COLORADO DEPARTMENT OF REGULATORY AGENCIES
OFFICE OF POLICY AND RESEARCH

COLORADO MIDWIVES REGISTRATION PROGRAM

2000 SUNSET REVIEW

October 15, 2000

Members of the Colorado General Assembly
c/o the Office of Legislative Legal Services
State Capitol Building
Denver, Colorado 80203

Dear Members of the General Assembly:

The Colorado Department of Regulatory Agencies has completed the evaluation of the Colorado Midwives Registration Program. I am pleased to submit this written report, which will be the basis for my office's oral testimony before the 2001 Legislative Committees of Reference. The report is submitted pursuant to §24-34-104(8)(a), of the Colorado Revised Statutes (C.R.S.), 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 supporting materials to the office of legislative legal services no later than October 15 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 of Registrations 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,

M. Michael Cooke
Executive Director

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Background

Sunset Process/Methodology

The Department of Regulatory Agencies (DORA) has concluded its sunset review of the regulation of direct-entry midwives as required by §12-37-101, et seq., Colorado Revised Statutes (C.R.S.), the Midwives Practice Act (Act). The review was conducted in accordance with the statutory criteria contained in §24-34-104, C.R.S., which are included in this report as Appendix A.

Currently, there are two distinct classifications of midwives authorized to practice in Colorado. Certified nurse midwives are licensed nurses who have undergone additional training in midwifery and are regulated by the Colorado Board of Nursing. Nurse midwives generally work under the supervision of a physician and most nurse midwife deliveries take place in hospitals or other regulated facilities. Direct-entry midwives (sometimes referred to as lay midwives), regulated by the Division of Registrations, Midwives Registration Program, are not required to have formal medical training before being registered as a midwife. Direct-entry midwives undergo an apprenticeship program and must certify that they have education or training in the health care areas specified in statute.

During this review, DORA conducted literature reviews, interviewed regulatory program staff, reviewed program records, reviewed other state regulatory programs, contacted interested parties including the Colorado Board of Medical Examiners, the Colorado Board of Nursing, the Colorado Medical Society, and professional associations for midwives and other related medical professions. Data collected by the Colorado Midwife Registration Program and the Colorado Department of Public Health and Environment, Vital Records Division were reviewed and compared. Meetings were held with individual registrants to solicit input and obtain insight into the profession. Telephone interviews were conducted with association representatives for various organizations representing health care professions as well as with representatives of midwife regulatory programs in other states.

History of the Profession

The practice of midwifery moved from Europe to the Americas before the founding of the United States. As with most health care professions, there was little or no governmental recognition of the profession. In many European countries, midwives are still the primary health care providers in routine childbirth situations. As medical science advanced in the 1800's, the emphasis on licensed physician and nurse involvement in childbirth expanded in this country. When obstetrics became a recognized medical specialty in the early 1900's, some states began to regulate, or prohibit, the practice of midwifery.

In 1917, the Colorado General Assembly created the first formal program to regulate midwives. The Colorado Board of Medical Examiners was required to develop a program to license midwives. Licensed midwives were allowed to attend births without the supervision of a physician. However, they were not permitted to use any instruments, such as forceps or drugs to assist with labor, delivery, or postpartum care.

In 1941, the General Assembly amended the Medical Practice Act to prohibit the issuance of new midwife licenses. This was intended to allow existing licensees to continue practicing, but to gradually eliminate the profession. Nationally, the concept of natural and home births began resurgence in the 1970's. As a result, a variety of organizations began promoting the concept of births attended by trained midwives.

In 1984, the Colorado Midwives Alliance (CMA) applied to the General Assembly for a regulatory program for direct-entry midwives through the sunrise process. Direct-entry or lay midwives differ from CNMs in that direct-entry midwives are not otherwise licensed as health care professionals. The CMA application requested that the Board of Nursing be empowered to approve midwife training and education, develop or approve an examination, issue licenses, and discipline direct-entry midwives. The 1985 legislation, HB 85-1338, to implement the program was unsuccessful.

In 1991, the CMA utilized the sunrise process again to apply for licensure. The Department of Regulatory Agencies (DORA) determined that the proposal for licensure did not meet the statutory criteria necessary to recommend a regulatory program. Legislation was introduced during the 1992 legislative session but was defeated in the House of Representatives.

