DEPARTMENT OF REGULATORY AGENCIES

COLORADO MIDWIVES REGISTRATION

RULES AND REGULATIONS

4 CCR 739-1

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RULE 1 - Repealed eff. 7/1/2007 PROFESSIONAL CONDUCT

The purpose of this rule is to establish the minimum requirements for professional conduct.

A direct-entry midwife shall not aid or knowingly permit any registered or unregistered direct-entry midwife to violate any law or rule governing the practice of direct-entry midwifery care.

RULE 2 – STANDARDS FOR EDUCATION

The purpose of this rule is to establish the minimum entry level education and training requirements <u>registryfor</u> an applicant to become registered as a direct-entry midwife as required by Section 12-37-103(6) and 106(1)(c), C.R.S.

- A. To <u>qualify for become a registration as a direct-entry midwife, ered in Colorado,</u> an applicant <u>shall provide proof of must have</u> graduat<u>ioned</u> from an accredited midwifery educational program approved by the Midwifery Education and Accreditation Council ("MEAC") and <u>achieved</u> a passing score on the national North American Registry of Midwives ("NARM") Examination.
- B. Alternatively, an applicant may demonstrate that the also become registered if such applicant has obtained a "substantially equivalent" education approved by the Director of Professions and Occupations Registrations ("Director"). A "substantially equivalent" education may be obtained by demonstrating that the applicant has either one of the following methods:
 - 1. <u>AAn applicant who is</u> currently credentialed as a Certified Professional Midwife ("CPM") credential, in good standing, as established and administered by the North American Registry of Midwives ("NARM") and has achieved a passing score on the NARM examination-shall be deemed eligible for registration;
 - 2. Completion of and certification under NARM's entry-level Portfolio Evaluation Process ("PEP") that determines the applicant has obtained a substantially equivalent education as that required in Colorado, and has achieved a passing score on the NARM examination. If the PEP determines that the applicant has obtained a substantially equivalent education as that required in Colorado, then such applicant shall be eligible for registration. All expenses associated with PEP shall be the applicant's responsibility;
 - 3. A credential review performed by the International Credentialing Associates ("ICA") or International Consultants of Delaware ("ICD") that determines the applicant has obtained a substantially equivalent education as that required in Colorado, and has achieved a passing score on the NARM examination shall deem the applicant eligible for registration. The Director will enly accept a credentials evaluation only from an organization listed in this rule. All expenses associated with the credential review shall be the applicant's responsibility; or
 - 4. Education, training, or service gained in military services outlined in § 24-34-102(8.5), C.R.S., that isto be accepted and applied towards receiving a license, must be substantially equivalent, as determined by the Director, to the qualifications otherwise applicable at the time of receipt of application. It is the applicant's responsibility to provide timely and complete evidence for

- review and consideration. Satisfactory evidence of such education, training, or service will be assessed on a case_-by_-case basis.
- C. Applicant's failure to verify their educational qualifications as established by this Rule 2 shall result in the Director denying the application.

RULE 4 - PRACTICE RESTRICTIONS

The purpose of this rule is to define and clarify the practice restrictions applicable to a direct-entry midwife pursuant to Sections 12-37-105 and 12-37-106(1)(a) C.R.S.

- A. The direct-entry midwife shall not provide care to any client who has a medical history of or who exhibits signs or symptoms including but not limited to:
 - Perevious diagnosis of diabetes mellitus or a diagnosis of gestational diabetes in the current pregnancy;
 - 2. Hhypertensive disease (blood pressure greater than 140/90 at rest);
 - 3. Peulmonary disease or cardiac disease which interferes with activities of daily living;
 - 4. <u>Ta history of thrombophlebitis or pulmonary embolism;</u>
 - 5. <u>H</u>hematological or coagulation disorders, *i.e.*, leukemia or sickle cell anemia;
 - Seizures controlled by medication if the client has seized within the last year;
 - 7. Hepatitis B, HIV positive, or AIDS;
 - 8. Ceurrent use of psychotropic medications if client is not under the care and monitoring of a physician during the pregnancy;
 - 9. Ceurrent substance abuse of drugs or alcohol;
 - 10. Rh sensitization (<u>or any</u> positive antibody titre), an incompetent cervix, or previous uncontrollable postpartum hemorrhage;
 - 11. Vaginal Birth after Cesarean Section (VBAC) unless compliant with Rule 12;
 - 12. <u>D</u>delivery of an infant who was premature or stillborn, or a neonatal death associated with maternal health conditions, *i.e.*, hypertension, Diabetes Mellitus, Rh Sensitization, clotting disorders; or
 - 13. delivery of an infant with a major genetic anomaly unless there is a normal prenatal screening ruling out genetic anomalies, or an intervening normal pregnancy.;

- 13. lincompetent cervix;
- 14. Pprevious uncontrolled postpartum hemorrhage; or
- 15. Deelivery of an infant with a major genetic anomaly as reviewed by a pediatrician, perinatologist, or genetic counselor regarding the likelihood of recurrence unless the mother declines the consultation.
- B. The direct-entry midwife shall not:
 - Perform any operative or surgical procedures (except an episiotomy in cases of an emergency);
 - 2. Uutilize forceps, vacuum extraction or other instruments or mechanical means to facilitate birth;
 - 3. Pperform versions; or
 - 4. <u>Aadminister any medications or IV fluids, except as permitted in Section 12-37-105.5, C.R.S., and in Rules 17 and 18; or</u>
 - <u>Uutilize a sonogram machine.</u>

RULE 5 – MINIMUM PRACTICE REQUIREMENTS REGARDING ANTEPARTUM CARE

The purpose of this rule is to define and clarify the minimum requirements of safe care for women and infants regarding antepartum care pursuant to Sections 12-37-105 and 25-4-201, C.R.S., which include but are not limited to:

