COLORADO DEPARTMENT OF REGULATORY AGENCIES
OFFICE OF POLICY AND RESEARCH

COLORADO REGISTRATION OF DIRECT-ENTRY MIDWIVES

1995 SUNSET REVIEW

Joint Legislative Sunrise/Sunset Review Committee
1995-1996 Members

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June 30, 1995

The Honorable Richard Mutzebaugh, Chair
Joint Legislative Sunrise/Sunset Review Committee
State Capitol Building
Denver, Colorado 80203

Dear Senator Mutzebaugh:

The Colorado Department of Regulatory Agencies has completed the evaluation of the **registration of direct-entry midwives**. We are pleased to submit this written report, which will be the basis for my office's oral testimony before the Joint Legislative Sunrise/Sunset Review Committee. The report is submitted pursuant to Section 24-34-104 (8)(a), of the Colorado Revised Statutes, which states in part:

> *"The Department of Regulatory Agencies shall conduct an analysis of the performance of each division, board or agency or each function scheduled for termination under this section...*
>
> *The Department of Regulatory Agencies shall submit a report and such supporting materials as may be requested, to the Sunrise and Sunset Review Committee created by joint rule of the Senate and House of Representatives, no later than July 1 of the year preceding the date established for termination..."*

The report discusses the question of whether there is a need for the regulation provided under article 37 of title 12, C.R.S. The report also discusses the effectiveness of the division and staff in carrying out the intention of the statutes and makes recommendations for statutory and administrative changes in the event this regulatory program is continued by the General Assembly.

Sincerely,

Joseph A. Garcia
Executive Director

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EXECUTIVE SUMMARY

The regulation of direct-entry midwives was created in the State of Colorado under the Department of Regulatory Agencies, Division of Registrations in July, 1993. The practice of direct-entry midwifery is defined as the advising, attending, or assisting of a woman during pregnancy, labor and natural childbirth at home, and during the postpartum period. The program was mandated to prepare or adopt suitable standards for education, training programs, examinations and to promulgate rules to carry out the provisions of the law.

The Department of Regulatory Agencies has conducted the 1995 Sunset Review of the Registration Program of Direct-Entry Midwives and recommends continuation of the program. The Department of Regulatory Agencies finds that the potential for harm to the health and safety of the public requires regulatory oversight. In the two years since the legalization of the practice of direct-entry midwifery, the Division of Registrations has successfully taken action against unregistered midwifery activity. In addition, individuals in midwifery practice can now be held accountable to a standard of care if they practice dangerously.

During the evaluation process, it was determined that certain statutory changes are necessary to allow for improved midwifery practice and improved enforcement of the program. The report makes the following key findings and recommendations.

1. It is recommended that a registry of apprentice midwives be established to identify apprentice midwives in Colorado.

2. Emergency situations will arise even though the best possible care is given to a pregnant woman. This report recommends that the scope of drugs a direct-entry midwife may administer be broadened to include RhoGam, Pitocin, Oxygen and Vitamin K.

3. The existing law prohibits any direct-entry midwife from simultaneously having a license or registration in any other health care provider field. It is unreasonable to have legislation that limits the field of midwifery by excluding some of the people who could provide excellent care. It is recommended that the prohibition regarding dual health licensure be deleted.

4. The standards for educational programs should be revised to allow the Director to prepare or adopt suitable education standards for applicants without the arduous task of complying with the Private Occupational Education Act.

BACKGROUND

Sunset Process

The regulation of direct-entry midwives pursuant to article 37 of title 12, C.R.S. is scheduled to terminate on July 1, 1996 unless continued by the General Assembly. During the year prior to that date, it is the responsibility of the Department of Regulatory Agencies to conduct a sunset review and evaluation of that regulatory program.

During this review, the Director of the Division of Registrations must demonstrate that there is a need for the continued existence of the program and that the regulation it provides is the least restrictive consistent with the public interest. The Department's findings and recommendations are submitted via this report to the Joint Legislative Sunrise and Sunset Committee of the Colorado General Assembly.

The sunset review process included an analysis of the statute and rules, interviews with Department staff, state officials, professional association members, registrants, assistant attorneys general and consumers. Research on related statutes and regulation in other states is also included.

Introduction

The Oxford English Dictionary defines midwife as being "a woman who is with the mother at birth." The International Confederation of Midwives, the International Federal of Gynecologists and Obstetricians, and the World Health Organization (WHO) jointly define a midwife. They wrote:

> ***"A midwife is a person who, having been regularly admitted to a midwifery educational program, duly recognized in the country in which it is located, has successfully completed the prescribed course of studies in midwifery and has acquired the requisite qualifications to be registered and/or legally licensed to practice midwifery. She must be able to give the necessary supervision, care and advice to women during pregnancy, labor and the postpartum period, to conduct deliveries on her own responsibility and to care for the newborn and the infant. This care includes preventive measures, the detection of abnormal conditions in mother and child, the procurement of medical assistance and the execution of emergency measures in the absence of medical help. She has an important task in health counseling and education, not only for the patients but also within the family and the community. She may practice in hospitals, clinics, health units, domiciliary conditions or in any other service."***

Direct entry midwives attend home deliveries, function as independent practitioners, and very rarely use interventive therapies. They do not augment labor through the use of pitocin, a synthetic hormone used by physicians to expedite labor.

Philosophically, direct entry midwives have an essentially different orientation to childbearing than the medical community. According to the midwives, they provide care that supports the woman and her family, is culturally sensitive, and reduces unnecessary interventions and dependence on technology.

Direct-entry midwives provide support and services to pregnant women during pregnancy, delivery and after birth. They have become more popular in recent years because they generally give more attention to each patient than do obstetricians.[1] Midwives' services are usually less expensive than those of an obstetrician, although they usually can treat only "normal" pregnancies; complications in pregnancy requires consultation with an obstetrician. A midwife may also be the only person available for an out-of-hospital birth.

Midwifery began as a respected occupation in the United States. During colonial times, any woman who had given birth and had assisted with the births of her family and friends could be a midwife. Childbirth was viewed as a natural process in which midwives played a central role. They were an important part of community life and held in high esteem. As payment for their services, they received housing, land, food, and salary.

Their status declined as the practices of medicine and nursing developed during the 1700's and 1800's. Controversy over midwives reached its height between 1910 and 1920. Physicians who hoped to have obstetrics recognized as a medical specialty sought to eliminate midwives. They contended that obstetrics required the skills of highly trained physicians. However, other public health officials did not agree.

In the 1970s the use of lay midwives reemerged when a variety of organizations began promoting home childbirth. Reacting to the treatment women received from obstetricians and hospitals, these groups questioned the medical domination of childbirth and extolled the benefits of a natural, more woman-centered process. Lay midwives were seen as an alternative to hospital births and their high cost.

[1] McCann, "The Modern Midwife," American Baby, January 1989, p.5..

The practice of direct-entry midwifery is different than the practice of nurse midwifery in that certified nurse-midwife practice takes place within a health care team in an institutional setting providing for physician consultation. A certified nurse-midwife is educated at the professional level in both nursing and midwifery. The approved nurse midwifery programs in the United States prepare individuals already trained as registered nurses to care for the health needs of healthy women and their infants during pregnancy, labor, delivery, and the postpartum period. Nurse-midwives must pass a national, written certification examination in addition to completing an approved educational program to use the designation of certified nurse-midwife.

Colorado Historical Perspective

The first mention of midwives in Colorado law appeared in 1917. The General Assembly enacted medical legislation which enabled the State Board of Medical Examiners to grant and revoke licenses for the practice of midwifery.

Midwifery was defined to mean the attending of a woman in childbirth. Applicants for a midwife license were required to pass an examination given by the medical board. A licensed applicant was then allowed to attend a childbirth without the aid of a physician, but was not allowed to use any instruments in delivering the child or prescribe any drugs.