The 1992 sunrise application also resulted in a recommendation from DORA for no regulation. However, this time the General Assembly passed HB 93-1051, which created a registry for direct-entry midwives. The registry requires the Director of the Division of Registrations in DORA to adopt education and training standards, promulgate regulations for implementation of the statute, and to accept applications for registrations. The statute also identifies prohibited acts of registered midwives and provides disciplinary options for the Director.

The legislation establishing the direct-entry midwife program required DORA to perform a sunset review of the program in 1995, three years after the program was authorized. The sunset review found that the program was performing its regulatory functions in an effective and efficient manner and recommended that the program be continued. The report prepared by DORA made 11 additional recommendations for improvements to the program. The recommendations contained in the 1995 sunset review were:

1. Clarify prohibited acts and disciplinary options available to the Director;

2. Grant governmental immunity to Division employees and witnesses testifying in good faith;

3. Authorize the confidentiality of investigation files until a final agency action is concluded;

4. Provide for the denial of registration applications;

5. Implement a two year waiting period for reinstatement of a revoked license;

6. Authorize subpoena powers for the Director during investigations;

7. Authorize the Director to refer disciplinary cases to an administrative law judge (ALJ);

8. Expand the registry to include apprentice midwives in Colorado;

9. Expand the scope of drugs a direct-entry midwife may administer to include Rhogam, Pitocin, Oxygen, and Vitamin K;

10. Eliminate the prohibition against direct-entry midwives simultaneously holding any other health care license; and

11. Allow the Director greater flexibility in establishing education standards for direct-entry midwives.

The Joint Legislative Sunrise and Sunset Review Committee agreed to seven of the eleven recommendations and a portion of two others that were included in the continuation legislation (SB 96-49) introduced in the 1996 legislative session. SB 96-49 was extensively amended during the legislative process and when passed included provisions to:

- Allow licensed acupuncturists to also register as a direct-entry midwife;

- Require a two year waiting period for an individual with a revoked registration to reapply;

- Require malpractice insurance of registered direct-entry midwives when insurance is available and economically feasible to purchase;

- Provide for the administration of oxygen by direct-entry midwives;

- Allow the Director greater flexibility in adopting education and training standards for applicants;

- Clarify prohibited acts and disciplinary options available to the Director;

- Grant governmental immunity to Division employees and witnesses testifying in good faith;

- Authorize the confidentiality of investigation files until a final agency action is concluded;

- Provide for the denial of registration applications;

- Grant subpoena powers to the Director; and

- Require direct-entry midwives and county coroners to report information related to prenatal care, deliveries and infant mortality to the State Registrar.

Summary of Statute

The statute regulating direct-entry midwives (midwives) is found at §12-37-101, et seq., C.R.S., and is included as Appendix B of this report. The Act begins by defining the scope of the article. The Act prohibits health care professionals other than registered acupuncturists from registering as a direct-entry midwife. The rendering of gratuitous midwife services in an emergency is exempt from regulation.

The Act establishes the qualifications for registration in section 103. This section also authorizes the Director to establish fees for registration and renewal. In order to be registered as a direct-entry midwife in Colorado, the applicant must meet the requirements of §12-37-103 (5), C.R.S.:

> (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 nineteen 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").

Direct-entry midwives are required to disclose specific information contained in section 104 to all clients. Included in the disclosure requirements are the education and experience of the midwife, whether the midwife has liability insurance and the midwife's registration number along with the address and telephone number of the Complaints and Investigations Unit in the Division of Registrations.

Midwives are prohibited from dispensing or administering medications other than oxygen and the prophylactic treatment required by §25-4-303, C.R.S., to be administered to all newborn infants. Registrants may administer oxygen provided they have successfully completed the training required by regulation. Midwives are prohibited by the Act from treating women with high-risk pregnancies or women who exhibit symptoms that the child may develop complications during the first six weeks of life.

Midwives are required to maintain client records, file birth certificates and perform newborn screening in the same manner as other health care professionals. Direct-entry midwives are required to prepare an emergency procedure plan for all births to facilitate transportation of the infant and/or mother to a medical facility in case it is necessary. Midwives must report practice statistics, such as deliveries attended, women screened out, and general birth information to the Director upon registration renewal.