- A. The direct-entry midwife shall schedule client visits at least once a month beginning in the first trimester through 28 weeks; every 2 weeks from 28 weeks through 35 weeks; and weekly from 36 weeks to delivery.
- B. At the time of the initial visit, the direct-entry midwife shall at a minimum:
 - 1. Oebtain a medical, obstetrical, family and nutritional history;
 - 2. Sscreen for diabetes if the mother has a previous history of gestational diabetes;
 - 23. Determine the estimated due date and perform a baseline physical examination;
 - <u>Aarrange</u> to or obtain laboratory testing including but not limited to: blood group and Rh type, if unknown; Coombs test for all Rh negative mothers; CBC with differential; rubella titre; serology for syphilis; hepatitis B screen, urine for protein and glucose, culture if indicated; Gonococcal Culture screen and Chlamydia culture if needed based on social history; ultrasound imaging, if indicated. Additionally, the blood specimen obtained shall be submitted to an approved

laboratory for a standard serological test for syphilis and HIV. If the client refuses consent for syphilis or HIV testing the direct-entry midwife shall document such refusal in the client record;

- 4. arrange to or obtain laboratory testing for a culture for Group B Streptococci at 35 37 weeks, and, if the culture is positive, inform the client about antibiotic treatment options and recommend an appropriate health care provider;
- 5. Deliscuss home birth, alternatives to home birth, risk assessment, and referral procedures;
- 6. <u>Ceomplete the emergency plan</u> the client with the "Mandatory Disclosure" form and obtain informed consent in a manner approved or provided by the Director; and
- 7. complete the emergency planProvide the client with the "mandatory disclosure" form and obtain informed consent in a manner approved or provided by the director which shall include at least the following:
- (a) Aa complete list of the name and corresponding qualifications of every registered midwife and unregistered birthing attendant who will be assisting in the care of the client and fetus throughout antepartum, intrapartum, and postpartum care;
 - (b) Aa clear outline of the expected duties and corresponding expectations of each registered assistant direct-entry midwife and unregistered birthing attendant who will be assisting in the care of the client or fetus; and
 - (c) Aall or part of the information required in sub-paragraphs (A) and (B) above may be added or amended at any time up to the time of birth.
- C. Safe care for women and infants during each prenatal visit shall, at a minimum, include but not be limited to:
 - Oebtaining vital signs and weight;
 - Performing a urine dipstick for protein and glucose;
 - Aassessing for:
 - (a) <u>E</u>edema, headaches, visual disturbances, dizziness or sharp pains in legs, abdomen, chest or head and reflexes if indicated,
 - (b) Mmother's psychological and emotional status,
 - (c) Nautritional status,
 - (d) Ffundal height, and
 - (e) <u>F</u>fetus for gestational age, presentation and position; estimated fetal weight; fetal activity, listen for fetal heart tones and record when first audible;

- 4. Rrecord all findings, interventions, and outcomes including the quickening date;
- 5. Perovide teaching, guidance, and referral as appropriate; and
- 6. <u>Deliscuss</u> the emergency plan, and revise if needed.
- D. Laboratory studies that should be repeated obtained during pregnancy include:
 - 1. Aan Indirect Coombs test at 28 and 36 weeks, if indicated;
 - Aa Hemoglobin or Hematocrit screening at 28 and 36 weeks;
 - and a one-hour Glucose Tolerance Test Aan oral gestational diabetes screening with a
 minimum of a 50 Gram glucose loading dose shall be offered to the client at 26-28 weeks; and
 - 4. Aa culture for Group B Streptococci at 35 to 37 weeks, and, if the culture is positive, inform the client about antibiotic treatment options and recommend an appropriate health care provider.
- 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.
- F. The direct-entry midwife shall refer clients for evaluation by a qualified licensed health care provider, and shall not continue as the care provider, when a multiple gestation or a presentation other than vertex at the onset of labor are noted.
- G. The direct-entry midwife shall refer a client for evaluation by a qualified licensed health care provider, and shall not continue as the primary care provider when any of the following conditions are noted:
 - Uurine glucose of 2+ or greater on two sequential visits or if other signs or symptoms of gestational diabetes occur with the urine glucose;
 - 2. Hhyperemesis beyond the 24th week of gestation requiring medical treatment;
 - 3. <u>H</u>hypertension blood pressure greater than 140/90-or an increase from the baseline of greater than 30 mm Hg in the systolic or 15 mm Hg in the diastolic pressure;
 - 4. Seigns and symptoms of preeclampsia including but not limited to persistent edema, increased blood pressure or proteinuria, increased reflexes, persistent headaches, epigastric pain, visual disturbances;
 - Seizures;
 - Vyaginal bleeding other than spotting after 20 weeks;
 - Seigns and symptoms of urinary infections or sexually transmitted disease;
 - Qeral temperature in excess of 101° F for more than 24 hours accompanied by other signs or symptoms of clinically significant infection or which does not resolve within 72 hours;

