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MEMORANDUM

TO: Committee on Legal Services

FROM: Christy Chase, Office of Legislative Legal Services

DATE: November 8, 2017

SUBJECT: Rules of the Director of the Division of Professions and Occupations, Department of Regulatory Agencies, concerning Colorado midwives registration, 4 CCR 739-1 (LLS Docket No. 170273; SOS Tracking No. 2017-00110).[1]

Summary of Problems Identified and Recommendations

No statute authorizes the Director of the Division of Professions and Occupations to promulgate rules regarding the practice of direct-entry midwifery by an unregistered birthing attendant. However, the Director's Rules 21 and 5B.7. authorize an unregistered birthing attendant to engage in the practice of direct-entry midwifery under the direct supervision of a registered direct-entry midwife. **Because the Director of the Division of Professions and Occupations lacks statutory authority to promulgate Rules 21 and 5B.7., we recommend that Rules 21 and 5B.7. of the Director of the Division of Professions and Occupations concerning the practice of direct-entry midwifery by an unregistered birthing attendant not be extended.**

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[1] Under § 24-4-103, C.R.S., the Office of Legislative Legal Services reviews rules to determine whether they are within the promulgating agency's rule-making authority. Under § 24-4-103 (8)(c)(I), C.R.S., the rules discussed in this memorandum will expire on May 15, 2018, unless the General Assembly acts by bill to postpone such expiration.

Section 12-37-106 (1)(a), C.R.S., authorizes the Director to promulgate rules "necessary to carry out the provisions of . . ." the direct-entry midwife practice act. The Director adopted Rule 8, which sets forth the minimum practice requirements regarding newborn care. However, Rule 8 failed to include the requirement in section 12-37-105 (9)(b), C.R.S., that a direct-entry midwife perform or refer a newborn for screening for congenital heart defects. **Because the Director failed to promulgate rules addressing the requirement that a direct-entry midwife perform or refer a newborn for screening for congenital heart defects, we recommend that Rule 8 of the rules of the Director of the Division of Professions and Occupations concerning minimum practice requirements regarding newborn care not be extended.**

Analysis

1. The Director lacks statutory authority to adopt a rule allowing an unregistered birthing attendant to practice direct-entry midwifery.

Article 37 of title 12, C.R.S., governs the practice of direct-entry midwifery in Colorado, which practice is defined as "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 [37 of title 12]."[2] Pursuant to section 12-37-103, C.R.S., "[e]very direct-entry midwife[3] shall register with the division of professions and occupations . . . ." Section 12-37-108, C.R.S., which addresses the unauthorized practice of direct-entry midwifery, specifies that "[a]ny person who practices or offers or attempts to practice direct-entry midwifery without an active registration issued under this article commits a class 2 misdemeanor . . . ." With only a few narrow exemptions, the direct-entry midwife practice act does not contain any exceptions to the requirement that a person practicing direct-entry midwifery must obtain a registration from the Division of Professions and Occupations.[4]

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[2] § 12-37-102 (3), C.R.S.

[3] § 12-37-102 (2), C.R.S., defines a "direct-entry midwife" as "a person who practices direct-entry midwifery."

[4] § 12-37-101 (1), C.R.S., exempts from the practice act persons who are "otherwise licensed by the state of Colorado under this title [12] if the practice of midwifery is within the scope of such licensure". Additionally, gratuitous rendering of services in an emergency and the rendering of services by a licensed physician, certified nurse-midwife, or other person licensed to practice a field of the healing arts are exempted from registration under § 12-37-101 (2), C.R.S. Otherwise, the unregistered practice of midwifery is prohibited.