In 1941, the General Assembly provided that no additional midwives would be licensed in Colorado. In 1977, an amendment to the Medical Practice Act (§12-36-106(3), C.R.S.) enabled certified nurse-midwives to legally practice in Colorado. Nurse-midwives are authorized to perform under the responsible supervision of a licensed physician. The practice of certified nurse-midwives (CNMs) is regulated by the State Board of Nursing.

Before the formalized efforts in 1993 that would impose regulatory standards on direct-entry midwives, the practice of lay midwifery was illegal in Colorado. The Colorado Midwives Alliance (CMA) sought licensure for the practice of direct-entry midwifery in 1985 under the State Board of Nursing. The applicants proposed that educational, training and examination requirements be established by the nursing board. House Bill 85-1338 empowered the State Board of Nursing to issue licenses to practice midwifery to qualified applicants, to evaluate midwifery education programs, to administer examinations, and to conduct hearings for discipline of licensees. In addition, the bill established an advisory committee on midwifery to the Board of Nursing, consisting of seven members. The bill was defeated in the State House of Representatives.

In 1991, The Colorado Midwives Alliance again applied for licensure. Although the Department of Regulatory Agencies recommended against licensure of direct-entry midwives, the Sunrise/Sunset Committee produced House Bill 91-1010, a bill that decriminalized lay midwifery. The bill established a direct entry midwifery registration program to be administered by Division of Registrations in the Department of Regulatory Agencies. HB 91-1010 also required the disclosure of certain information regarding education, experience, and other qualifications. The bill established criminal penalties for practicing direct entry midwifery if they were not registered and for violations of the disclosure requirements.

HB 91-1010 was amended extensively during second reading in the House of Representatives. The bill was amended to require a direct-entry midwife, in order to register as a direct-entry midwife in Colorado, to provide proof of having successfully completed the national competency examination administered by the Midwives Alliance of North America. Other amendments gave the Director of the Division of Registrations disciplinary authority over registered direct-entry midwives, specifically prohibiting a midwife from dispensing drugs and a requirement that a registered direct entry midwife file a birth certificate if the birth of a client's baby occurred outside of a medical facility. The amended bill passed in the House of Representatives but was defeated in the Senate.

The 1992 sunrise application submitted by CMA to the Department of Regulatory Agencies differed from the previous attempts in that it proposed the creation of a registry of direct-entry midwives. The 1992 report by OPR recommended against regulation. House Bill 93-1051 sponsored by Representative David Owens was introduced in the House of Representatives. After considerable amendments, the Colorado Legislature passed HB 93-1051 in 1993 and created the direct-entry midwifery registration program within the Division of Registrations. The program was mandated to prepare or adopt suitable standards for education and training programs and examinations, to accept applications from qualified applicants, to promulgate rules to carry out the provisions of the Article, and to enjoin any person from committing any act prohibited by law.

The following statistical information summarizes birth outcomes of Colorado registered midwives from the inception of the program in December 1993 through November 1994.

Women screened out at first visit	23
Women to whom care was provided	289
Women requiring no referral to other individuals for care during or after pregnancy	189
Women whose care was transferred to a licensed health care provider at some time during this pregnancy prior to beginning of labor	62
Deliveries attended as the primary midwife	218
Deliveries attended as supervisor of apprentice midwife	35
Mothers transported to a health care facility during labor	24
Mothers transported to a health care facility after delivery	7
Mothers referred to licensed health care providers during the postpartum period	9
Maternal deaths	0
Apgar scores of infants (1 minute)	0-3 3 3-6 14 7-10 195
Apgar scores of infants (5 minutes)	0-3 2 3-6 1 8-10 209
LGA infants delivered *	35
SGA infants delivered **	1
Perinatal deaths	2
Infants requiring no referral to licensed health care providers except for well care during the first 6 weeks of life	220
*** LGA (Large for gestational age) ** SGA (Small for gestational age)**	

Legal Status in Other States

Legal status of direct-entry midwives is continually changing, as are the state-by-state regulations. There is considerable diversity in the legal status of direct-entry midwives throughout the United States. The following chart lists the states where midwifery is legal by licensure, certification or registration and where it is prohibited. In many of the 19 remaining states , although neither licensure, registration, nor certification processes exist, statutory inference or judicial interpretation convey legal status to midwives, enabling them to practice openly. In addition, a few states have not legally defined direct-entry midwifery but have not prohibited it either.

LEGAL BY LICENSURE, CERTIFICATION OR REGISTRATION	***PROHIBITED BY LAW OR JUDICIAL INTERPRETATION***
Alaska	Alabama
Arkansas	Delaware
Arizona	Hawaii
Colorado	Illinois
Florida	Indiana
Louisiana	Kentucky
Minnesota	Maryland
New Hampshire	Missouri
New Jersey*	North Carolina
New Mexico	Ohio
New York*	Virginia
Oregon (voluntary licensure)	West Virginia
Pennsylvania*	
Rhode Island*	
South Carolina	
Texas	
Washington	
Wyoming	

* Legal but licensure is unattainable or overly restrictive.

The following chart illustrates the authority for administering certain drugs by direct-entry midwives where midwifery is legalized.

State	Oxytocin Drugs	Local Anesthetic	IV's	Oxygen	RhoGam	Suture	Vitamin K
Arizona	x	x		x	x	x	x
Arkansas	x				x		
Florida	x	x			x	x	
Louisiana	x	x	x	x		x	x
Minnesota	x	x		x		x	
Montana	x	x				x	x
New Hampshire	x	x	x	x	x	x	x
New Mexico	x	x	x	x	x	x	x
South Carolina	x	x			x	x	
Texas							
Washington	x	x	x	x	x	x	x

RhoGam (Rho(D)) immune globulin) is given to Rh negative mothers at the start of the third trimester of pregnancy and again after the birth if the child is Rh positive. This works to prevent the mother from developing and passing on to subsequent Rh positive children antibodies against their blood cells. If a mother has these antibodies and passes them on to a child who is Rh positive, anemia will result for the child. The level of antibodies and the subsequent degree of severity of the anemia increase with each Rh positive child the mother carries. The anemia may become so severe as to require one or more exchange transfusions after the infant's birth and may result in the child being stillborn. RhoGam must be given to the mother within 72 hours after birth.

Pitocin is an oxytoxic drug. It is given to cause the uterus to contract after the birth. Contraction of the uterus has the same effect on stopping bleeding from the placenta site as direct pressure has on a skin cut. Normally a woman will produce this hormone in sufficient amounts after the birth. However, if the uterus is fatigued (mother has a long labor, is dehydrated, has a low blood sugar, etc.) it requires additional pitocin to contract sufficiently.

Vitamin K is used in the newborn to provide the vitamin which is utilized in the body for blood clotting before the infant has time to manufacture its own (it has stopped getting it from mother). This vitamin is manufactured by bacteria in the intestine. The intestinal tract of the newborn is sterile at birth and it takes approximately 8 days for infant's intestinal tract to begin meeting its needs.

Local anesthetics (xylocaine, etc.) would be needed if the midwife was doing **suturing** for the mother's comfort. Reactions are rare. **Suturing** is done for first and second degree perineum lacerations. First degree lacerations include the skin and vaginal mucosa, but no muscle tear while second degree lacerations include skin, mucosa and the muscles of the perineum.

SUMMARY OF STATUTE

Article 37 of Title 12 of the Colorado Revised Statutes provides for the regulation of direct-entry midwives in the State of Colorado. The Legislative Declaration creating the regulatory scheme declares that it is the intent of the General Assembly that health care be provided pursuant to this article as an alternative to traditional licensed health care and not for the purpose of enabling providers of traditional licensed health care to circumvent the regulatory oversight to which they are otherwise subject under any other article of this title. No person who is a licensed health care provider under any other article may simultaneously be registered under this article. A licensed health care provider who holds a license in good standing may relinquish the license and subsequently be registered as a direct-entry midwife.

The General Assembly declares that the authority granted for the provision of unlicensed midwifery services does not constitute an endorsement of such practices. It further states that it is the responsibility of individuals seeking such services to ascertain the qualifications of the registered direct-entry midwife.

Scope of Practice

The statute defines the practice of direct-entry midwifery 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.

