. THE POLICY SHALL:

(1) ADDRESS PRE-EMPLOYMENT HEALTH REQUIREMENTS, IF ANY.

(2) IDENTIFY WHICH COMMUNICABLE DISEASES RENDER AN EMPLOYEE INELIGIBLE FOR DUTY AND THE PROCESS FOR RESTORING ELIGIBILITY FOR DUTY.

(3) PROVIDE THAT STAFF EXPOSED TO BLOOD SHALL HAVE FULL IMMUNIZATION AGAINST HEPATITIS B OR DOCUMENTATION OF REFUSAL.

8.4 THE FACILITY SHALL REQUIRE ALL PERSONS, INCLUDING STUDENTS, WHO EXAMINE, OBSERVE, OR TREAT CLIENTS TO WEAR IDENTIFICATION STATING, AT MINIMUM, THE PERSON'S NAME AND CREDENTIALS.

SECTION 9 – ~~VIII~~ ADMISSIONS AND DISCHARGE

~~A. Admissions: All persons admitted to a birth center shall be under the direct care of a member of the provider staff and agree to remain at the center not less than four hours postpartum.~~

9.1 ~~A.~~ ONLY MEMBERS OF THE CLINICAL STAFF SHALL ADMIT CLIENTS TO THE FACILITY.

9.2 ~~B. Disclosure Document~~: As a condition of ~~acceptance for birth center care~~ ADMISSION all persons shall sign prior to the onset of labor a disclosure document which shall contain:

(A) ~~1.~~ an explanation of the services available~~;~~.

(B) ~~2.~~ an explanation of the services not available, including types of anesthesia~~;~~.

(C) ~~4. a statement of the additional risk involved in having a child at a birth center instead of a hospital;~~ THE RISKS, BENEFITS AND ELIGIBILITY REQUIREMENTS FOR CARE.

(D) ~~3.~~ THE FACILITY'S PLAN FOR PROVISION OF EMERGENCY AND NON-EMERGENCY CARE IN THE EVENT OF COMPLICATIONS WITH CLIENT OR NEWBORN, AND a statement of the time to and location of the nearest hospital ~~facilities~~ for care of ~~mother~~ THE CLIENT and ~~child~~ NEWBORN~~;~~ .

(E) ~~5. a statement of cost~~ A WRITTEN STATEMENT OF FEES FOR SERVICES AND RESPONSIBILITIES FOR PAYMENT.

9.3 ONLY LOW RISK PREGNANT PERSONS FOR WHOM PRENATAL AND INTRAPARTUM HISTORY, PHYSICAL EXAMINATION, AND LABORATORY SCREENING PROCEDURES HAVE DEMONSTRATED A NORMAL, UNCOMPLICATED COURSE OF PREGNANCY AND LABOR SHALL BE ADMITTED.

(A) THE FACILITY SHALL SPECIFY IN POLICY AND PROCEDURE THE CRITERIA USED TO EVALUATE RISK STATUS. THE CRITERIA SHALL BE BASED ON A CURRENT NATIONAL STANDARD OF CARE, SUCH AS, BUT NOT LIMITED TO, INDICATORS ESTABLISHED BY THE AMERICAN ASSOCIATION OF BIRTH CENTERS. THE SOCIAL, MEDICAL, OBSTETRIC, FETAL AND/OR NEONATAL RISK FACTORS WHICH EXCLUDE PERSONS FROM THE LOW-RISK INTRAPARTUM GROUP SHALL BE CLEARLY DELINEATED AND ANNUALLY REVIEWED AND UPDATED AS APPROPRIATE.

(B) THE CRITERIA USED TO EVALUATE RISK STATUS SHALL BE APPLIED FOR EACH CLIENT DURING THE ENTIRE COURSE OF CARE DELIVERED BY THE FACILITY.

(C) PRENATAL CARE IN ACCORDANCE WITH CURRENT STANDARDS OF PRACTICE SHALL BE A PREREQUISITE FOR ADMISSION.

~~C. Prohibitions from Birth Center Delivery:~~

~~(A) 1. Medical limitations:~~

~~a. current drug or alcohol addiction;~~

~~b. paraplegia, quadraplegics;~~

~~c. hypertensives on medications;~~

~~d. hypertension over 140/90;~~

~~e. diabetes (insulin dependent or gestational);~~

~~f. history of significant deep vein thrombophlebitis or any thrombophlebitis with this pregnancy;~~

~~g. severe anemia (hct. below 30 at admission);~~

~~h. epileptics on medication;~~

~~i. mental impairment that would interfere with the ability to follow directions;~~

~~j. morbid obesity (100% over ideal body weight).~~

~~(B) 2. Obstetrical Limitations:~~

~~a. grand multiparity (over five births);~~

~~b. previous birth of a baby with serious congenital anomaly of a probably repeating type that cannot be excluded through antenatal evaluation;~~