The Director is authorized under section 12-37-106 (1)(a) "[t]o adopt such rules as are necessary to carry out the provisions of this article [37 of title 12]." Under this general authority, the Director adopted Rule 21, which provides:

> **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**. (**Emphasis added**)

Rule 21 clearly allows a person who is not registered to perform an "act that constitutes the practice of direct-entry midwifery care" if under the direct supervision of a registered direct-entry midwife. There is no authority in article 37 of title 12, C.R.S., for the Director to adopt Rule 21, and in fact, the unregistered practice of direct-entry midwifery is prohibited under sections 12-37-103 (1) and 12-37-108, C.R.S. Accordingly, the Director lacks statutory authority to adopt Rule 21.

Additionally, Rule 5B.7. refers to an "unregistered birth attendant" in the context of disclosing to a client the name and duties of any person who will be assisting with the birth and provides:

> **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:
>
> *****
>
> B. At the time of the initial visit, the direct-entry midwife shall at a minimum:
>
> *****
>
> 7. Provide 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) A complete list of the names 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) A 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) All 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. (**Emphases added**)

Rule 5B.7. contemplates that an unregistered birthing attendant would assist in the care of a client.

As noted earlier, the practice of direct-entry midwifery includes "assisting of a woman during pregnancy, labor and natural childbirth at home . . . ." Thus, Rule 5B.7. purports to authorize an unregistered birth attendant, by authorizing the listing of an unregistered birthing attendant on disclosures regarding persons who will assist with the birth, to engage in the practice of direct-entry midwifery without a registration. As noted regarding Rule 21, the Director lacks statutory authority to adopt a rule to permit the unregistered practice of direct-entry midwifery, and a rule permitting unregistered practice contradicts the requirements of sections 12-37-103 (1) and 12-37-108, C.R.S.

It is important to note that there appears to be an error in the practice act that the Director may have been attempting to address by adopting Rules 21 and 5 B. 7. Section 12-37-103 (5), C.R.S., sets forth the qualifications an applicant for a direct-entry

midwife must satisfy in order to obtain a registration. Among the qualifications, an applicant must have:

> (d) Acquired practical experience including, at a minimum, experience with the conduct of at least one hundred prenatal examinations on no fewer than thirty different women and observation of at least thirty births;
>
> (e) Participated as a birth attendant, including rendering care from the prenatal period through the postpartum period, in connection with at least thirty births;[5]

It appears that to qualify for a direct-entry midwife registration, an applicant must actually engage in activities that constitute the practice of direct-entry midwifery.[6] However, under the practice act, a person who is not registered cannot engage in the practice and can actually be prosecuted for doing so.[7]

Most practice acts governing the practice of a health care profession provide an exception for a student enrolled in the required education program or a person obtaining experience required for licensure, certification, or registration, thus permitting the student or person to engage in the practice of the profession without first obtaining a license, certification, or registration.[8] The direct-entry midwife practice

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[5] § 12-37-103 (5)(d) and (5)(e), C.R.S.

[6] See § 12-37-102 (3), C.R.S.

[7] See §§ 12-37-103 (1) and 12-37-108, C.R.S.

[8] See, for example, §12-29.5-105 (2), C.R.S. (exception for persons training under supervision as an acupuncturist); §12-29.7-109 (1)(a), C.R.S. (exception for students enrolled in accredited athletic training educational program); §12-29.9-102 (1)(c), C.R.S. (exception for student enrolled in audiology educational program); §12-33-118, C.R.S. (exception for bona fide chiropractic students or interns); §12-35-115 (1)(e), C.R.S. (exception for students in dental hygiene or dentistry educational program); §12-35.5-110 (1)(a), C.R.S. (exception for students enrolled in massage therapy program); §12-36-106 (3)(k), C.R.S. (exception for students enrolled in approved medical school); §12-37.3-105 (4)(g), C.R.S. (exception for students enrolled in approved naturopathic medical college); §12-38-125 (1)(f), C.R.S. (exception for nursing students); §12-38.1-117 (1)(d), C.R.S. (exception for nurse aides obtaining on-the-job training required for certification); §12-40-105 (1)(d), C.R.S. (exception for persons in post-doctoral optometry residency and for optometry students); §12-40.5-108 (1)(b) and (1)(c), C.R.S. (exception for occupational therapy students and for persons completing required supervised fieldwork experience, respectively); §12-41-114 (1)(a), C.R.S. (exception for physical therapy and physical therapy assistant students); §12-41.5-110 (2)(a), C.R.S. (exception for respiratory therapy students); §12-42-116 (2), C.R.S. (exception for psychiatric technician students); §§12-43-305 (7), 12-43-504 (5), and 12-43-603 (5), C.R.S. (exceptions for candidates acquiring supervised experience required for licensure as a psychologist, marriage and family therapist, or licensed professional counselor, respectively); §12-43.2-103 (1)(b), C.R.S. (surgical assistant and surgical technologist students); and §12-43.7-108 (1)(c) and (1)(d), C.R.S. (exception for speech-language pathology students and persons participating in a clinical fellowship required for certification).