Powers of the Director

The Director of the Division of Registrations is empowered to perform the following duties under §12-37-106, C.R.S. and §12-37-107, C.R.S.:

- Promulgate rules and regulations;
- Establish fees for registration and renewal;
- Adopt standards for education, training programs and examinations;
- Deny or revoke registration of a direct-entry midwife;
- Require applicants to demonstrate competence by examination, education, and training;
- Seek injunctions against any person in violation of the law.

Qualifications for direct-entry midwifery registration

A person who wishes to become a registered direct-entry midwife in Colorado must meet the qualifications established in §12-37-103(5), C.R.S.:

- Attained the age of eighteen years;
- Earned at least a high school diploma or the equivalent;
- Successfully completed training approved by the director in:
  - ∗ provision of care during labor and delivery and during the antepartum and postpartum periods;
  - ∗ parenting education for prepared childbirth;
  - ∗ aseptic techniques and universal precautions;
  - ∗ management of birth and immediate care of the mother and the newborn;

  * recognition of early signs of possible abnormalities;
  * recognition and management of emergency situations;
  * special requirements for home birth;
  * recognition of communicable diseases affecting pregnancy, birth, newborn, and postpartum periods;
  * and recognition of the signs and symptoms of increased risk of medical, obstetric, or neonatal complications or problems.

- Acquired practical experience in home setting as an apprentice, including experience with one hundred prenatal examinations on no fewer than thirty different women and observation of thirty births;
- Completed required education, training, and experience;
- Supervised participation as the primary birth attendant, including, rendering care from prenatal to postpartum in connection with at least thirty births; and
- Certified by the American Heart Association or the American Red Cross to perform adult and infant cardiopulmonary resuscitation (CPR).

Mandatory disclosure of information requirements

Every direct-entry midwife must provide the following information in writing to each patient during the initial patient contact:

- name, business address and phone number;
- education, experience, degrees, membership in professional organizations, and certificates;
- statement indicating whether the direct-entry midwife has liability insurance for the practice of direct-entry midwifery;
- listing of any license, certificate or registration in the health care field previously held by the direct-entry midwife;
- statement that the practice of direct-entry midwifery is regulated by the Department of Regulatory Agencies; and
- copy of the emergency plan.

Recordkeepin g

Direct-entry midwives must keep records of midwifery-related activity including:

- birth certificates;
- appropriate client records;
- client's informed consent;
- number of women to whom care was provided;
- number of deliveries performed;
- Apgar scores of delivered infants;
- number of prenatal transfers;

- number of transfers during labor, delivery, and immediately following birth;
- perinatal deaths; and
- other morbidity statistics as required by the director.

Prohibited Acts

The statute sets forth the following prohibited acts in relation to the practice of direct-entry midwifery:

- dispensing or administering any medication or drugs except for required eye prophylactic therapy;
- performing any operative or surgical procedure; and
- providing care to a pregnant woman exhibiting signs or symbols of increased risk of medical, obstetric or neonatal complications or problems; and
- providing care to a pregnant woman exhibiting signs or symbols of increased risk that the child may develop complications or problems during the first six weeks of life.

Disciplinary Action

The Director of the Division of Registrations is authorized to deny, revoke or suspend a registration (§12-37-107, C.R.S.). The Director is also empowered to issue a letter of admonition or impose probation on any registrant. The Director is empowered to apply for a temporary or permanent injunction through the Attorney General. Such injunctive proceedings are in addition to and not in lieu of any other penalties.

As an alternative or in addition to suspension or revocation, the director may assess a fine not to exceed five thousand dollars.

Criminal Penalties

Anyone who practices as a direct-entry midwife without complying with the registration and disclosure requirements of Title 12, Article 37, commits a class 2 misdemeanor and will be punished as provided in §18-1-106, C.R.S. for the first offense. For the second or subsequent offense, an individual commits a class 6 felony and will be punished as provided in §18-1-105, C.R.S.

Liabilities

Registrants are liable for their acts or omission in their services, and licensed physicians, nurses, pre-hospital emergency medical personnel, or health care institutions are not liable for any act or omission resulting from the services of a registered direct-entry midwife.

In addition, the above-mentioned health care providers are not relieved of any liability for any willful and wanton act or omission, or any act of gross negligence. These health care providers may provide consultation or education to the direct-entry midwife without establishing a business or supervisory relationship.

Rules and Regulations

The Division of Registrations has promulgated several rules to augment the statutory authority to regulate direct-entry midwives. These rules address several broad areas including: registration, fees, approval of direct-entry midwifery education programs, and standards of practice.

Chapter I - Registration deals with the administration of the registration examination and registration procedures. It provides for qualifications for admittance to the examination, requirements for registration, renewal of registration, and the establishment of fees.

Chapter II - Approval of Direct-Entry Midwifery Education Programs defines the initial procedures for approval, standards for approval, curriculum, faculty, accreditation, and withdrawal of approval.

Chapter III - Standards of Practice outlines restrictions for midwifery care, antepartal care, intrapartal care, postpartal care, newborn care, record keeping requirements, and emergency plans.

PROGRAM DESCRIPTION AND ADMINISTRATION

Registration

The Director of the Division of Registrations of the Department of Regulatory Agencies administers and enforces the direct-entry midwifery registration program in the State of Colorado. The direct-entry registration and enforcement program is cash-funded. The following designated positions within the Board of Nursing spend a percentage of their work schedule on the registration program.

.10 FTE (educational consultant)

.15 FTE (clerical support)

Section 12-37-103, C.R.S. provides that, upon application for a direct-entry midwife registration from the Division of Registrations, payment of a fee determined by the Director, and fulfillment of minimum qualifications, a direct-entry midwife registration will be issued. The fee is currently $1000 for the examination and $1300 for an annual renewal. In 1993, there were originally 19 registrants; currently there are 25 registered direct-entry midwives.

Examinations

The Director of the Division of Registrations currently administers a multiple-choice examination which was originally authored by the State of Arkansas for their direct-entry midwifery program. It was then adopted with modifications to conform to Colorado standards. The exam is given twice a year, in April and October.

The minimum passing score is established at 77% The following table illustrates the number of persons who passed and failed the examination during the period of 1993 through October 1994. There have been no examinations given in 1995.

Date or Exam	***Number Taking***	***Number Passing***	***Percent passing***
December 1993	25	19	76%
April 1994	5 (first time) 4 (repeat)	4 1	80% 25%
October 1994	4 (first time) 2 (repeat)	3 2	75% 100%

Complaint and Investigation Procedure

The Director of the Division of Registrations is charged with handling all complaints against registered direct-entry midwives. Complaints are received by the Director by phone or mail from a variety of sources: physicians, coroners, nurses, anonymous sources, etc. The program staff screens complaints to make sure that the Director has jurisdiction to respond and that the complaint at least arguably rises to the level of being a violation of the law. After this initial screening, complaints are either referred to the Complaints and Investigations Section of the Division of Registrations in the Department of Regulatory Agencies, or are reviewed by the Assistant Attorney General assigned to the Program.

At this point, the Director or the investigator contacts the registrant, stating the terms of the complaint and requesting a response in writing within 20 days. Once the investigator has had an opportunity to gather facts on the matter, a report of the complaint and the findings of the investigator is sent to the Director for further action. The Director may dismiss the case or refer the case to the Attorney General's Office.

Since the inception of the registration program in 1993, and through April 1995, the Division has received a total of seventeen complaints. Statistics for complaints processed by the Division during this period illustrate that of the 17 complaints received, 3 involved unregistered practice and 2 involved apprentices. Permanent injunctions were filed against the three cases of unregistered practice and two complaints regarding substandard care were dismissed.

Four of the seventeen complaints were related to one midwife's standard of care. This particular midwife currently has 31 charges filed against her practice. Her case is the first disciplinary action filed under the Midwives Registration statute.

The chart on the following page summarizes the complaints received and investigated by the Division from January 1994 through April 1995. The Division reports that all the midwives under investigation fully cooperated and submitted records pertaining to the quality of care in question. This cooperation has reduced investigative time and costs.