~~c. suspected congenital anomaly;~~

~~d. previous Cesarean delivery;~~

~~e. preeclampsia;~~

~~f. multiple gestation;~~

~~g. intrauterine growth retardation or macrosomia;~~

~~h. documented oligohydramnios or polyhdramnios;~~

~~i. abnormal fetal surveillance studies;~~

~~j. fetal presentation other than vertex;~~

~~k. rising antibody titre of any type that is known to affect fetal well-being;~~

~~l. all RH sensitizations;~~

~~m. significant third trimester bleeding of unexplained cause;~~

~~n. need for induction of labor (no induction allowed);~~

~~o. need for general or conduction anesthesia;~~

~~p. need for C-section (no C-sections allowed);~~

~~q. placental abnormalities (previa or abruptio) which might threaten the neonate r;~~

~~r. known or suspected active genital herpes at the time of admission;~~

~~s. premature labor (before 37 weeks) or postmaturity (after 42 weeks);~~

~~t. any other condition or need which will adversely affect the health of the mother or infant during pregnancy, labor, birth, or the immediate postpartum period.~~

9.4 DISCHARGE PLANNING

(A) AN INDIVIDUALIZED DISCHARGE PLAN SHALL BE COMMUNICATED TO THE CLIENT AND RECORDED IN THE CLIENT'S CHART. THE DISCHARGE PLAN SHALL INCLUDE:

(1) INFORMATION ABOUT FOLLOW UP VISITS. A FOLLOW UP VISIT SHALL BE SCHEDULED PRIOR TO DISCHARGE.

(2) REFERRALS FOR CONTINUITY OF CARE FOR BOTH THE CLIENT AND NEWBORN. THE FACILITY SHALL PROVIDE THE RELEVANT PORTIONS OF THE NEWBORN RECORDS TO THE CLIENT. UPON REQUEST BY THE CLIENT OR THE PEDIATRIC CARE PROVIDER, THE FACILITY SHALL PROVIDE A COPY OF THE NEWBORN RECORDS TO THE PEDIATRIC CARE PROVIDER.

(B) THE FACILITY SHALL PROVIDE A LIST OF AVAILABLE COUNSELORS AND COUNSELING SERVICES TO CLIENTS KNOWN TO BE CONSIDERING RELINQUISHING OR TERMINATING PARENTAL RIGHTS. THE LIST SHALL ALSO BE PROVIDED TO ANY OTHER FAMILY OR SUPPORT PERSON DESIGNATED BY THE CLIENT.

(C) THE FACILITY SHALL FILE BIRTH CERTIFICATES WITH THE STATE REGISTRAR IN ACCORDANCE WITH SECTION 25-2-112, C.R.S.

~~VIIII Admissions D. Conditions Requiring Intrapartum Transfer from Birth Center to a Hospital: E. Conditions Requiring for Post-partum Transfer from Birth Center to a Hospital~~

SECTION 10 – LABORATORY SERVICES

10.1 CLINICAL LABORATORY SERVICES SHALL BE AVAILABLE AS REQUIRED BY THE NEEDS OF THE CLIENTS AS DETERMINED BY THE CLINICAL STAFF. WHETHER PROVIDED ON-SITE OR BY CONTRACT, THE LABORATORY SHALL MEET THE REQUIREMENTS OF THE "CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988," 42 USC § 263a, AND THE CORRESPONDING REGULATIONS AT 42 CFR PART 493.

~~X. LABORATORY A. Services: Clinical pathology services shall be available as required by the needs of the patients as determined by the provider staff.~~

~~1. Quality Control: Internal quality control shall be established to insure compliance with generally accepted standards of laboratory practice and procedure.~~

SECTION 11 – FOOD SERVICES

11.1 SAFE FOOD STORAGE AND PREPARATION PRACTICES SHALL BE FOLLOWED, IN ACCORDANCE WITH POLICIES AND PROCEDURES DEVELOPED BY THE FACILITY, WHETHER FOOD IS PREPARED AT THE FACILITY, BY A CONTRACTED CATERING SERVICE, OR BROUGHT BY CLIENTS.

SECTION 12 – EMERGENCY CARE AND TRANSFERS

12.1 POLICIES AND PROCEDURES REGARDING EMERGENCY CARE AND TRANSFER SHALL ADDRESS, BUT NOT BE LIMITED TO, THE FOLLOWING:

(A) TRANSFER TO A HOSPITAL, WHEN APPROPRIATE, IN A TIMELY MANNER TO ENSURE THE WELL-BEING OF THE ADULT CLIENT AND NEWBORN.

(B) TRANSFER OF INFORMATION REQUIRED FOR PROPER CARE AND TREATMENT OF THE INDIVIDUAL(S) TRANSFERRED, INCLUDING CLIENT HEALTH RECORDS.