- 9. <u>L</u>laboratory results indicating need for medical treatment, for example, <u>a positive culture urinary</u> tract or yeast infections not responding to non-prescription treatment;
- 10. Aanemia not responding to over the counter iron therapy as measured by Hemoglobin below 11 grams or Hematocrit below 34% at term;
- 11. Seigns and symptoms of polyhydramnios or oligohydramnios;
- 12. Seuspected fetal demise lack of fetal movement, inability to auscultate fetal heart tones;
- Decreased fetal movements;
- 14. <u>Gg</u>estation longer than 42 weeks;
- 15. Rrupture of membranes for:
 - (a) Lionger than 12 hours without labor for Group B Streptococci positive clients and unknown Group B Streptococci status; or
 - (b) Longer than 18 hours without labor for Group B Streptococci negative clients;
- 16. Peremature labor less than 37 completed weeks gestation;
- 17. Aactive herpes;
- 18. <u>lintrauterine growth retardation restriction</u>; or
- 19. Ssuspected abnormality of pelvis;
- H. Once any of the conditions provided in paragraph G. are noted, the direct-entry midwife shall not resume care for the client until a qualified health care provider assesses the client and determines that the client is not exhibiting signs or symptoms of increased risk of medical, obstetrical, or neonatal complications, or problems during the completion of the pregnancy, labor, delivery, or the postpartum period, and is not exhibiting signs and symptoms of increased risk that the infant may develop complications or problems during the first six weeks of life.
- I. The registered direct-entry midwife shall perform pelvimetry by 36 weeks gestation.

RULE 6 - MINIMUM PRACTICE REQUIREMENTS REGARDING SAFE INTRAPARTUM CARE

The purpose of this rule is to define and clarify minimum practice requirements of safe care for women and infants regarding intrapartum care pursuant to Section 12-37-105, C.R.S., which include but are not limited to:

A. The direct-entry midwife is responsible for making arrangements to be with the client by the time active labor has been established as determined by contractions occurring every 5 minutes and lasting for 60

- seconds or cervical dilation of 56 cm or more. Once labor has been so established, the direct-entry midwife shall remain with the client.
- B. When membranes rupture, the direct-entry midwife shall perform a sterile vaginal exam for prolapsed cord if the presenting part is not engaged and record fetal heart tones. In the case of pre-mature rupture of the membranes, no further vaginal checks shall be made until active labor.
- C. Aseptic technique and universal precautions shall be used while rendering care.
- D. The direct-entry midwife is responsible for monitoring the status of the client and fetus during labor and delivery including but not limited to:
 - 1. Mmaternal vital signs and physical well being such as:
 - (a) Mmeasurement of maternal temperature, pulse, and respirations, and blood pressure at least every 4 hours; and
 - (b) measurement of maternal blood pressure at least every four hours in early labor and hourly during the active phase of labor, and
 - (eb) Cehecking for bladder distention, signs of maternal fatigue, and hydration status;
 - 2. <u>Ee</u>valuating fetal vital signs and well being such as:
 - (a) <u>F</u>fetal heart tones in response to contractions as well as when the uterus is at rest. These tones shall be assessed, at a minimum, every hour during early labor, every half hour during active labor, and every 5-10 minutes during the second stage of labor, and
 - (b) Naormality of fetal lie, presentation, attitude and position;
 - 3. Perogress of labor including cervical effacement and dilation, station, presenting part and position;
 - 4. Ceoaching the birthing family:
 - 5. obtaining a cord blood specimen, if feasible, which shall accompany the infant in case of transport;
 - <u>65</u>. <u>Cehecking the placenta and blood vessels and estimating blood loss;</u>
 - 76. Cehecking the perineum and vaginal vault for tears; and
 - **87**. Cehecking the cervix for tears and, if present, making appropriate referral.
- E. The direct-entry midwife shall arrange for immediate consultation and transport according to the emergency plan if the following conditions exist:
 - 1. <u>B</u>eleeding other than capillary bleeding ("show") prior to delivery;

- 2. Seigns of placental abruption including continuous lower abdominal pain and tenderness;
- 3. Pprolapse of the cord;
- 4. <u>Aany meconium staining without reassuring fetal heart tones, moderate or greater meconium staining regardless of status of fetal heart tones;</u>
- 5. significant change in maternal vital signs such as;
 - (a) <u>T</u>temperature greater than 101°F,
 - (b) Ppulse over 100 with decrease in blood pressure, or
 - (c) <u>lincrease in blood pressure greater than 140/90 or an increase of 30 mm Hg systolic or 15 mm Hg diastolic;</u>
- 6. <u>F</u>failure to progress in labor such as:
 - (a) Lack of steady progress in dilation and descent after 24 hours in the primipara or 18 hours in the multipara,
 - (b) <u>Second</u> stage of labor without steady progress of descent through the mid-pelvis and/or pelvic outlet longer than <u>two-three</u> hours in the primipara or <u>one hour two hours</u> in the multipara, or
 - (c) <u>T</u>third stage of labor longer than one hour;
- 7. Ffetal heart rate below 120110 or above 160 between contractions;
- 8. Perotein or glucose in the urine;
- 9. Seeizures;
- 10. Aatonic uterus;
- 11. Rretained placental fragments; or
- 12. vaginal or cervical lacerations requiring repair; or
- 4312. Celient requests transport.

RULE 7 – MINIMUM PRACTICE REQUIREMENTS REGARDING POSTPARTUM CARE

The purpose of this rule is to define and clarify minimum practice requirements of safe care for women and infants regarding postpartum care pursuant to Sections 12-37-105 and 12-37-105.5, C.R.S., which include but are not limited to:

- A. The direct-entry midwife who is authorized to administer medications may administer Oxytocin (Pitocin) in accordance with Rule 17.
- B. The direct-entry midwife shall remain with the client and infant for a minimum of two (2) hours after the birth or until the client and infant are stable, whichever is longer.
- C. At a minimum, the direct-entry midwife shall make follow up visits to assess the progress of the client and infant within 24 to 48 hours postpartum, 3 to 7 days postpartum, 2-4 weeks postpartum and 6 weeks postpartum. If the client is seen by an appropriate health care provider at any of these intervals, the direct-entry midwife need not visit the client for that particular interval. Such visits shall include, but not be limited to, an assessment of the fundus, lochia, perineum, breasts, nutrition, hydration, elimination, emotional adjustment and bonding.
- D. The direct-entry midwife shall instruct the client and family in self care at each follow up visit.
- E. The direct-entry midwife who is authorized to administer medications may administer Rh(D) Immune Globulin to Rh negative mothers in accordance with Rule 17. Otherwise, the direct-entry midwife shall refer all Rh negative mothers for Rhogam within seventy two (72) hours of the birth if the baby is RH positive.
- F. The direct-entry midwife shall arrange for consultation and/or transport when:
 - 1. There is maternal blood loss of more than 500 cc <u>unless bleeding is controlled and all maternal vital signs are stable</u>;
 - 2. The client has a fever of greater than 101°F on any of the 2nd-through 10th-days postpartum;
 - 3. The client cannot void within 6 hours after birth:
 - 4. The lochia is excessive, foul smelling, or otherwise abnormal; or
 - 5. The client exhibits signs of clinically significant depression (not the "baby blues")-;
 - 6. There are vaginal or cervical lacerations requiring repair (unless otherwise addressed in Rule 20); or
 - 7. Persistent blood pressure greater than 140/90.

RULE 8 - MINIMUM PRACTICE REQUIREMENTS REGARDING NEWBORN CARE

The purpose of this rule is to define and clarify minimum practice requirements of safe care for women and infants regarding newborn care pursuant to Sections 12-37-105.5 and 12-37-106 C.R.S.

A. The direct-entry midwife will perform care for the infant including but not limited to:

- Apgar scores at one minute and five minutes after birth and at 10 minutes if the 5 minute score is below 7:
- 2. Aa physical assessment including assessing presence of femoral pulses;
- 3. Eeye prophylaxis within 1 hour after birth as provided by Section 25-4-303, C.R.S.;
- 4. Wweigh the infant, measure height and head circumference, and check for normal reflexes;
- 5. perform a gestational age assessment;
- <u>Aarrange</u> to or obtain laboratory testing on the infant of an Rh negative mother to include blood type and Coombs test; and
- 76. <u>Eensure first latch and encourage first feeding prior to departure sucking and rooting reflexes are present and ensure baby is fed.</u>
- B. The direct-entry midwife shall arrange for or obtain the required newborn screenings required by Section 25-4-1004, C.R.S.
- C. The direct-entry midwife authorized to administer medications may administer Vitamin K in accordance with Rule 17. Otherwise, the direct-entry midwife shall recommend that the mother arrange for the administration of Vitamin K by a licensed health care provider birth within seventy two (72) hours.
- D. The direct-entry midwife shall arrange for immediate transport for the infant who exhibits the following signs:
 - 1. Apgar of 7 or less at ten minutes after birth;
 - 2. Respiratory distress exhibited by respirations greater than 60 per minute, grunting, retractions, nasal flaring at one hour of age that is not showing consistent improvement;
 - 3. **li**nability to maintain body temperature;
 - 4. Mmedically significant anomaly;
 - 5. Seizures;
 - Efontanel full and bulging;
 - 7. Ssuspected birth injuries;
 - 8. Ceardiac irregularities and ardiac irregularities projectile or bilious vomiting;
 - 9. Ppale, cyanotic, gray newborn; or
 - 10. Llethargy or poor muscle tone.

- E. The direct-entry midwife shall arrange for consultation and <u>possible</u> transport for an infant who exhibits the following:
 - Ssigns of hypoglycemia including jitteriness;
 - 2. Aabnormal cry;
 - Ppasses no urine in 12 hours or meconium in 24 hours;
 - 4. projectile vomiting Tthe baby's gestational age appears to be less than 37 completed weeks;
 - 5. <u>linability to suck;</u>
 - 6. Ppulse greater than 180 or less than 80 at rest;
 - 7. Jiaundice within 24 hours of birth; or
 - 8. Ppositive Coombs test.
- F. At a minimum, the direct-entry midwife shall make a referral to an appropriate pediatric healthcare provider within 7 days of birth; and shall perform follow up visits to assess the progress of the client and infant within 24 to 48 hours postpartum, 3 to 7 days postpartum, 2-4 weeks postpartum and 6 weeks postpartum. If the client and infant are seen by an appropriate pediatric healthcare provider at any of these intervals, the midwife need not see the client and infant for that particular interval. Follow-up visits shall include assessment of the infant to include umbilical cord, temperature, pulse, respirations, weight, skin color and hydration status, feeding and elimination, sleep/wake patterns, and bonding.

RULE 9 – MINIMUM PRACTICE REQUIREMENTS REGARDING RECORD KEEPING

The purpose of this rule is to clarify the minimally appropriate records of direct-entry midwifery related activity that are required pursuant to Sections 12-37-105(5)(a) and 25-4-201, C.R.S.