FIRST NOTICE	FORMAL COMPLAINT	TO C & I	FROM C & I	TO DIRECTOR	TO ATTORNEY GENERAL'S OFFICE	TYPE
telephone call	filed for TRO and preliminary injunction			signature for TRO	reviews case	not registered, substandard care, infant death
telephone call from physician	fax from physician			signed for preliminary injunction	hearing for preliminary injunction	not registered, doing VBAC, no backups
telephone call from coroner	written complaints from relatives				filed charges	substandard care, infant death
anonymous individual sent in business card of practicing midwife		investigated complaint	not registered but practicing		preparing an injunction	not registered
telephone call from hospital	written complaints received from physician and nurse	investigated complaint	midwife told the truth		reviewed	substandard care, fetal demise
telephone call	fax sent			investigated complaint, dismissed case		practicing without being registered
	letter from physician and hospital			dismissed case	advised Director	substandard care
letter from physician to Medical Board	telephone call from physician	investigated complaint			legal action	apprentice practiced substandard care
telephone call from county nurse		investigated complaint	poor judgment	20 day letter sent	injunction	substandard care
letter from physician to Medical Board	telephone call from physician	investigated complaint		dismissed		substandard care
anonymous phone call		investigation in process				unregistered practice
letter from physician	letter from physician			20 day letter sent		substandard care
telephone call	written complaint			20 day letter sent		substandard care
letter from physician	letter from physician			20 day letter sent	reviewing case	substandard care

TRO = Temporary restraining order	***VBAC = Vaginal birth after cesarean***

Disciplinary Actions

The Director of the Division of Registrations has a variety of enforcement mechanisms available which are created in statute to assure that direct-entry midwifery provide for the health, welfare, and safety of the citizens of Colorado. The Director of the Division of Registrations has the authority to deny, revoke, or suspend any registration, issue a letter of admonition, place a registrant on probation, or apply for a temporary or permanent injunction against a direct-entry midwife, through the attorney general. The Director may also assess a civil penalty in the form of a fine, not to exceed five thousand dollars.

Any person practicing direct-entry midwifery without a registration commits a class 2 misdemeanor with a minimum penalty of 3 months imprisonment and/or $250 fine or a maximum penalty of 6 months imprisonment and/or $750 fine. For the second offense such person commits a class 6 felony and is punishable by a one year imprisonment and/or $1000 fine or a maximum penalty of 18 months imprisonment and/or $100,000 fine.

The following table illustrates the outcome of the complaints received in 1994 and 1995:

Summary of Disposition of Complaints - 1994-1995

Date	Incident	Action
2/7/94	not registered, substandard care, infant death	permanent injunction
3/29/94	substandard care	case dismissed
4/4/94	practicing without a registration	negotiated settlement
4/6/94	not registered, doing VBAC, no backups	permanent injunction
4/8/94	practicing without a registration	filed preliminary injunction
5/13/94	substandard care, fetal demise	case dismissed
7/12/94	substandard care, VBAC more than 30 minutes from C section	negotiated settlement
7/21/94	practicing without a registration	case pending
8/25/94	substandard care, infant death	filed charges, case pending
8/25/94	practicing without a registration	case dismissed - apprentice midwife
8/25/94	substandard care, meconium aspiration	case dismissed
8/25/94	substandard care, infant death	case pending
3/8/95	postpartum hemorrhage	case dismissed
3/20/95	violation of diabetic mother	case pending
VBAC = Vaginal birth after cesarean		

RECOMMENDATIONS

Should the Program Be Continued?

Recommendation 1: The General Assembly should continue the Direct-Entry Midwifery Registration Program in the Division of Registrations of the Department of Regulatory Agencies.

This report examines the history of the statute on registering direct-entry midwives and the public health, safety, and welfare that the statute was designed to protect. It assesses the effectiveness of the statute in preventing public injury and the continuing need for regulation.

The practice of direct-entry midwifery poses a significant potential for harm to the health and safety of the public. Midwives provide prenatal, intra-partum, and post-partum care of low-risk pregnant women and newborn children. They characteristically deliver babies in the home. However, they do not normally use drugs and they do not perform surgery.

The regulatory program provides the service of protecting the public's health and safety by addressing registration, training, and education requirements for people practicing as direct-entry midwives. Individuals in the midwifery practice can now be held accountable to a standard of care if they practice dangerously.

The Division has spent a considerable amount of time in developing regulations for education programs, apprenticeship/clinical instruction, standards of practice and in establishing registration and registration renewal requirements.

The Division's enforcement program has actively taken action against unregistered midwifery activity. Complaints are reviewed and investigated in a timely manner.

For these reasons it is clear that deregulating direct-entry midwifery would be inappropriate. In order to attempt to safeguard public welfare, at least minimum standards must be enforced.

If the General Assembly decides to continue the direct-entry midwifery registration program under the Department of Regulatory Agencies, Division of Registrations, the following statutory recommendations are offered to improve the statutes and improve regulation.

Grounds for Discipline

Recommendation 2: Amend statute by adding a section on grounds for discipline.

The statute currently contains a section that authorizes disciplinary action and a section that authorizes grounds for revocation, but there is no section that specifically lists grounds for disciplinary action. The amended section would include language from §12-37-107 and §12-37-103(4), C.R.S. and list additional grounds for discipline. The amended section would read as follows:

> ***(1) Disciplinary actions of the Director pursuant to this section shall be taken in accordance with the provisions of title 12 section 37, C.R.S.***
>
> ***(2) The Director has the power to deny, revoke, or suspend any registration, issue a letter of admonition to any registered direct-entry midwife, or place a registrant on probation for any of the following acts or omissions*** *(previously §12-7-107 (1), C.R.S.);*
>
> ***(a) Any violation of the provisions of §12-37-103, 12-37-104, or §12-37-105 or any rule or regulation promulgated pursuant to §12-37-106(a*** *) (previously §12-7-107 (1), C.R.S.);*
>
> ***(b) Failed to provide any information required, or to pay any fee assessed, in accordance with this section, or provided false, deceptive, or misleading information to the division of registrations when the direct-entry midwife knew or should reasonably have known that the information was false, deceptive, or misleading*** *(previously §12-37-103(a), C.R.S.);*

(c) Been responsible for any act or omission which does not meet generally accepted standards of safe care for women and infants, whether or not actual injury to a patient is established *(previously §12-37-103(b), C.R.S.);*

(d) Habitual intemperance with regard to or excessive use of any habit-forming drug, as defined in section 12-22-102 (13), any controlled substance, as defined in section 12-22-303 (7), or any alcoholic beverage *(previously §12-37-103(d), C.R.S.);*

(e) Has procured or attempted to procure a registration by fraud, deceit, misrepresentation, misleading omission, or material misstatement of fact *(new addition);*

(f) Has had a license or registration to practice direct-entry midwifery or any other health care occupation suspended or revoked in any jurisdiction. A certified copy of the order of suspension or revocation shall be prima facie evidence of such suspension or revocation *(new addition);*

(g) Violation of any law or regulation governing the practice of direct-entry midwifery in another state or jurisdiction. A plea of nolo contendere or its equivalent accepted by any state entity of another state or jurisdiction may be considered to be the same as a finding of violation for purposes of any proceeding under this part 7 *(new addition);*

(h) Has falsified or in a negligent manner made incorrect entries or failed to make essential entries on client records *(new addition);*

(i) Has been convicted of a felony or has had accepted by a court a plea of guilty or nolo contendere to a felony. A certified copy of the judgment of a court of competent jurisdiction of such conviction or plea shall be prima facie evidence of such conviction *(new addition);*

(j) Has violated any provision of this article or has aided or knowingly permitted any person to violate any provision of his article *(new addition);****or***

(k) Has advertised through newspapers, magazines, circulars, direct mail, directories, radio, television, or otherwise that the registrant will perform any act prohibited by this article 37 *(new addition****).***

(3) As an alternative to or in addition to a suspension or revocation of registration under 12-37-103 (4), the director may assess a civil penalty in the form of a fine, not to exceed five thousand dollars, for any act or omission enumerated in the said *section (previously §12-37-107(2), C.R.S.).*

(4) Any proceeding to deny, suspend, revoke, or place on probation a registrant shall be conducted pursuant to sections 24-4-104 and 24-4-105, C.R.S. Such proceeding may be conducted by an administrative law judge designated pursuant to part 10 or article 30 of title 24, C.R.S. *(new addition).*

There is no single section currently in the direct-entry midwifery statute that specifically addresses grounds for disciplinary action. This section needs to be added so that all matters relating to disciplinary actions are distinct and explicit. Recommendation 2 consolidates this information from other sections in the statute, adds new grounds for discipline, and clarifies the Director's responsibility regarding disciplinary actions. Recommendations 2(a), 2(b), 2(c), and 2(d) above presently exist in the midwifery statute.