(C) SECURITY AND ACCOUNTABILITY OF THE PERSONAL EFFECTS OF THE INDIVIDUAL(S) BEING TRANSFERRED.

(D) COMMUNICATION WITH THE RECEIVING HOSPITAL.

12.2 ~~VIII Admissions D. Conditions Requiring Intrapartum Transfer from Birth Center to a Hospital:~~ CLIENTS WITH THE FOLLOWING CONDITIONS INTRAPARTUM SHALL BE TRANSFERRED TO A HOSPITAL:

(A) ~~1. a desire~~ CLIENT REQUEST for transfer from birth center care~~;~~.

(B) ~~2. patient inadvertently~~ CLIENT admitted with any ~~of the listed~~ conditions which preclude birth center delivery~~;~~.

~~3. excessive need for analgesia during labor, or for anesthesia other than pudendal or local;~~

(C) NEED FOR PHARMACOLOGIC AGENTS FOR CERVICAL RIPENING, INDUCTION, AND AUGMENTATION OF LABOR.

(D) ~~4.~~ failure of progressive cervical dilation or descent after trial of therapeutic steps capable of being applied at the ~~center~~ FACILITY~~;~~.

(E) FETAL MONITORING BEYOND INTERMITTENT AUSCULTATION.

(F) ~~5.~~ fetal distress without delivery imminent~~;~~.

~~6. passage of any meconium when delivery is not imminent;.~~

(G) ~~7.~~ development of ~~hypertension or~~ preeclampsia~~;~~.

(H) ~~8.~~ intrapartum hemorrhage (placenta previa or abruptio placentae)~~;~~.

(I) ~~9.~~ prolapsed cord~~;~~.

(J) ~~10.~~ change to non-vertex presentation~~;~~.

(K) ~~11.~~ evidence of amnionitis~~;~~.

(L) ~~12.~~ development of ANY other ~~severe medical or surgical problems~~ COMPLICATION BEYOND THE FACILITY'S SCOPE OF SERVICES IDENTIFIED BY THE GOVERNING BOARD PURSUANT TO SECTION 4.2 (C) OF THESE REGULATIONS.

12.3 ~~VIII Admissions E. Conditions Requiring for Post-partum Transfer from Birth Center to a Hospital~~ CLIENTS WITH THE FOLLOWING CONDITIONS POST-PARTUM SHALL BE TRANSFERRED TO A HOSPITAL:

(A) ~~1. Maternal:~~ ADULT CLIENT

(1) ~~a.~~ hemorrhage not responding to treatment~~;~~..

~~b. need for transfusion;~~

(2) ~~c.~~ retained placenta ~~greater than 30 minutes,~~ .

(3) ~~d.~~ need for extended observation ~~that prevents discharge home;~~ .

(4) ~~e. any other significant morbidity~~ DEVELOPMENT OF ANY OTHER COMPLICATION BEYOND THE FACILITY'S SCOPE OF SERVICES IDENTIFIED BY THE GOVERNING BOARD PURSUANT TO SECTION 4.2 (C) OF THESE REGULATIONS.

(B) ~~2. Infant:~~ NEWBORN

(1) ~~a.~~ Apgar less than 7 at 5 minutes~~;~~.

(2) ~~b.~~ need for oxygen beyond 5 minutes~~;~~.

(3) ~~c.~~ signs of prematurity~~;~~.

(4) ~~d.~~ signs of respiratory distress~~;~~.

(5) ~~e.~~ jaundice, anemia, polycythemia, or hypoglycemia~~;~~.

(6) ~~f.~~ persistent hypothermia (less than 97° F at 2 hours of life)~~;~~.

(7) ~~g.~~ persistent hypotonia~~;~~ .

(8) ~~h.~~ exaggerated tremors, seizures or irritability~~;~~.

(9) ~~i.~~ any significant congenital anomaly, seen or suspected~~;~~.

(10) ~~j.~~ sign of significant birth trauma~~;~~.

~~k. feeding difficulty;~~ .

(11) ~~l. any other significant morbidity~~. DEVELOPMENT OF ANY OTHER COMPLICATION BEYOND THE FACILITY'S SCOPE OF SERVICES IDENTIFIED BY THE GOVERNING BOARD PURSUANT TO SECTION 4.2 (C) OF THESE REGULATIONS.

SECTION 13 – RESERVED

SECTION 14 – ~~XI.~~ PHARMACEUTICAL SERVICES

14.1 THE FACILITY SHALL MAINTAIN AN INVENTORY OF MEDICATIONS SUFFICIENT TO CARE FOR THE NUMBER OF ADULT CLIENTS AND NEWBORNS REGISTERED FOR CARE.