- A. The direct-entry midwife shall keep appropriate records on all clients. All records shall, at a minimum:
 - 1. <u>Bbe</u> accurate, current, and comprehensive, giving information concerning the condition and care of the client and associated observations;
 - 2. Perovide a record of any problems that arise and the actions taken in response to them;
 - 3. Perovide evidence of care required, interventions by professional practitioners and client responses;
 - 4. Linclude a record of any factors (physical, psychological or social) that appear to affect the client:
 - 5. Record the chronology of events and the reasons behind decisions made;

- 6. Perovide baseline data against which improvement or deterioration may be judged;
- 7. Reflect any recommendation for, or initiation of, transfer to a hospital;
- 8. Heave a signature and date for each entry; and
- 9. Aall records shall be made available to the receiving health care provider in the event of transfer of care or the transport of client or newborn.
- B. The client records shall include, at a minimum:
 - 1. <u>T</u>the risk assessment as required in Section 12-37-105(11), C.R.S.;
 - 2. Mmandatory disclosure form;
 - 3. <u>linformed consent form and emergency plan</u>;
 - 4. Aassessments, interventions and recommendations for each prenatal visit;
 - 5. Perogress of labor and maternal assessments during labor;
 - Ffetal assessments during labor;
 - AApgar scores and newborn examination;
 - 8. Aadministration of any medications and/or intravenous fluids;
 - 9. Rrefusal of care by the client;
 - 10. Ffiling the birth certificate as required by Section 25-2-112, C.R.S.;
 - 11. Ffollow-up postpartum visits;
 - 12. <u>setatement of verification that one copy of the record was provided to the client or the health care provider of her choice;</u>
 - 13. <u>b</u>baseline blood pressure determined prior to the end of the second trimester or upon the initial visit if such visit occurs subsequent to the second trimester; and
 - 14. <u>Delocumentation of laboratory referral for syphilis</u>, HIV, and Group B Streptococci testing, or documentation of the client's refusal for such tests.
- C. A copy of the record shall be provided to the client and/or other health care provider(s) at the completion of care or when requested.

RULE 11 - DECLARATORY ORDERS

The purpose of this rule is to establish procedures for the handling of requests for declaratory orders filed pursuant to the Colorado Administrative Procedures Act at Section 24-4-105(11), C.R.S.

- A. Any person registered pursuant to Article 37, Title 12, C.R.S., may petition the Director of Registrations ("Director") for a declaratory order to terminate controversies or remove uncertainties as to the applicability of any statutory provision or of any rule or order of the Director.
- B. The Director will determine, in the Director will determine, in the Director will determine, in the Director will not to rule upon such a petition, the Director shall promptly notify the petitioner of his/her action and state the reasons for such decision.
- C. In determining whether to rule upon a petition filed pursuant to this rule, the Director will consider the following matters, among others:
 - 1. Whether a ruling on the petition will terminate a controversy or remove uncertainties as to the applicability to petitioner of any statutory provisions or rule or order of the Director.
 - Whether the petition involves any subject, question or issue that is the subject of a formal or informal matter or investigation currently pending before the Director or a court involving one or more petitioners.
 - 3. Whether the petition involves any subject, question or issue which is the subject of a formal or informal matter or investigation currently pending before the Director or a court but not involving any petitioner.
 - 4. Whether the petition seeks a ruling on a moot or hypothetical question or will result in an advisory ruling or opinion.
 - 5. Whether the petitioner has some other adequate legal remedy, other than an action for declaratory relief pursuant to Colorado Rule of Civil Procedure 57, that will terminate the controversy or remove any uncertainty as to the applicability to the petitioner of the statute, rule, or order in question.
- D. Any petition filed pursuant to this rule shall set forth the following:
 - 1. The name and address of the petitioner and whether the petitioner is registered pursuant to Article 37, Title 12, C.R.S.
 - 2. The statute, rule, or order to which the petition relates.
 - 3. A concise statement of all of the facts necessary to show the nature of the controversy or uncertainty and the manner in which the statute, rule, or order in question applies or potentially applies to the petitioner.
- E. If the Director <u>decides determines tothat s/he will</u> rule on the petition, the following procedures shall apply:

- 1. The Director may rule upon the petition based solely upon the facts presented in the petition. In such a case:
 - a. Any ruling of the Director will apply only to the extent of the facts presented in the petition and any amendment to the petition.
 - b. The Director may order the petitioner to file a written brief, memorandum, or statement of position.
 - c. The Director may set the petition, upon due notice to petitioner, for a non-evidentiary hearing.
 - d. The Director may dispose of the petition on the sole basis of the matters set forth in the petition.
 - e. The Director may request the petitioner to submit additional facts in writing. In such event, such additional facts will be considered as an amendment to the petition.
 - f. The Director may take administrative notice of facts pursuant to the Colorado Administrative Procedures Act at Section 24-4-105(8), C.R.S., and may utilize the Director's his/her experience, technical competence, and specialized knowledge in ruling uponthe disposition of the petition.
- 2. If the Director rules upon the petition without a hearing, the Directors/he shall promptly notify the petitioner of thehis/her decision.
- 3. The Director may, at the Director'shis/her discretion, set the petition for hearing, upon due notice to petitioner, for the purpose of obtaining additional facts or information or to determine the truth of any facts set forth in the petition or to hear oral argument on the petition. The hearing notice to the petitioner shall set forth, to the extent known, the factual or other matters that the Director intends to inquire. For the purpose of such a hearing, to the extent necessary, the petitioner shall have the burden of proving all of the facts stated in the petition, all of the facts necessary to show the nature of the controversy or uncertainty and the manner in which the statute, rule or order in question applies or potentially applies to the petitioner and any other facts the petitioner desires the Director to consider.
- F. The parties to any proceeding pursuant to this rule shall be the Director and the petitioner. Any other person may seek leave of the Director to intervene in such a proceeding, and leave to intervene will be granted at the sole discretion of the Director. A petition to intervene shall set forth the same matters as are required by Paragraph D of this rule. Any reference to a "petitioner" in this rule also refers to any person who has been granted leave to intervene by the Director.
- G. Any declaratory order or other order disposing of a petition pursuant to this rule shall constitute agency action subject to judicial review pursuant to Section 24-4-106, C.R.S.

RULE 17 – ADMINISTRATION OF MEDICATIONS

The purpose of this rule is to clarify the limited administration of medications by a direct-entry midwife as authorized by Sections 12-37-105.5(1) through (5), C.R.S.