In reference to Recommendations 2(f) and 2(g), the Director currently does not have the authority to deny, revoke, or suspend a registration if a registrant has incurred disciplinary action relating to the practice of midwifery in another jurisdiction. It should be able to accept as prima facie evidence any previous suspension or revocation of a direct-entry midwife's license or registration in another jurisdiction as grounds for denial of a Colorado registration. If a registrant is considered to be a public threat sufficient to warrant suspension, revocation or denial of registration in one jurisdiction, then it is reasonable to conclude that the registrant may be a threat to the health, safety, and welfare of the citizens of Colorado regardless of whether wrongdoing was admitted.

Recommendations 2(e), 2(f), 2(g), 2(h), 2(i), 2(j) and 2(k) contain language similar to that which appears in many regulatory statutes administered by the Department of Regulatory Agencies and provides additional public protection.

Recommendation 3: Grant Provisions for Governmental Immunity

Governmental Immunity

The prevailing statute does not provide for immunity for the good faith reasonable actions of agents of the Midwives Registration program and any witnesses. The General Assembly has regularly extended this type of immunity to Board members and other persons participating in disciplinary matters when those persons are acting in good faith in their official capacities. By providing immunity to anyone who lodges a complaint in good faith, it encourages compliance with the law and provides the Director with additional information regarding substandard practice.

The language below would satisfy this concern:

> ***The Director, Division staff, any person acting as a consultant to the Director, any witness testifying in a proceeding authorized under this article, and any person who lodges a complaint pursuant to this article shall be immune from criminal liability and suit in any civil action brought by any person based upon an action of the director, if such person, staff person, consultant or witness acts in good faith within the scope of this article, has made a reasonable effort to obtain the facts of the matter as to which he acts, and acts in the reasonable belief that the action taken by him is warranted by the facts. The immunity provided shall also extend to any person participating in good faith in any investigative proceeding.***

Confidentiality of Records

Recommendation 4: Files should be confidential during the investigatory period.

Most occupational boards have the authority to keep investigation files confidential during the investigatory process. This limited period of confidentiality protects the registrant during the course of the investigation that may reveal that the allegation may not be substantiated. In addition, people may be willing to cooperate with the investigation if they know it is confidential during this period. The recommended language reads as follows:

"The director may keep any investigation authorized under this article closed until the results of such investigation are known and either the complaint is dismissed or notice of hearing and charges are served upon the registrant."

Denial of Registration

Recommendation 5: Grant provisions for denial of registration.

The Director has the authority to deny an applicant a registration if they do not meet the requirements set forth in the Article. The Director should also be able to accept as prima facia evidence any disciplinary action in another jurisdiction against a midwife's registration or license as grounds for disciplinary action or denial of a registration in Colorado. If a registrant is considered to be a public threat sufficient to warrant suspension, revocation or denial of license in one jurisdiction, then it is reasonable to assume that the registrant may be a threat to the health, safety and welfare of the citizens of Colorado. The recommended language should read as follows:

"In any proceeding held under this section, the director may accept as prima facie evidence of grounds for disciplinary action any disciplinary action taken against a registrant or licensee from another jurisdiction if the violation which prompted the disciplinary action in that jurisdiction would be grounds for disciplinary action under this article."

Waiting Period for Reinstatement

Recommendation 6: Enforce a two-year waiting period for reinstatement of a revoked registration.

Section 12-37-103, C.R.S. addresses the director's ability to deny a registration. However, there is no stated waiting period after a license revocation before which the midwife can apply for re-registration. In practice, it often takes several months to revoke a registration, depending upon whether or not the case goes to hearing or is settled. Once the registration is revoked, a waiting period for reinstatement should be required. This period is intended to serve the purpose of reminding the registrant of their accountability for their behavior and to assure rehabilitation of the registrant. Without a substantial wait that message is lost. Both the Medical Board and the Nursing Board require a two-year wait which is becoming the regulatory standard.

Subpoena Powers

Recommendation 7: Authorize subpoena power for the Director.

The Director currently has no subpoena power. This puts the program at a significant disadvantage in the investigative stage. If there is good evidence to proceed with filing the action, then the program's attorney may issue subpoenas for evidence under the Administrative Procedures Act or Rules of Civil Procedure. There may be cases, however, where the attorney does not feel that there is sufficient evidence to file the case. If the respondent and the witnesses are uncooperative, then the program may find itself unable to pursue a case that needs further investigation. Most of DORA's regulatory boards have the authority to subpoena records and documents and to compel testimony during investigations. Therefore, there should be provision for subpoena power in the statute. The language could be similar to that in §12-38-123(7), C.R.S. of the Nurse Practice Act which reads:

> ***In order to aid the Director in any hearing or investigation instituted pursuant to this section, the Director shall have the power to issue subpoenas for the appearance or production of persons and copies of any records containing information relevant to the practice of direct-entry midwifery rendered by any registrant, including, but not limited to, hospital and physician records. The person providing such copies shall prepare them from the original record and shall delete from the copy provided pursuant to the subpoena the name of the patient, but he/she shall identify the patient by a numbered code, to be retained by the custodian of the records from which the copies were made. Upon certification of the custodian that the copies are true and complete except for the patient's name, they shall be deemed authentic, subject to the right to inspect the originals for the limited purpose of ascertaining the accuracy of the copies. No privilege of confidentiality shall exist with response to such copies and no liability shall lie against the Director or the custodian or his authorized employee for furnishing or using such copies in accordance with this section.***

Administrative Law Judges

Recommendation 8: Empower the Director to hire an administrative law judge.

The Director should have the authority to refer cases to be heard by administrative law judges. Right now there is nothing in the statute that specifically allows it. Most regulatory boards and commissions have the statutory authority to hire Administrative Law Judges (ALJ) from the Department of Administrative Hearings to hear disciplinary cases. This power would give the Director the opportunity to hold disciplinary hearings before an impartial party trained in conducting administrative hearings. The authority to refer to an administrative law judge would read as follows:

> ***The Director, through the Department of Regulatory Agencies, may employ administrative law judges, on a part-time basis, to conduct hearings as provided by this article or on any matter within the Director's jurisdiction upon such conditions and terms as the Director may determine.***
>
> ***Disciplinary proceedings shall be conducted in the manner prescribed by article 4 of title 24, C.R.S., and the hearing and opportunity for review shall be conducted pursuant to said article by the Director or an administrative law judge.***

Registry for Apprentice Midwives

Recommendation 9: Establish a registry for apprentice midwives.

Currently, persons who reach the required level of education in the direct-midwifery program are allowed to apprentice in approved programs, under the supervised direction of a registered midwife. However, there is no requirement in the statute that they be required to register as apprentices with the Midwives' Registration Program.

As discussed in the disciplinary section, there have been a few complaints that were determined to be against apprentice midwives. But that determination was only made after an investigation by the Division of Registrations. Because there is no apprentice midwife registry to refer to, the Division investigated the complaint regarding unregistered practice. A registry would assist the program in keeping better track of all persons apprenticing under registered direct-entry midwives.