14.2 ~~There shall be~~ THE FACILITY SHALL DEVELOP AND IMPLEMENT POLICIES AND PROCEDURES FOR THE STORAGE, DISPENSING AND ADMINISTRATION OF DRUGS AND BIOLOGICALS IN ACCORDANCE WITH PROFESSIONAL STANDARDS OF PRACTICE AND APPLICABLE STATE AND FEDERAL LAWS AND REGULATIONS, INCLUDING BUT NOT LIMITED TO 21 CFR SECTION 1300, ET SEQ., PERTAINING TO FEDERAL DRUG ENFORCEMENT ADMINISTRATION REQUIREMENTS FOR CONTROLLED SUBSTANCES. ~~B. When the facility maintains its own pharmaceutical services, it shall comply with applicable regulations of the Colorado State Board of Pharmacy~~.

14.3 MEDICATION SHALL BE ADMINISTERED ONLY BY A LICENSED NURSE OR THE CLINICAL STAFF.

14.4 THE FACILITY SHALL MONITOR THE EXPIRATION DATE OF ALL MEDICATIONS.

14.5 MEDICATIONS MAINTAINED IN THE FACILITY SHALL BE APPROPRIATELY STORED AND SAFEGUARDED AGAINST DIVERSION OR ACCESS BY UNAUTHORIZED PERSONS.

(A) APPROPRIATE RECORDS SHALL BE KEPT REGARDING THE DISPOSITION OF ALL MEDICATIONS. EXPIRED MEDICATIONS ARE DISPOSED OF IN ACCORDANCE WITH STATE LAW.

(B) CONTROLLED SUBSTANCES

(1) CONTROLLED SUBSTANCES SHALL BE MAINTAINED IN DOUBLE-LOCKED, SECURED CABINETS. THERE SHALL BE A WRITTEN PROCEDURE FOR MAINTAINING ACCOUNTABILITY AND MONITORING FOR DIVERSION.

(2) ON-SITE DESTRUCTION OF CONTROLLED SUBSTANCES SHALL BE WITNESSED AND DOCUMENTED IN WRITING BY TWO CLINICALLY LICENSED INDIVIDUALS AND DESTROYED IN A MANNER THAT RENDERS THE CONTROLLED SUBSTANCES TOTALLY IRRETRIEVABLE.

SECTION 15 – CLIENT CARE

15.1 CLIENT RIGHTS. THE FACILITY SHALL BE COMPLIANT WITH 6 CCR 1011.1, CHAPTER 2, PART 6.

15.2 POLICIES AND PROCEDURES. THE FACILITY SHALL DEVELOP AND IMPLEMENT WRITTEN POLICIES AND PROCEDURES TO PROVIDE COMPREHENSIVE PERINATAL CARE FOR LOW-RISK PREGNANCY, NEWBORN CARE AND REFERRAL OF HIGH RISK PREGNANCY CONSISTENT WITH CURRENT STANDARDS OF PRACTICE. POLICIES AND PROCEDURES SHALL INCLUDE BUT NOT BE LIMITED TO:

(A) PARENT EDUCATION, INCLUDING ORIENTATION TO THE PHILOSOPHY OF CARE AND THE SCOPE OF SERVICES OF THE FACILITY.

(B) CONTINUOUS SCREENING FOR HIGH RISK THAT ADDRESSES:

(1) A SCREENING PROCESS THAT INCLUDES WRITTEN CRITERIA FOR ADMISSION OF ONLY LOW RISK PREGNANCIES.

(2) THE ROUTINE EVALUATION OF CLIENTS THROUGHOUT PREGNANCY TO ASSURE THAT THEIR PREGNANCY REMAINS LOW RISK.

(3) PROTOCOLS FOR REFERRAL OF HIGH RISK PERSONS AND NEWBORNS TO APPROPRIATE PROVIDERS OF OBSTETRICAL AND NEWBORN CARE.

(C) BREASTFEEDING SUPPORTIVE PRACTICES.

(D) AVAILABILITY OR ACTUAL CONTACT WITH CLINICAL STAFF ON A 24 HOUR PER DAY, 7 DAYS PER WEEK BASIS.

15.3 PROVISION OF CARE

(A) ~~VIII.A.~~ All persons admitted to ~~a birth center~~ THE FACILITY shall be under the direct care of a member of the ~~provider~~ CLINICAL staff and agree to remain at the ~~center~~ facility not less than four hours postpartum.

(B) ANTENATAL CARE

(1) THERE SHALL BE A PROGRAM OF EDUCATION INCLUDING PROVISION OF INFORMATION TO INCLUDE BUT NOT BE LIMITED TO:

(a) ANTICIPATED CHANGES DURING PREGNANCY.

(b) THE SIGNS OF PRETERM LABOR.

(c) PREPARATION FOR LABOR AND DELIVERY, INCLUDING PAIN MANAGEMENT AND OBSTETRICAL COMPLICATIONS AND PROCEDURES.