- A. A direct-entry midwife may obtain and administer medications only as set forth in this rule. A direct-entry midwife shall obtain authorized medications only from a Colorado-registered prescription drug outlet, manufacturer, or wholesaler.
- B. A direct-entry midwife must receive prior approval from the Director to obtain and administer medications. A direct-entry midwife who seeks such approval must submit a Medication Authority application in a manner approved by the Director-of the Division of Registrations-and pay the applicable fee.
 - 1. A direct-entry midwife applying for medication authority must have satisfactorily completed a course in pharmacology, within six months prior to submitting an application, that:
 - is offered by a post-secondary educational institution accredited by an accrediting board recognized by the Council for Higher Education Accreditation of the American Council on Education, is a program or course approved by the Midwifery Education and Accreditation Council ("MEAC"), or is a program or course otherwise approved by the Director;
 - (b) is, at a minimum, eight clock hours in length and includes basic pharmacotherapeutic principles and administration of medications, including the drugs listed in paragraph (C) of this Rule; and
 - (c) includes the following elements:
 - i. Mechanism of Pharmacological Action;
 - ii. Indications;
 - iii. Therapeutic Effects;
 - iv. Side Effects/Adverse Reactions;
 - v. Contraindications;
 - vi. Incompatibilities/Drug Interactions;
 - vii. Drug administration, including:
 - Dosage;
 - Dosage Form and Packaging;
 - 3. Routes of Administration;

- 4. Onset of Action;
- 5. Peak Effect; and
- 6. Duration of Action;
- viii. Administration of medications through injection, which includes:
 - 1. Universal precautions including the use and disposal of sharps;
 - 2. Safe injection practices;
 - 3. Equipment, including:
 - a. Needles;
 - b. Filter Needles (for use with glass ampules);
 - c. Syringes;
 - d. Skin surface disinfectants; and
 - e. Medication containers (ampules, single-use vials);
- ix. Appropriate injection sites;
- x. Procedures for drawing up and administering drugs;
- xi. Proper disposal of hazardous and other contaminated materials; and
- xii. Student demonstration of competence in administering medications.
- 2. An applicant who does not meet the requirements of subparagraph (1) above may request to demonstrate competency to obtain and administer medications by other means. The Director shall consider such a request on a case-specific basis. The decision to approve such a request shall be at the sole discretion of the Director. In considering whether to approve such a request, the Director shall consider public safety and such other factors as the Director deems appropriate. If the Director grants approval under this subparagraph (2) to obtain and administer medications, the Director may subject such approval to lawful conditions the Director finds necessary to protect the public.
- C. The preferred drug list of medications a direct-entry midwife may obtain and administer consists of:
 - 1. Vitamin K_1 (phylloquinone, phytonadione) to a newborn, as prophylaxis for vitamin K deficiency bleeding. One 1 mg dose of 2 mg / ml concentration vitamin K_1 is authorized via intramuscular injection.

- 2. Rho D immune globulin to Rh-negative, antibody negative mothers, for the prevention of isoimmunization in Rh (D) negative women. One 300 mcg dose (or as recommended by the manufacturer) at 26 28 weeks gestation is authorized via intramuscular injection. In addition, one 300 mcg dose (or as recommended by the manufacturer) administered via intramuscular injection to the mother is authorized within 72 hours of delivery of an Rh-positive infant (or an infant with unknown blood type) to an Rh-negative, antibody negative mother.
- 3. Antihemorrhagic drugs for control of postpartum bleeding, limited to the following:
 - a. Oxytocin (Pitocin) at 10 units/ml administered intramuscularly for postpartum hemorrhage or, following delivery of the newborn, to prevent postpartum hemorrhage. One or two doses of 10 units/ml in a 1 ml vial may be administered via intramuscular injection. If a second dose is administered, for any reason, transport must be initiated in accordance with the emergency plan.
 - b. Methylergonovine (Methergine) at 0.2 mg/ml administered intramuscularly for postpartum hemorrhage (only), one 0.2 mg per 1 ml dose ampule administered via intramuscular injection. If Methylergonovine (Methergine) is administered, transport must be initiated in accordance with the emergency plan.
 - c. Misoprostol (Cytotec) at 800 mcg administered rectally or 400 to 600 mcg administered sublingually for postpartum hemorrhage (only), in an 800 mcg dose (four 200 mcg tabs) administered rectally or a 400-600 mcg dose (two or three 200 mcg tabs) administered sublingually. If Misoprostol (Cytotec) is administered, transport must be initiated in accordance with the emergency plan.
 - D. Postpartum hemorrhage may be prevented by the administration of one dose of oxytocin following the birth of a baby and before the delivery of the placenta. If bleeding remains normal and maternal signs are stable, immediate transport is not necessary.
 - E. If a preventative dose of oxytocin has not been given, postpartum hemorrhage may be controlled by administering one dose of oxytocin followed by, if necessary, a second dose of oxytocin or one dose of misoprostol or one dose of methylergonovine.

 Immediate transport must be initiated if bleeding is not controlled or if the mother displays signs and symptoms of shock.
 - F. If a preventative dose of oxytocin has been given, postpartum hemorrhage may be controlled by administering one additional dose of oxytocin, or one dose of misoprostol or one dose of one dose of methylergonovine. Immediate transport must be initiated if bleeding is not controlled or if the mother displays signs and symptoms of shock.
- 4. Erythromycin Ophthalmic Ointment to a newborn, for prophylaxis of neonatal ophthalmia, as provided by Section 25-4-303, C.R.S. A single topical dose of Erythromycin Ophthalmic Ointment USP (0.5%) is to be administered within one (1) hour after birth via topical application of a ribbon of ointment approximately 1 cm in length into each eye.
- 5. Local anesthetics to perform sutures of first-degree and second-degree perineal tears and limited to lidocaine 1% or 2% for injection with or without epinephrine.