It is recommended that upon application, an apprentice permit be issued which authorizes the person to obtain the required clinical experience under the supervision of a registered direct-entry midwife. The applicant must pay a fee established by the Director and provide verification of apprentice supervisor relationship from the person or persons supervising the applicant. Section 12-37-102, C.R.S. should be amended to include a definition of apprentice midwife which reads as follows:

> ***apprentice midwife** is any person who is granted a permit to obtain the educational and clinical experience required to apply for a registration.*

Furthermore, the statute should state that any apprentice permit shall expire and become null and void on any date that the apprentice's relationship with his or her supervising registered midwife is terminated.

Emergency Situations

Recommendation 10: Grant authority for midwives to administer certain drugs under emergency situations.

Section 12-37-105(1), C.R.S. prohibits midwives from dispensing or administering any medication except eye prophylactic therapy. Emergency situations are going to arise even though efforts are made to prevent midwives from administering care to high-risk women. The statute should be expanded to allow midwives to administer oxytocin drugs (such as pitocin) and oxygen only in emergency situations and Vitamin K and RhoGam when the health of the mother or newborn are determined to be to be at sufficient risk. An oxytocin drug should only be administered for the control of postpartum hemorrhage while arranging for immediate transport to a medical center/hospital.

Pitocin and oxygen are rarely used in the home setting, but are essential to providing safe care in the event of an emergency. Women do hemorrhage after birth even with the best possible care. Pitocin allows for immediate attention, thus reducing blood loss and subsequent problems. Reactions from intramuscular injections in the postpartum period are rare. Oxygen also should be a mandatory part of the midwives equipment, not a dangerous item in need of restriction. When a newborn is in need of resuscitation, and it is not always apparent before delivery, then the midwife needs to be able to provide immediate support. There are many statistics that report that the sooner resuscitation efforts are begun, the better the outcomes.

RhoGam is given to Rh negative mothers at the start of the third trimester of pregnancy and again after the birth if the child is Rh positive. This works to prevent the mother from developing and passing on to subsequent Rh positive children antibodies against their blood cells. If a mother has antibodies and passes them on to a child who is Rh positive, anemia will result in the child. The level of antibodies and the subsequent degree of severity of the anemia increase with each Rh positive child the mother carries. The anemia may become so severe as to require one or more exchange transfusions after the infant's birth or may result in the child being stillborn. RhoGam must be given to the mother within 72 hours after birth. The only ill effects known from this medication is local reaction. This might include redness and swelling around the injection site.

Vitamin K is used in the newborn to provide the vitamin which is utilized in the body for blood clotting before the infant has time to manufacture his own. This vitamin is manufactured by bacteria in the intestine. The intestinal tract of the newborn is sterile at birth and it takes approximately 8 days for the infant's intestinal tract to begin meeting his needs. This cannot be given by mouth because the enzymes in the stomach inactivate it. In therapeutic doses it is nontoxic.

This report recommends that oxygen and pitocin only be administered by a direct-entry midwife as part of emergency measures. In an emergency, it is the responsibility of the midwife to provide the best possible care to women and their infants until they can get access to further medical treatment. Performing an intramuscular injection is considered a standard procedure which is taught during midwifery training.

The definition of "natural childbirth" in §12-37-102(4), C.R.S. would need to be amended if the use of additional drugs were granted to midwives. Natural childbirth is currently defined as "the birth of a child without the use of prescriptive drugs, instruments or surgical procedures." In addition, §12-37-105(1) and (2), C.R.S. would need to conform to the expanded list of drugs that direct-entry midwives would be allowed to administer.

If the statute is amended to allow direct-entry midwives to administer certain drugs, there should be a provision that would allow midwives to legally purchase these drugs. The following statutory language in the Optometrist's Act §12-40-109(5), C.R.S. would satisfy this requirement:

The recommended revised language would read as follows:

"Notwithstanding the provisions of §12-21-121, C.R.S., a registered midwife may purchase, possess, and administer the specific drugs authorized by §12-37-105.1, C.R.S., only if the midwife has been trained to administer intramuscular injections and oxygen."

Direct-entry midwives in most states where the practice is legal (refer to chart on page 10) are authorized to administer these drugs and perform suturing as emergency measures in the absence of medical assistance.

Dual Health Care Licensure

Recommendation 11: Delete prohibition regarding dual health care licensure.

Section 12-37-101, C.R.S. currently prohibits any direct-entry midwife from simultaneously having a license or registration in any other health care provider field. If a licensed or registered health care provider chooses to become a registered direct-entry midwife, they must first relinquish that license. The legislative intent was to prohibit providers of traditional licensed health care from circumventing the regulatory oversight to which they are otherwise subject. However, those health care providers who had their license revoked from another health care profession are able to practice direct-entry midwifery, yet those in good standing with their profession are forbidden to practice.

This restriction is a barrier to the nurses, acupuncturists, and other health care providers who would like to become direct-entry midwives but do not want to relinquish their license or practice. In addition, several direct-entry midwives would like to acquire a registration in acupuncture but are not allowed because of this restriction.

The regulations governing specific care would still determine their scope of practice while the requirements for registration would ensure the same basic skill level as anyone trained from a different avenue. It is unreasonable to have legislation that limits the field of midwifery by excluding some of the people who could provide excellent care.

Training and Educational Programs

Recommendation 12: Revise standards for educational programs.

Section 12-37-106(c), C.R.S. authorizes the Director to prepare or adopt suitable standards for education and training programs and examinations, including the initial examination. The Director has received and reviewed one application for program approval. The Director's standards as outlined in Chapter II 3.1 of the Rules and Regulations require that the program also comply with the Private Occupational Education Act of 1981 (§23-60-704(2), C.R.S.), which has jurisdiction over those programs preparing individuals for entry level positions in an occupation. Schools apply to the Private Schools Division of the Colorado Department of Education for program approval or for an exemption. Applicants must submit a fee of $2,000 and a lengthy application including:

- a surety or bonding alternative;
- a current balance sheet, income and expense statement prepared by an independent public accountant or CPA;
- current and appropriate safety inspection reports;
- catalog published or proposed catalog; and
- facilities lease, etc.

Based upon the program submitted to the Director and the inability to comply with the above state statutorily mandated requirements, the program application was not approved. These regulations are quite onerous for a group with 12 students, 2 of whom complete the program successfully in any given year.

While there is an exemption in the Private Occupational Act for apprenticeship programs, and the midwifery program does refer to its students at one point in the program as apprentices, it does not meet the Bureau of Apprenticeship and Training definition for an apprenticeship.

Public health and safety can be equally well protected by a review of the credentials of the individual applicant at the time of application to take the registration examination. Therefore, this report recommends that §12-37-106(c), C.R.S. be amended to read:

> ***To prepare or adopt suitable education standards for applicants and to adopt a registration examination.***

The rules and regulations in Chapter II - Rules and Regulations for Approval of Direct-Entry Midwifery Programs should be revised to conform with the new statutory language.

APPENDICES

Sunset Statutory Evaluation Criteria

(I) Whether regulation by the agency is necessary to protect the public health, safety and welfare; whether the conditions which led to the initial regulation have changed; and whether other conditions have arisen which would warrant more, less or the same degree of regulation;

(II) If regulation is necessary, whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest, considering other available regulatory mechanisms and whether agency rules enhance the public interest and are within the scope of legislative intent;

(III) Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, rules, procedures and practices of the Department of Regulatory Agencies and any other circumstances, including budgetary, resource and personnel matters;

(IV) Whether an analysis of agency operations indicates that the agency performs its statutory duties efficiently and effectively;

(V) Whether the composition of the agency's board or commission adequately represents the public interest and whether the agency encourages public participation in its decisions rather than participation only by the people it regulates;

(VI) The economic impact of regulation and, if national economic information is available, whether the agency stimulates or restricts competition;

(VII) Whether complaint, investigation and disciplinary procedures adequately protect the public and whether final dispositions of complaints are in the public interest or self-serving to the profession;

(VIII) Whether the scope of practice of the regulated occupation contributes to the optimum utilization of personnel and whether entry requirements encourage affirmative action;

(IX) Whether administrative and statutory changes are necessary to improve agency operations to enhance public interest.