(d) FEEDING OPTIONS AND CARE OF THE NEWBORN, INCLUDING INFANT SAFE SLEEP PRACTICES.

(e) SIGNS OF DEPRESSION DURING PREGNANCY AND AFTER CHILDBIRTH.

(f) PREPARATION NEEDED FOR DISCHARGE OF THE CLIENT AND THE NEWBORN FOLLOWING DELIVERY, INCLUDING REFERRALS ASSOCIATED WITH ENSURING THE CONTINUITY OF CARE.

(2) EACH CLIENT SHALL HAVE A PLAN OF CARE DEVELOPED BY CLINICAL STAFF. THE PLAN SHALL IDENTIFY THE CARE TO BE PROVIDED AND THE NEED FOR POSTPARTUM SERVICES. THE CLIENT SHALL BE INVOLVED IN REASSESSMENTS AND REVISIONS OF THE PLAN THAT MAY BE REQUIRED.

(3) EACH CLIENT SHALL BE ASSESSED FOR IMMUNITY TO RUBELLA AND COUNSELLED ON ASSOCIATED RISKS.

(4) EACH CLIENT SHALL UNDERGO PRENATAL TESTING IN ACCORDANCE WITH PROFESSIONAL STANDARDS OF CARE.

(C) CARE DURING LABOR AND DELIVERY

(1) THE FACILITY SHALL PROVIDE REGULAR AND APPROPRIATE ASSESSMENT OF THE CLIENT AND FETUS THROUGHOUT LABOR.

(2) ANESTHESIA

(a) ONLY LOCAL ANESTHESIA FOR EPISIOTOMIES AND REPAIR OF LACERATIONS MAY BE PROVIDED.

(D) POSTPARTUM CARE. CARE DURING THE POSTPARTUM PERIOD SHALL INCLUDE BUT NOT BE LIMITED TO:

(1) CLIENT

(a) MATERNAL ASSESSMENTS AND FOLLOW UP CARE.

(b) SCREENING AND REFERRAL FOR POSTPARTUM DEPRESSION.

(2) NEWBORN

(a) NEWBORN ASSESSMENTS AND FOLLOW UP CARE.

(b) EYE PROPHYLAXIS IN ACCORDANCE WITH SECTION 25-4-301, C.R.S.

(c) NEWBORN SCREENINGS BASED ON CURRENT STANDARDS OF PRACTICE AS WELL AS IN ACCORDANCE WITH SECTION 25-4-1001, ET SEQ., C.R.S. IF THE FACILITY DOES NOT PROVIDE NEWBORN HEARING SCREENING, IT SHALL PROVIDE INFORMATION REGARDING WHERE PARENTS MAY HAVE THEIR INFANTS' HEARING SCREENED AND THE IMPORTANCE OF SUCH SCREENING.

(d) A NEWBORN IDENTIFIED WITH ABNORMALITIES SHALL BE REFERRED FOR APPROPRIATE FOLLOW-UP, IN ACCORDANCE WITH FACILITY POLICY. THE FACILITY SHALL COMMUNICATE WITH THE PEDIATRIC CARE PROVIDER AND TRANSFER BIRTH AND NEWBORN RECORDS TO THE PEDIATRIC CARE PROVIDER.

15.4 STAFFING

(A) THERE SHALL BE SUFFICIENT STAFF TO MEET THE DEMANDS FOR SERVICES ROUTINELY PROVIDED AND COVERAGE DURING PERIODS OF HIGH DEMAND OR EMERGENCY. ~~VI.A. Nursing Personnel; There shall be sufficient registered professional nurses and auxiliary nursing personnel on duty to meet the total nursing needs of the patients. V.D.6. Additional and sufficient personnel shall be provided when more than one woman is in active labor~~

(B) ~~IV.D.5. A physician or certified nurse mid-wife~~ CLINICAL STAFF shall be present at each birth and until the ~~woman~~ CLIENT and newborn are stable postpartum. AT A MINIMUM, THERE SHALL BE A second person in addition to the ~~above~~ CLINICAL STAFF, who is a registered nurse with adult and infant resuscitation skills, ~~shall be~~ present during the delivery.

(C) ~~IV.D.6. A certified nurse-midwife~~ CLINICAL STAFF or registered nurse with adult and infant resuscitation skills shall be present at the ~~birthing center~~ FACILITY at all times when a ~~patient~~ CLIENT OR NEWBORN is present POSTPARTUM THROUGH DISCHARGE. Additional and sufficient personnel shall be provided when more than one ~~woman~~ CLIENT is in active labor.