act, however, does not contain a similar exception, thereby making it nearly impossible for an applicant for registration to satisfy the experience requirements needed for registration without engaging in the unregistered, and thus unauthorized, practice of direct-entry midwifery in violation of sections 12-37-103 (1) and 12-37-108, C.R.S. Regardless of this catch-22 in the statute, the Director lacks the statutory authority to fix this problem by adopting a rule that allows a person to engage in the unregistered practice of direct-entry midwifery.

Because the Director lacks the statutory authority to adopt rules permitting the unregistered practice of direct-entry midwifery, Rules 21 and 5 B. 7. should not be extended.

2. The Director failed to include a requirement to screen newborns, or refer newborns for screening, for congenital heart defects in the list of minimum practice requirements regarding newborn care.

The Director is authorized under section 12-37-106 (1)(a) "[t]o adopt such rules as are necessary to carry out the provisions of this article [37 of title 12]." Under this general rulemaking authority, the Director adopted Rule 8, which provides:

> **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:
>
> 1. Apgar scores at one minute and five minutes after birth and at 10 minutes if the 5 minute score is below 7;
>
> 2. A physical assessment including assessing presence of femoral pulses;
>
> 3. Eye prophylaxis within 1 hour after birth as provided by Section 25-4-303, C.R.S.;
>
> 4. Weigh the infant, measure height and head circumference, and check for normal reflexes;
>
> 5. Arrange to or obtain laboratory testing on the infant of an Rh negative mother to include blood type and antibody screen; and
>
> 6. Ensure sucking and rooting reflexes are present and ensure baby is fed.
>
> 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. Inability to maintain body temperature;
4. Medically significant anomaly;
5. Seizures;
6. Fontanel full and bulging;
7. Suspected birth injuries;
8. Cardiac irregularities;
9. Projectile or bilious vomiting;
10. Pale, cyanotic, gray newborn; or
11. Lethargy or poor muscle tone.

E. The direct-entry midwife shall arrange for consultation and possible transport for an infant who exhibits the following:

1. Signs of hypoglycemia including jitteriness;
2. Abnormal cry;
3. Passes no urine or meconium in 24 hours;
4. The baby's gestational age appears to be less than 37 completed weeks;
5. Inability to suck;
6. Pulse greater than 180 or less than 80 at rest;
7. Jaundice within 24 hours of birth; or
8. Positive Antibody Screen.

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 8 appears to include an exhaustive list of the minimum requirements imposed on registered direct-entry midwives regarding the care of newborns, including most of the requirements listed in section 12-37-105, C.R.S. (which is attached as **Addendum A**) For example, the requirement in section 12-37-105 (7), C.R.S., to refer a newborn child for evaluation within seven days after birth to a licensed health care provider with expertise in pediatric care is contained in Rule 8F. Additionally, the requirements under section 12-37-105 (7), C.R.S., to prepare and transmit newborn specimens for newborn screening and section 12-37-105 (9)(a), C.R.S, to provide eye prophylactic therapy to newborns are contained in Rules 8B. and 8A.3., respectively. Rule 8 expands upon the statutory requirements and includes other "minimum practice requirements" that the Director deemed "necessary to carry out the provisions of" the practice act, as authorized under the Director's rulemaking authority in section 12-37-106 (1)(a), C.R.S.