Direct-Entry Midwives Statute

12-37-101. Scope of article - exemptions. (1) The provisions of this article shall apply only to direct-entry midwives, also known as "lay" midwives, and shall not apply to those persons who are otherwise licensed by the state of Colorado under this title if the practice of midwifery is within the scope of such licensure. No person who is a licensed health care provider under any other article of this title shall simultaneously be so licensed and also be registered under this article. A licensed health care provider who holds a license in good standing may relinquish said license and subsequently be registered under this article. It is the intent of the general assembly that health care be provided pursuant to this article as an alternative to traditional licensed health care and not for the purpose of enabling providers of traditional licensed health care to circumvent the regulatory oversight to which they are otherwise subject under any other article of this title.

(2) Nothing in this article shall be construed to prohibit, or to require registration under this article, with regard to:

(a) The gratuitous rendering of services in an emergency;

(b) The rendering of services by a physician licensed pursuant to article 36 of this title or otherwise legally authorized to practice in this state;

(c) The rendering of services by nurse-midwives licensed pursuant to article 38 of this title and certified by the american college of nurse midwives; or

(d) The practice by persons licensed or registered under any law of this state, in accordance with such law, to practice a limited field of the healing arts not specifically designated in this section.

12-37-102. Definitions. As used in this article, unless the context otherwise requires:

(1) "Direct-entry midwife" means a person who practices traditional, direct-entry midwifery as defined in subsection (2) of this section for compensation.

(2) "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.

(3) "Director" means the director of the division of registrations in the department of regulatory agencies.

(4) "Natural childbirth" means the birth of a child without the use of prescription drugs, instruments, or surgical procedures.

(5) "Postpartum period" means the period of six weeks after birth.

(6) "Registrant" means a direct-entry midwife registered pursuant to section 12-37-103.

12-37-103. Requirement for registration with the division of registrations - annual fee - grounds for revocation. (1) Every direct-entry midwife shall register with the division of registrations by providing an application to the director in the form the director shall require. Said application shall include the information specified in section 12-37-104.

(2) Any changes in the information required by subsection (1) of this section shall be reported within thirty days of said change to the division of registrations in the manner prescribed by the director.

(3) Every applicant for registration shall pay an annual registration fee to be established by the director in the manner authorized by section 24-34-105, C.R.S.

(4) The director may deny registration to or revoke the registration of a direct-entry midwife pursuant to section 24-4-104, C.R.S., if the director finds that the direct-entry midwife has:

(a) Failed to provide any information required, or to pay any fee assessed, in accordance with this section, or provided false, deceptive, or misleading information to the division of registrations when the direct-entry midwife knew or should reasonably have known that the information was false, deceptive, or misleading;

(b) Been responsible for any act or omission which does not meet generally accepted standards of safe care for women and infants, whether or not actual injury to a patient is established;

(c) Violated any provision of section 12-37-105;

(d) Habitual intemperance with regard to or excessive use of any habit-forming drug, as defined in section 12-22-102 (13), any controlled substance, as defined in section 12-22-303 (7), or any alcoholic beverage; or

(e) Violated any rule of the director promulgated under this article.

(5) To qualify to register, a direct-entry midwife shall have successfully completed an examination evaluated and approved by the director as an appropriate test to measure competency in the practice of direct-entry midwifery, which examination shall have been developed by a person or entity other than the director or the division and the acquisition of which shall require no expenditure of state funds. The national registry examination administered by the midwives' alliance of North America, incorporated, shall be among those evaluated by the director. The director is authorized to approve any existing test meeting all the criteria set forth in this subsection (5). In addition to successfully completing such examination, a direct-entry midwife shall be deemed qualified to register if such person has:

(a) Attained the age of eighteen years;

(b) Earned at least a high school diploma or the equivalent;

(c) Successfully completed training approved by the director in:

(I) The provision of care during labor and delivery and during the antepartum and postpartum periods;

(II) Parenting education for prepared childbirth;

(III) Aseptic techniques and universal precautions;

(IV) Management of birth and immediate care of the mother and the newborn;

(V) Recognition of early signs of possible abnormalities;

(VI) Recognition and management of emergency situations;

(VII) Special requirements for home birth;

(VIII) Recognition of communicable diseases affecting the pregnancy, birth, newborn, and postpartum periods; and

(IX) Recognition of the signs and symptoms of increased risk of medical, obstetric, or neonatal complications or problems as set forth in section 12-37-105 (3).

(d) Acquired practical experience in a home setting, including, at a minimum, apprenticeship providing experience with the conduct of one hundred prenatal examinations on no fewer than thirty different women and observation of thirty births;

(e) Following completion of the education, training, and experience enumerated in paragraphs (a) to (d) of this subsection (5), supervised participation as the primary birth attendant, including rendering care from the prenatal period through the postpartum period, in connection with no less than thirty births; and

(f) Filed documentation with the director that the direct-entry midwife is currently certified by the American heart association or the American red cross to perform adult and infant cardiopulmonary resuscitation ("CPR").

12-37-104. Mandatory disclosure of information to patients. (1) Every direct-entry midwife shall provide the following information in writing to each patient during the initial patient contact:

(a) The name, business address, and business phone number of the direct-entry midwife;

(b) A listing of the direct-entry midwife's education, experience, degrees, membership in any professional organization whose membership includes not less than one-third of all registrants, certificates or credentials related to direct-entry midwifery awarded by any such organization, and the length of time and number of contact hours required to obtain said degrees, certificates, or credentials;

(c) 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;

(d) A listing of any license, certificate, or registration in the health care field previously held by the direct-entry midwife and revoked by any local, state, or national health care agency;

(e) A statement that the practice of direct-entry midwifery is regulated by the department of regulatory agencies. The statement shall provide the address and telephone number of the complaints and investigations section of the division of registrations in the department of regulatory agencies and shall state that violation of the provisions of this article may result in revocation of registration and of the authority to practice direct-entry midwifery in the state of Colorado; and

(f) A copy of the emergency plan as provided in section 12-37-105 (6).

(2) Any changes in the information required by subsection (1) of this section shall be reflected in the mandatory disclosure within five days of the said change.

(3) For purposes of registration under this article, no credentials, licensure, or certification issued by any other state shall constitute or be deemed to meet the requirements of this article, and to that extent there shall be no reciprocity with other states.

12-37-105. Prohibited acts - practice standards - informed consent - emergency plan - risk assessment - referral. (1) A direct-entry midwife shall not dispense or administer any medication or drugs except for required eye prophylactic therapy.

(2) A direct-entry midwife shall not perform any operative or surgical procedure.

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

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

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

(c) Prior to 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:

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

(II) 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;

(III) The available alternatives to direct-entry midwifery care;

(IV) A description of the risks of birth, including but not limited to those that are different from those of hospital birth and including but not limited to those conditions that may arise during delivery;

(V) 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

(VI) A statement informing the client that, in the event 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.

(d) 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 and procedure, in a form prescribed by the director, for emergency situations which shall include, but not be limited to, 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.

(8) A direct-entry midwife shall ensure that appropriate laboratory testing, as determined by the director, is completed for each pregnant woman in such direct-entry midwife's care.

(9) A direct-entry midwife shall provide eye prophylactic therapy to all newborn children in such direct-entry midwife's care in accordance with section 25-4-303, 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) (b).

(12) At the time of re-registration, each registrant shall submit the following data on a form prescribed 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; and

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

12-37-106. Director - powers and duties. (1) In addition to any other powers and duties conferred on the director by law, the director has the following powers and duties:

(a) To adopt such rules and regulations as may be necessary to carry out the provisions of this article;

(b) To establish the fees for registration and renewal of registration in the manner authorized by section 24-34-105, C.R.S.;

(c) To prepare or adopt suitable standards for education and training programs and examinations, which may consist of programs and examinations developed by persons or entities other than the director and approved or certified by the director; except that, in preparing or adopting the initial examination required for registration, the director shall consult with certified nurse-midwives, qualified physicians, and qualified direct-entry midwives as to the validity and scope of the examination;

(d) To accept applications for registration which meet the requirements set forth in this article, and to collect the annual registration fees authorized by this article;

(e) To seek, through the office of the attorney general, an injunction in any court of competent jurisdiction to enjoin any person from committing any act prohibited by this article. When seeking an injunction under this paragraph (e), the director shall not be required to allege or prove the inadequacy of any remedy at law or that substantial or irreparable damage is likely to result from a continued violation of this article.