SECTION 16– ~~IX.~~ EQUIPMENT AND SUPPLIES

16.1 EACH FACILITY SHALL BE EQUIPPED WITH THOSE ITEMS NEEDED TO PROVIDE LOW RISK MATERNITY CARE AND SHALL INCLUDE EQUIPMENT TO INITIATE EMERGENCY PROCEDURES. THE FACILITY SHALL HAVE READILY ACCESSIBLE EQUIPMENT AND SUPPLIES IN ORDER TO:

(A) PERFORM INITIAL AND ONGOING ASSESSMENT OF THE CLIENT AND FETUS.

(B) PROVIDE CARE DURING BIRTH, INCLUDING REPAIR OF LACERATIONS AND MANAGEMENT OF UTERINE ATONY.

(C) PERFORM EVALUATION AND, IF NECESSARY, RESUSCITATION OF THE NEWBORN.

(D) PERFORM SCREENING AND ONGOING ASSESSMENT OF THE NEWBORN.

(E) PROVIDE OXYGEN SUPPLEMENTATION FOR THE ADULT CLIENT OR NEWBORN AS NEEDED.

(F) ESTABLISH AND PROVIDE INTRAVENOUS ACCESS AND FLUIDS, AS NEEDED.

16.2 THERE SHALL BE A READILY ACCESSIBLE EMERGENCY CART OR TRAY FOR THE ADULT CLIENT AND THE NEWBORN TO CARRY OUT THE EMERGENCY PROCEDURES OF THE FACILITY. THERE SHALL BE WRITTEN LOGS OF ROUTINE MAINTENANCE FOR READINESS.

16.3 THERE SHALL BE A SYSTEM TO MONITOR THE READINESS OF ALL EQUIPMENT, MEDICATIONS, INTRAVENOUS FLUIDS AND SUPPLIES.

(A) EQUIPMENT SHALL BE MAINTAINED AND TESTED IN ACCORDANCE WITH MANUFACTURER'S INSTRUCTIONS.

(B) THE INVENTORY OF SUPPLIES AND INTRAVENOUS FLUIDS SHALL BE SUFFICIENT TO CARE FOR THE NUMBER OF ADULT CLIENTS AND NEWBORNS REGISTERED FOR CARE.

16.4 SUPPLIES SUCH AS NEEDLES, SYRINGES AND PRESCRIPTION PADS SHALL BE APPROPRIATELY STORED TO AVOID PUBLIC ACCESS.

~~A. There shall be appropriate equipment and supplies maintained for the mother and newborn to include, but not be limited to:~~

~~1. a bed suitable for labor, birth and recovery;~~

~~2. oxygen with flow meters and masks or equivalent;~~

~~3. mechanical suction and bulb suction (immediately available);~~

~~4. resuscitation equipment to include resuscitation bags, endotracheal tubes and oral airways for the mother and newborn;~~

~~5. firm surfaces suitable for resuscitation;~~

~~6. emergency medications, intravenous fluids, and related supplies and equipment for both mother and newborn;~~

~~7. fetoscope and doptone for fetal monitoring;~~

~~8. a means for monitoring and maintaining the optimum body temperature of the newborn;~~

~~9. infant scale;~~

~~10. a clock with a sweep second hand;~~

~~11. sterile suturing equipment and supplies;~~

~~12. adjustable examination light;~~

~~13. containers for soiled linen and waste materials which shall be closed or covered;~~

~~14. autoclave;~~

SECTION 17 ~~XII.~~ – HOUSEKEEPING SERVICES

17.1 ~~A. Organization:~~ Each facility shall provide housekeeping services which ensure a pleasant, safe and sanitary environment. ~~The facility shall be kept clean and orderly.~~ IF THE FACILITY CONTRACTS WITH AN OUTSIDE VENDOR TO PROVIDE HOUSEKEEPING SERVICES, THERE SHALL BE A WRITTEN AGREEMENT REGARDING THE SERVICES AND THE FACILITY SHALL BE ULTIMATELY RESPONSIBLE FOR QUALITY CONTROL OF THE CONTRACTOR.

17.2 ~~B. Written Policies and Procedures: Appropriate~~ Written policies and procedures shall be established and followed which ensure adequate cleaning and/or disinfection of the ~~physical plant~~ FACILITY and equipment.

17.3 ~~C. Storage:~~ All cleaning materials, solutions, cleaning compounds and hazardous substances shall be properly identified and stored in ~~a safe place~~ ACCORDANCE WITH MANUFACTURER'S INSTRUCTIONS.

17.4 ~~D. Rubbish and Refuse Containers:~~ All ~~rubbish and refuse~~ WASTE containers in ~~treatment~~ CLIENT CARE areas shall be impervious, lined and clean.

17.5 ~~E. Handwashing:~~ All personnel shall wash their hands immediately after handling ~~refuse~~ WASTE.