However, Rule 8 fails to include the requirement, enacted by the General Assembly in 2016 and codified in section 12-37-105 (9)(b), C.R.S., that a direct-entry midwife either perform congenital heart defect screening using pulse oximetry or refer the newborn to a health care provider who can perform the screening. Rule 8 sets forth the "minimum" requirements for newborn care yet fails to include a requirement contained in the statutes governing the practice of direct-entry midwifery. Accordingly, Rule 8 should not be extended.

Recommendations

We therefore recommend that the following rules of the Director of the Division of Professions and Occupations not be extended:

1. Rules 21 and 5B.7. concerning the practice of direct-entry midwifery by unregistered birthing attendants, because the Director lacks statutory authority to adopt those rules; and
2. Rule 8 concerning the minimum practice requirements regarding newborn care, because the Director failed to promulgate rules addressing the requirement that a direct-entry midwife perform or refer a newborn for screening for congenital heart defects.

Addendum A

12-37-105. Prohibited acts - practice standards - informed consent - emergency plan - risk assessment - referral - rules. (1) A direct-entry midwife shall not dispense or administer any medication or drugs except in accordance with section 12-37-105.5.

(2) A direct-entry midwife shall not perform any operative or surgical procedure; except that a direct-entry midwife may perform sutures of perineal tears in accordance with section 12-37-105.5.

(3) A direct-entry midwife shall not provide care to a pregnant woman who, according to generally accepted medical standards, exhibits signs or symptoms of increased risk of medical or obstetric or neonatal complications or problems during the completion of her pregnancy, labor, delivery, or the postpartum period. Such conditions include but are not limited to signs or symptoms of diabetes, multiple gestation, hypertensive disorder, or abnormal presentation of the fetus.

(4) A direct-entry midwife shall not provide care to a pregnant woman who, according to generally accepted medical standards, exhibits signs or symptoms of increased risk that her child may develop complications or problems during the first six weeks of life.

(5) (a) A direct-entry midwife shall keep appropriate records of midwifery-related activity, including but not limited to the following:

(I) The direct-entry midwife shall complete and file a birth certificate for every delivery in accordance with section 25-2-112, C.R.S.

(II) The direct-entry midwife shall complete and maintain appropriate client records for every client.

(III) Before accepting a client for care, the direct-entry midwife shall obtain the client's informed consent, which shall be evidenced by a written statement in a form prescribed by the director and signed by both the direct-entry midwife and the client. The form shall certify that full disclosure has been made and acknowledged by the client as to each of the following items, with the client's acknowledgment evidenced by a separate signature or initials adjacent to each item in addition to the client's signature at the end of the form:

(A) The direct-entry midwife's educational background and training;

(B) The nature and scope of the care to be given, including the possibility of and procedure for transport of the client to a hospital and transferral of care prenatally;

(C) A description of the available alternatives to direct-entry midwifery care, including a statement that the client understands she is not retaining a certified nurse midwife or a nurse midwife;

(D) A description of the risks of birth, including those that are different from those of hospital birth and those conditions that may arise during delivery;

(E) A statement indicating whether or not the direct-entry midwife is covered under a policy of liability insurance for the practice of direct-entry midwifery; and

(F) A statement informing the client that, if subsequent care is required resulting from the acts or omissions of the direct-entry midwife, any physician, nurse, prehospital emergency personnel, and health care institution rendering such care shall be held only to a standard of gross negligence or willful and wanton conduct.