12-37-107. Disciplinary action authorized. (1) If a direct-entry midwife has violated any of the provisions of section 12-37-103, 12-37-104, or 12-37-105, the director may deny, revoke, or suspend any registration, issue a letter of admonition to a registrant, place a registrant on probation, or apply for a temporary or permanent injunction against a direct-entry midwife, through the attorney general, in any court of competent jurisdiction, enjoining such direct-entry midwife from practicing midwifery or committing any violation of the provisions of the said section 12-37-103, 12-37-104, or 12-37-105. Such injunctive proceedings shall be in addition to and not in lieu of any other penalties or remedies provided in this article.

(2) As an alternative to or in addition to a suspension or revocation of registration under section 12-37-103 (4), the director may assess a civil penalty in the form of a fine, not to exceed five thousand dollars, for any act or omission enumerated in the said section.

12-37-108. Criminal penalties. Any person who practices or offers or attempts to practice direct-entry midwifery without first complying with the registration requirements of section 12-37-103 and the disclosure requirements of section 12-37-104 commits a class 2 misdemeanor and shall be punished as provided in section 18-1-106, C.R.S., for the first offense, and for the second or any subsequent offense, such person commits a class 6 felony and shall be punished as provided in section 18-1-105, C.R.S.

12-37-109. Assumption of risk - no vicarious liability - legislative declaration. (1) (a) The general assembly hereby finds, determines, and declares that the authority granted in this article for the provision of unlicensed midwifery services does not constitute an endorsement of such practices, and that it is incumbent upon the individual seeking such services to ascertain the qualifications of the registrant direct-entry midwife. It is the policy of this state that registrants shall be liable for their acts or omissions in the performance of the services that they provide, and that no licensed physician, nurse, prehospital emergency medical personnel, or health care institution shall be liable for any act or omission resulting from the administration of services by any registrant. The provisions of this subsection (1) shall not relieve any physician, nurse, prehospital emergency personnel, or health care institution from liability for any willful and wanton act or omission or any act or omission constituting gross negligence, or under circumstances where a registrant has a business or supervised relationship with any such physician, nurse, prehospital emergency personnel, or health care institution. A physician, nurse, prehospital emergency personnel, or health care institution may provide consultation or education to the registrant without establishing a business or supervisory relationship.

(b) The general assembly further finds, determines, and declares that the limitation on liability provided in section 13-64-302, C.R.S., is predicated upon full licensure, discipline, and regulatory oversight and that the practice of unlicensed midwifery by registrants pursuant to this article is authorized as an alternative to such full licensure, discipline, and regulatory oversight and is therefore not subject to the limitations provided in section 13-64-302, C.R.S.

(2) Nothing in this article shall be construed to indicate or imply that a registrant providing services under this article is a licensed health care provider for the purposes of reimbursement by any health insurer, third party payer, or governmental health care program.

(3) At such time as liability insurance becomes available at an affordable price, the direct-entry midwife shall be required to carry such insurance.

Direct Entry Midwives Questionnaire

Questionnaires were sent to all 25 registered direct-entry midwives. Seventeen survey responses were received, representing a response rate of 68% In addition to answering the questions posed in the survey, the majority of the respondents wrote comments on their impression of the regulatory program. The purpose of the survey was to elicit such comments as well as to provide general information from the regulated community on its view of the effectiveness of the regulatory program. The survey results were as follows. Please note that the totals of responses in each category may not equal 16 since some respondents left some questions blank.

1. **Have you been in contact with the Department of Regulatory Agencies, Division of Registrations' Midwifery Registration program with regard to the following? Check as many as applicable.**
   Problems with licensing - 1
   Complaints (please specify) - 5
   Clarification of law - 7
   Examination questions - 3
   Other (please specify)
   - list of registered midwives
   - approval of CMA certificate program
   - fee increase

2. **Do you feel that the Division of Registrations is responsive to your needs? (Please check one)**
   Very responsive - 10
   Usually responsive - 3
   Somewhat responsive - 3
   Unresponsive - 0

3. **What suggestions would you have for improving the relationship between the Division and the registrants?**
   - an 800 telephone number
   - volunteer registrant advisory board
   - publish monthly memos
   - have a registered midwife attend any meeting where regulations are discussed

4. **Do you currently have a license or registration as a direct-entry midwife in another state?**
   Yes - 2 (from New Mexico)
   No - 15

5. **Did you move to Colorado from another state after the practice of midwifery became legal?**
   Yes - 1 (from Texas)
   No - 15

6. **Currently persons who reach the required level of education are allowed to apprentice in approved programs. However, there is no requirement in the statute that they be required to register as an apprentice with the Midwives' Registration Program. do you feel that apprentices should have to register?**
   Yes - 6
   No - 6
   What do you feel is a reasonable fee?
   $50, $100, $150, $650

7. **Do you have any physicians who are willing to provide back-up services? Please discuss what problems exist (if any) in acquiring physician back-up services.**
   5 midwives reported that they have physicians willing to provide some sort of back-up care. The other 11 respondents have no physicians in their area willing to provide this service. The response from these eleven midwives was that physicians are concerned about liability and threatened by malpractice insurance loss.

8. **Presently, direct-entry midwives are not allowed to administer pitocin or oxygen during delivery. Are you in favor of revising the law to allow midwives this capability if they are adequately trained? Please discuss.**
   In favor - 17
   The unanimous response from the midwives was that pitocin and oxygen should be allowed in certain emergencies if the midwife had been adequately trained in their use. The midwives contend that having the ability to perform these procedures would aid with the safety of homebirth. A majority of the midwives would also like to be able to administer Vitamin K, RhoGam, IV's and suture in certain cases.

9. **Assuming that there are still unregistered midwives practicing, do you have any suggestions for changes to the program that would encourage these persons to become registered?**
   - lower the fee
   - approved training program
   - resistant to state regulation

10. In general, do you feet that the practice of lay midwifery in the State of Colorado has benefited due to the regulatory laws imposed on it? Please discuss,

Yes - 16
No - 1
Comments:

- ◊ standards of the Colorado Midwives Association were in effect years before regulation and there isn't much difference between the two
- ◊ easier to find medical help for those clients that develop problems during their pregnancy and/or during labor. Hospitals allow us to accompany our clients to the hospital and accept our records and dialogue with us.
- ◊ makes it easier on homebirth parents
- ◊ legal access to a valid appropriate, safe, and economical health-care option
- ◊ has clarified and raised the standard of care
- ◊ clients are less resistant to necessary transport because the midwife can accompany them without fear of punitive actions.
- ◊ some of the worse midwives left the state due to registration requirements

11. Do you favor continuation of the Registration Program for Direct-Entry Midwives?

Yes - 16

Discussion of Survey Results

The survey results show a substantial agreement among the registrants regarding the difficulty in obtaining physician back-up, the administration of certain drugs, high fees and the continuation of the regulatory program. Most of the midwives expressed the need to be legally able to administer pitocin, oxygen, RhoGam, vitamin K, and local anesthetic for suturing. The midwives expressed their frustration with the Colorado medical malpractice insurer that denies liability insurance to those physicians who consult with midwives and their clients.

Another concern of the midwives is the duel licensure clause in the law that prohibits midwives from simultaneously being registered or licensed as another health care provider. When asked about the benefits of the regulatory program, the majority of respondents indicated that the citizens of Colorado benefit from the regulation. Hospitals now allow midwives to accompany their clients, clients are easier to transport to hospitals, and finally there is a standard of care that must be adhered to by registered direct-entry midwives.