SECTION 18 – ~~XIII.~~ LAUNDRY AND LINENS

18.1 THE FACILITY SHALL MAKE ARRANGEMENTS FOR THE CLEANING OF LINEN AND LAUNDRY EITHER ON THE PREMISES OR PER CONTRACTUAL ARRANGEMENT.

18.2 THE FACILITY SHALL DEVELOP AND IMPLEMENT WRITTEN POLICIES AND PROCEDURES FOR THE HANDLING, STORAGE AND TRANSPORTING OF CLEAN AND SOILED LINEN THAT PREVENTS CONTAMINATION.

18.3 LINEN SHALL BE CLEANED IN A MANNER THAT PREVENTS CONTAMINATION AND LAUNDRY CHEMICALS SHALL BE USED IN ACCORDANCE WITH MANUFACTURER'S INSTRUCTIONS. LINEN SHALL BE MAINTAINED IN GOOD REPAIR.

18.4 A FACILITY WITH LAUNDRY SERVICE ON THE PREMISES SHALL HAVE SPACE AND EQUIPMENT FOR THE SAFE AND EFFECTIVE OPERATION OF A LAUNDRY SERVICE. THERE SHALL BE DISTINCT AREAS FOR THE SEPARATE STORAGE AND HANDLING OF CLEAN AND SOILED LINENS.

~~Written provisions shall be made for the proper handling of linens and washable goods~~.

~~A. Outside Laundry: Laundry that is sent out shall be sent to a commercial or hospital laundry. A contract for laundry services performed by commercial laundries for birth centers shall include these standards.~~

~~B. Storage: If soiled linen is not processed on a daily basis, a separate, properly ventilated storage area shall be provided.~~

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

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

~~E. Packaging: The linens to be returned from the outside laundry to the facility shall be completely wrapped or covered to protect against contamination.~~

~~F. Soiled Linen Transportation; Soiled linen shall be enclosed in an impervious bag and removed from surgery units after each procedure.~~

~~G. Soiled Linen Carts; Carts, if used to transport soiled linen, shall be constructed of impervious materials, cleaned and disinfected after each use.~~

~~H. Clean Linen Storage: Adequate provisions shall be made for storage of clean linen.~~

~~I. Contaminated Linens: Contaminated linens shall be afforded appropriate special treatment by the laundry.~~

~~J. Procedures: Adequate procedures for the handling of all laundry and for the positive identification and proper packaging and storage of sterile linens must be developed and followed.~~

SECTION 19 – ~~XIV. MAINTENANCE~~ INTERIOR AND EXTERIOR ENVIRONMENT

19.1 ~~A. Written Policies and Procedures~~ : ~~There shall be~~ THE FACILITY SHALL DEVELOP AND IMPLEMENT written policies and procedures for a ~~preventive~~ maintenance program ~~which is implemented~~ to keep the ~~entire~~ facility ~~and equipment~~ in good repair and to provide for the safety, welfare and comfort of the occupants of the building~~(s)~~.

19.2 THE FACILITY SHALL ELIMINATE HAZARDS TO CLIENTS AND VISITORS. IN AREAS ACCESSIBLE TO CHILDREN, ELIMINATION OF HAZARDS SHALL INCLUDE BUT NOT BE LIMITED TO, UNCOVERED ELECTRICAL OUTLETS.

~~XV. PEST CONTROL~~

19.3 ~~A. Pest Control : Adequate written policies and procedures shall be developed and implemented~~ THE FACILITY SHALL DEVELOP AND IMPLEMENT WRITTEN POLICIES AND PROCEDURES TO PROVIDE FOR EFFECTIVE CONTROL AND ERADICATION OF ~~INSECTS AND RODENTS~~ VERMIN. ~~B. Outer Air Openings :~~ All openings to the outer air shall be effectively protected against the entrance of ~~insects and rodents, etc.,~~ VERMIN by self-closing doors, closed windows, screens, controlled air currents or other effective means.

SECTION 20 – ~~XVI.~~ WASTE STORAGE AND DISPOSAL

~~A. Sewage and Sewer Systems : All sewage shall be discharged into a public sewer system, or if such is not available, shall be disposed of in a manner approved by the Colorado State Department of Health.~~

20.1 FACILITIES SHALL MANAGE, TRANSPORT, AND DISPOSE OF MEDICAL WASTE IN ACCORDANCE WITH THE STATE SOLID WASTE REGULATIONS, 6 CCR 1007-2, PART 1.

20.2 FACILITIES THAT GENERATE WASTE, INCLUDING MEDICAL WASTE, SHALL CONDUCT A HAZARDOUS WASTE DETERMINATION IN ACCORDANCE WITH PART 261 OF THE STATE HAZARDOUS WASTE REGULATIONS (6 CCR 1007-3). IF THE FACILITY GENERATES HAZARDOUS WASTE, IT SHALL MANAGE, TRANSPORT, AND DISPOSE OF SUCH WASTE IN ACCORDANCE WITH 6 CCR 1007-3.