- D. Client refusals of medication or treatment.
 - 1. Informed consent. If a client refuses the administration of either Vitamin K₁ to her infant or Rho D immune globulin to herself, the direct-entry midwife shall provide the client with an informed consent form containing a detailed statement of the benefits of the medication and the risks of refusal, and shall retain a copy of the form acknowledged and signed by the client.
 - 2. Transport. If a client experiences uncontrollable postpartum hemorrhage, the direct-entry midwife shall immediately initiate the transportation of the client in accordance with the emergency plan.
 - 3. Eye prophylaxis. If a client refuses the administration of eye prophylaxis to her infant, the direct-entry midwife shall:
 - (a) Perovide the client with a form setting forth the requirements of Section 25-4-303, C.R.S.: and
 - (b) Rretain a copy of the form acknowledged and signed by the client.
- E. Medication administration procedures must meet safe and professional standards and must be performed in a manner consistent with generally accepted parameters, including safe injection practices and the standards of the Centers for Disease Control and Prevention ("CDC").
- F. In order to best serve the needs and ensure the safety of their clients, direct-entry midwives who obtain and administer medications shall maintain competency regarding their use through continuing education and other professional development activities.
- G. A direct-entry midwife must be able to supply written documentation, upon request by the Director, which substantiates appropriate training as required by this rule. Failure to provide written documentation is a violation of this rule, and is prima facie evidence that the direct-entry midwife is not competent and not permitted to obtain or administer medications.

RULE 18 – ADMINISTRATION OF INTRAVENOUS FLUIDS

The purpose of this rule is to clarify the administration of intravenous fluids by a direct-entry midwife to a client in order to restore fluid volume lost due to <u>dehydration</u>, <u>fatigue</u>, <u>or</u> postpartum hemorrhage, as authorized by Section 12-37-105.5(1), (4)(b), and (5), C.R.S.

- A. A direct-entry midwife may obtain and administer intravenous ("IV") fluids only as set forth in this rule. A direct-entry midwife shall obtain authorized IV fluids only from a Colorado-registered prescription drug outlet, manufacturer, or wholesaler.
- B. A direct-entry midwife must receive prior approval from the Director to obtain IV fluids and administer IV therapy. A direct-entry midwife who seeks such approval must:
 - Submit an IV Authority application in a manner approved by the Director of the Division of Registrations and pay the applicable fee; and

- 2. <u>S</u>eatisfactorily complete an intravenous therapy course, within six months prior to submitting an application, that:
 - (a) <u>l</u>is offered by a post-secondary educational institution accredited by an accrediting board recognized by the Council for Higher Education Accreditation of the American Council on Education, is a program or course approved by the <u>Midwifery Education and Accreditation Council ("MEAC")</u>, or is a program or course otherwise approved by the Director;
 - (b) Lis at least at least six clock hours in length and includes basic principles of the administration of medications intravenously, including the IV fluids listed in paragraph (C) of this Rule; and
 - (c) lincludes the following elements:
 - Basic principles of intravenous therapy, including when to initiate and when to discontinue IV therapy;
 - ii. Purpose of IV fluid therapy;
 - iii. Safe infusion and infection control practices;
 - iv. Equipment;
 - v. Appropriate sites;
 - vi. Procedure and technique;
 - vii. Rate of administration;
 - viii. Care of equipment;
 - ix. Proper disposal of hazardous and other contaminated materials; and
 - x. Student demonstration of competence in the ability to administer IV fluids.
- 3. A direct-entry midwife who does not meet the requirements of subparagraph (2) above may request to demonstrate completion of an equivalent IV course or program to obtain and administer IV fluids. The Director shall consider such a request on a case-specific basis. The decision to approve such a request shall be at the sole discretion of the Director. In considering whether to approve such a request, the Director shall consider public safety and such other factors as the Director deems appropriate. If the Director grants approval under this subparagraph (3) to obtain and administer IV fluids, the Director may subject such approval to lawful conditions the Director finds necessary to protect the public.
- C. The preferred drug list of IV fluids a direct-entry midwife may obtain and administer to restore fluid volume lost due to dehydration, fatigue, or postpartum hemorrhage consists of:

- 1. 0.9% sodium chloride in sterile water (Normal saline)
- 2. Lactated Ringer's solution (LR)
- D. A direct-entry midwife may administer IV fluids only to restore fluid volume lost due to postpartum hemorrhage. If IV therapy is initiated, transport must be initiated in accordance with the emergency plan.—A direct-entry midwife may administer IV fluids only to restore fluid volume lost due to dehydration, fatigue or postpartum hemorrhage. If therapy is initiated, transport must be initiated if vital signs demonstrate sustained instability, blood loss is not controlled and/or the client is not responding to therapy.
- E. IV therapy procedures must meet safe and professional standards and must be performed in a manner consistent with generally accepted parameters, including safe infusion and infection control practices consistent with the standards of the Centers for Disease Control and Prevention ("CDC").
- F. In order to best serve the needs and ensure the safety of their clients, direct-entry midwives who obtain and administer IV fluids shall maintain competency regarding their use through continuing education and other professional development activities.
- G. A direct-entry midwife must be able to supply written documentation, upon request by the Director, which substantiates appropriate training as required by this rule. Failure to provide written documentation is a violation of this rule, and is prima facie evidence that the direct-entry midwife is not competent and not permitted to obtain or administer IV fluids.