(IV) (A) Until the liability insurance required pursuant to section 12-37-109 (3) is available, each direct-entry midwife shall, before accepting a client for care, provide the client with a disclosure statement indicating that the midwife does not have liability insurance. To comply with this section, the direct-entry midwife shall ensure that the disclosure statement is printed in at least twelve-point bold-faced type and shall read the statement to the client in a language the client understands. Each client shall sign the disclosure statement acknowledging that the client understands the effect of its provisions. The direct-entry midwife shall also sign the disclosure statement and provide a copy of the signed disclosure statement to the client.

(B) In addition to the information required in sub-subparagraph (A) of this subparagraph (IV), the direct-entry midwife shall include the following statement in the disclosure statement and shall display the statement prominently and deliver the statement orally to the client before the client signs the disclosure statement: "Signing this disclosure statement does not constitute a waiver of any right (insert client's name) has to seek damages or redress from the undersigned direct-entry midwife for any act of negligence or any injury (insert client's name) may sustain in the course of care administered by the undersigned direct-entry midwife."

(b) As used in this subsection (5), "full disclosure" includes reading the informed consent form to the client, in a language understood by the client, and answering any relevant questions.

(6) A direct-entry midwife shall prepare a plan, in the form and manner required by the director, for emergency situations. The plan must include procedures to be followed in situations in which the time required for transportation to the nearest facility capable of providing appropriate treatment exceeds limits established by the director by rule. A copy of such plan shall be given to each client as part of the informed consent required by subsection (5) of this section.

(7) A direct-entry midwife shall prepare and transmit appropriate specimens for newborn screening in accordance with section 25-4-1004, C.R.S., and shall refer every newborn child for evaluation, within seven days after birth, to a licensed health care provider with expertise in pediatric care.

(8) A direct-entry midwife shall ensure that appropriate laboratory testing, as determined by the director, is completed for each client.

(9) (a) A direct-entry midwife shall provide eye prophylactic therapy to all newborn children in the direct-entry midwife's care in accordance with section 25-4-301, C.R.S.

(b) A direct-entry midwife shall inform the parents of all newborn children in the direct-entry midwife's care of the importance of critical congenital heart defect screening using pulse oximetry in accordance with section 25-4-1004.3, C.R.S. If a

direct-entry midwife is not properly trained in the use of pulse oximetry or does not have the use of or own a pulse oximeter, the direct-entry midwife shall refer the parents to a health care provider who can perform the screening. If a direct-entry midwife is properly trained in the use of pulse oximetry and has the use of or owns a pulse oximeter, the direct-entry midwife shall perform the critical congenital heart defect screening on newborn children in his or her care in accordance with section 25-4-1004.3, C.R.S.

(10) A direct-entry midwife shall be knowledgeable and skilled in aseptic procedures and the use of universal precautions and shall use them with every client.

(11) To assure that proper risk assessment is completed and that clients who are inappropriate for direct-entry midwifery are referred to other health care providers, the director shall establish, by rule, a risk assessment procedure to be followed by a direct-entry midwife for each client and standards for appropriate referral. Such assessment shall be a part of each client's record as required in section 12-37-105 (5)(a)(II).

(12) At the time of renewal of a registration, each registrant shall submit the following data in the form and manner required by the director:

(a) The number of women to whom care was provided since the previous registration;

(b) The number of deliveries performed;

(c) The Apgar scores of delivered infants, in groupings established by the director;

(d) The number of prenatal transfers;

(e) The number of transfers during labor, delivery, and immediately following birth;

(f) Any perinatal deaths, including the cause of death and a description of the circumstances; and

(g) Other morbidity statistics as required by the director.

(13) A registered direct-entry midwife may purchase, possess, carry, and administer oxygen. The department of regulatory agencies shall promulgate rules concerning minimum training requirements for direct-entry midwives with respect to the safe administration of oxygen. Each registrant shall complete the minimum training requirements and submit proof of having completed such requirements to the director before administering oxygen to any client.

(14) A registrant shall not practice beyond the scope of his or her education and training.