SECTION 21 ~~XVII~~. – PHYSICAL PLANT STANDARDS

21.1 ~~O.~~ Effective July 1, 2013, all birth centers shall be constructed in conformity with the standards adopted by the Director of the Division of Fire Prevention and Control (DFPC) at the Colorado Department of Public Safety. For construction initiated or systems installed on or after July 1, 2013, that affect patient health and safety and for which DFPC has no applicable standards, each facility shall conform to the relevant section(s) of the Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute. The Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute (FGI), is hereby incorporated by reference and excludes any later amendments to or editions of the Guidelines. The 2010 FGI Guidelines are available at no cost in a read only version at: https://www.fgiguidelines.org/guidelines/2010-edition/read-only-copy/.

~~A. Reserved~~

21.2 BIRTHING ROOM

(A) ~~B.~~ Each birthing room shall be maintained in a condition which is adequate and appropriate to provide for the equipment, staff, supplies and emergency procedures required for the physical and emotional care of a ~~mother~~ CLIENT, ~~her support person(s)~~ THE CLIENT'S DESIGNATED FAMILY MEMBER OR SUPPORT PERSON, and the newborn during birth, labor and the recovery period.

~~1. Birthing rooms shall have at least 120 square feet with a minimum room dimension of 10 feet.~~

(B) ~~2.~~ Birthing rooms shall be located to provide unimpeded, rapid access to an exit of the building which will accommodate emergency transportation vehicles and equipment.

(C) A WINDOW IN THE BIRTHING ROOM SHALL NOT BE REQUIRED SOLELY FOR THE PURPOSE OF NATURAL LIGHT.

~~C. Patient toilet and bathing facilities.~~

~~1. A toilet and lavatory shall be maintained in or adjacent to the vicinity of the birthing room.~~

~~2. A shower shall be available for mother's CLIENT'S use.~~

~~3. All wall, ceiling, floor surfaces, toilets, lavatories, tubs and showers shall be kept clean and in good repair.~~

21.3 DOORS

(A) ~~D. Hallways and~~ Doors providing entry/exit and access into the ~~birthing center~~ FACILITY and birth room(s) shall be of adequate width and/or configuration to accommodate maneuvering of ambulance stretchers and wheelchairs and other emergency equipment.

(B) ~~I. Every bathroom door lock shall be designed to permit the opening of the locked door from the outside in an emergency.~~ THE DOORS TO THE TOILETS IN LABOR, DELIVERY AND

POSTPARTUM CARE AREAS FOR CLIENT USE SHALL HAVE HARDWARE THAT ALLOWS STAFF EMERGENCY ACCESS.

~~E. Water Supply: There shall be an adequate supply of hot and cold running water under pressure for human consumption and other purposes which shall be approved by the Colorado Department of Health as meeting the Colorado Primary Drinking Water Regulations, 1981.~~

~~F. Heating and Ventilation:~~

~~1. A safe and adequate source of heat capable of maintaning a room temperature of at least 72°F. shall be provided and maintained.~~

~~2. Ventilation shall remove objectionable odors, excessive heat and condensations.~~

~~3. Mechanically operated systems shall be used to supply air to and/or exhaust air from soiled workrooms or soiled holding rooms, janitor's closets, soiled storage areas, toilet rooms, and from spaces which are not provided with openable windows or outside doors. All fans serving exhaust systems shall be located at the discharge end of the system.~~

~~G. Food Services:~~

~~1. When birth center policy provides for allowing the preparation and/or storage of personal food brought in by the patient or families of patients for consumption of that family, there shall be an adequate electric or gas refrigerator and dishwashing facilities.~~

~~H. Fire Safety and Accident Prevention:~~

~~1. Emergency numbers shall be located near the telephone.~~

~~2. There shall be a written evacuation and fire plan for the removal of patients in case of fire and other emergencies. The plan shall be posted in a conspicuous place in the building.~~

~~3. A simulated drill shall be performed every quarter per work shift. A written record of each drill shall be kept on file.~~

~~J. There shall be no pets on the premises.~~

~~K. Each birthing room shall be equipped with a nurse call system.~~

~~L. Grab bars and a nurse call system shall be installed in each patient bathing and toilet area.~~

~~M. Automatic regulation of water supply temperature not to exceed 110 F. at shower, bathing and handwashing facilities. Control devices shall be inaccessible to unauthorized personnel.~~

~~N. The birth center shall be maintained to provide a safe, clean sanitary environment.~~

~~**SPECIFIC STATUTORY AUTHORITY**~~

~~These standards were developed under the statutory authority found at 25-1-107(1)(L)I and II and 25-3-101 which requires the Department of Health to annually license and to establish and enforce standards for the operation of hospitals and other institutions of a like nature.~~