RULE 20 - SUTURING

The purpose of this rule is to define perineal tear and various degrees of perineal tears, and to specify the limitations and requirements in order to perform the suturing of first-degree and second-degree perineal tears.

- A. "Perineal tear" means a laceration of the skin and other soft tissue structures which, in women, separate the vagina from the anus.
- B. "First-degree perineal tear" means a laceration limited to the fourchette and superficial perineal skin or vaginal mucosa.
- C. "Second-degree perineal tear" means a laceration extending beyond fourchette, perineal skin and vaginal mucosa to perineal muscles and fascia, but not the anal sphincter.
- <u>D.</u> "Third-degree perineal tear" means the tearing of the fourchette, perineal skin, vaginal mucosa, muscles and anal sphincter.
- E. "Fourth-degree perineal tear" means the tearing of the forchette, perineal skin, vaginal mucosa, muscles, anal sphincter and rectal mucosa.
- F. A direct-entry midwife may perform the suturing of first-degree and second-degree perineal tears if the following conditions are met:

- A direct-entry midwife shall apply to the Director, on a form and manner required by the
 Director, and pay any application fee the Director may impose, for an authorization to perform sutures of first-degree and second-degree perineal tears;
- 2. A direct-entry midwife shall attend and successfully complete an eight (8) hour live class or workshop, accredited by the Midwifery Education Accreditation Counsel (MEAC), which instructs attendees regarding the: identification of muscles and anatomy of the vagina and perineum including the affected nerves; the selection of appropriate instruments; the suture material and needles types required for suturing; and appropriate techniques for basic repair. This instruction shall include identification of third and fourth-degree perineal tears and the proper referral of such tears; and
- 3. A direct-entry midwife shall provide proof of the MEAC-accredited training specified in this Rule 20(F)(2) to the Director when applying for an authorization to perform sutures of first-degree and second-degree perineal tears.
- H. A direct-entry midwife shall arrange for consultation and/or transport all third and fourth-degree perineal tears as required pursuant to Rule 7(F)(6).

RULE 21 – DIRECT SUPERVISION OF UNREGISTERED BIRTHING ATTENDANTS

The purpose of this rule is to define the term "direct supervision" and "unregistered birthing attendant", and to specify the application of each with a registered direct-entry midwife.

- A. "Direct supervision" means, for the purpose of rules governing the practice of direct-entry midwifery care, the continuous, direct and physical oversight of an unregistered birthing attendant by a registered direct-entry midwife when performing any act constituting the practice of direct-entry midwifery care.
- B. "Unregistered birthing attendant" means a person who is:
 - 1. Enrolled in a professional degree program as specified in Rule 2;
 - 2. A graduate of a professional degree program as specified in Rule 2 who has not submitted an application to the Division of Professions and Occupations for a direct-entry midwife registration;
 - 3. A direct-entry midwife applicant awaiting a registration; or
 - 4. Not enrolled in or a graduate of a professional degree program as specified in Rule 2 and is assisting a registered direct-entry midwife in the practice of direct-entry midwifery care.
- C. A registered direct-entry midwife shall assure that any unregistered birthing attendant providing assistance to the registered direct-entry midwife is at all times under the direct supervision of a registered direct-entry midwife when performing any act that constitutes the practice of direct-entry midwifery care.

RULE 22 – CONFIDENTIAL AGREEMENTS.

- A. No later than thirty (30) days from the date a physical or mental illness or condition impacts a directentry midwife's ability to practice direct-entry midwifery care with reasonable skill and safety, the directentry midwife shall provide the Director, in writing, the following information:
 - 1. The diagnosis and a description of the illness or condition;
 - 2. The date that the illness or condition was first diagnosed;
 - 3. The name of the current treatment provider and documentation from the current treatment provider confirming the diagnosis, date of onset, and treatment plan;
 - 4. A description of the direct-entry midwife's practice and any modifications, limitations or restrictions to that practice that have been made as a result of the illness or condition; and
 - 5. Whether the direct-entry midwife has been evaluated by, or is currently receiving services from qualified treatment provider related to the illness or condition and, if so, the date of initial contact and whether services are ongoing.
- B. The direct-entry midwife shall further notify the Director of any significant change in the illness or condition ("change of condition") that impacts the direct-entry midwife's ability to practice direct-entry midwifery care with reasonable skill and safety. The direct-entry midwife must notify the Director of a positive or negative change of condition. Such notification shall occur within thirty (30) days of the change of condition. The direct-entry midwife shall provide the Director, in writing, the following information:
 - 1. The date of the change of condition;
 - 2. The name of the current treatment provider and documentation from the current treatment provider confirming the change of condition, the date that the condition changed, the nature of the change of condition, and the current treatment plan; and
 - 3. A description of the licensee's practice and any modifications, limitations or restrictions to that practice that have been made as a result of the change of condition.
- C. Compliance with this rule is a prerequisite for eligibility to enter into a Confidential Agreement with the Director pursuant to Section 12-37-108.5, C.R.S. However, mere compliance with this rule does not require the Director to enter into a Confidential Agreement. Rather, the Director will evaluate all facts and circumstances to determine if a Confidential Agreement is appropriate.
- D. If the Director discovers that a direct-entry midwife has a mental or physical illness or condition that impacts the direct-entry midwife's ability to practice direct-entry midwifery care with reasonable skill and safety and the direct-entry midwife has not timely notified the Director of such illness or condition, the direct-entry midwife shall not be eligible for a Confidential Agreement and may be subject to disciplinary action pursuant to Section 12-37-107(3)(n), C.R.S.
- E. A direct-entry midwife who is addicted to, dependent on, or engages in the habitual or excessive use or abuse of intoxicating liquors, a habit-forming drug, or a controlled substance as defined in Section 18-