The Director is authorized to establish rules and regulations necessary to carry out the provisions of the Act. The Director is responsible for adopting appropriate education standards for applicants as well as fees for registration and renewal. The Director is required to investigate complaints and enforce the Act and regulations, as well as administer disciplinary actions when necessary in accordance the Administrative Procedure Act (APA).

The Director may deny, revoke, suspend, issue a letter of admonition or place a registrant on probation for violations of the Act or regulations. As an alternative to the previously mentioned disciplinary options, the Director may assess civil monetary penalties of up to five thousand dollars against registrants. All disciplinary actions are subject to hearings as required by the APA.

Practicing midwifery without first complying with the registration requirements is a violation subject to criminal penalties. The first offense is a Class 2 misdemeanor and the second offense is considered a Class 6 felony. The Director may, through the Office of the Attorney General, seek an injunction against any person violating any provision of the Act, including practicing without a registration.

Registration as a midwife is not considered licensure as a health care professional and therefore registrants are not protected by civil liability provisions for health care professionals contained in §13-64-302, C.R.S. In addition, the Act specifically states that other health care professionals and institutions shall not be liable for the acts or omissions of registered midwives during subsequent treatment of patients initially treated by a midwife.

The Director, division staff, authorized agents, and witnesses testifying in proceedings authorized by the Act are granted immunity from criminal and civil actions brought by a party based on actions of the Director, provided the individual in question acted in good faith.

The Director may keep investigation files and records confidential until the complaint is dismissed or a notice of charges is filed.

Related Statutes

The Colorado Medical Practice Act contains an exemption in §12-36-106(1)(f)(II)(A), C.R.S. for the practice of midwifery by an individual registered by the Director. This exemption expires with the sunset of the direct-entry midwife registration program.

Regulation in Other States

There is no direct federal regulation of direct-entry midwives, although licensed midwives are eligible for Medicaid reimbursement in some states, such as Alaska, Arizona and Washington. State regulation varies greatly. Some states have formal licensing programs that require education and/or experience before taking a state approved examination while others recognize midwifery as a profession, but exhibit little regulatory control. Nine states prohibit the practice of midwifery. Table 1 on the following page details the legal status of midwifery practice in the United States.

Table 1

Legal Status of Direct-Entry Midwives: State-by-State Analysis*

State	Legal By:			Prohibited By:		Midwifery Education and Accreditation Council Accredited Programs	Medicaid Reimbursement
	Licensure (L) Certification (C) Registration (R) Documented (D)	Judicial Interpretation or Statutory Inference	Not Legally Defined, but Not Prohibited	Statute, but Licensure Unavailable	Statute, Case Law, or Stricture of Safe Practices		
AK	L						X
AL				X			
AR	L						
AZ	L						X
CA	L					1	X
CO	R						
CT			X				
DE				X			
DC					X		
FL	L						X
GA				X			
HI				X			
ID		X					
IL		X					
IN					X		
IA					X		
KS		X					
KY					X		
LA	L					1	
ME		X				1	
MD					X		
MA		X					
MI		X					
MN	L						
MS		X					
MO					X		
MT	L						
NE			X				
NV		X					
NH	L						X
NJ				X			
NM	L						X
NY				X			
NC					X		
ND		X					
OH			X				
OK		X					
OR	Voluntary-L					3	X
PA		X					
RI				X			
SC	L						X
SD			X				
TN		X					
TX	D					1	
UT		X				1	
VT			X				
VA					X		
WA	L					1	X
WV			X				
WI			X				
WY					X		

*Information for this chart was provided by the Midwives Alliance of North America (MANA), the Midwifery Education and Accreditation Council (MEAC), and the North American Registry of Midwives (NARM).

Private Credentialling

The North American Registry of Midwives (NARM) is a private credentialling agency for direct-entry midwives. NARM issues a Certified Professional Midwife (CPM) credential to applicants who meet education, experience, and examination standards developed by the organization. There are several alternative paths to recognition as a CPM authorized by NARM. In addition to the traditional apprenticeship program, NARM recognizes graduation from an educational program approved by the Midwifery Education and Accreditation Council (MEAC). NARM's educational standards were developed using the procedures developed by the National Organization of Competency Assurance and the examination has been reviewed for validity.

When a prospective midwife completes the minimum education and experience standards established by NARM, the midwife may apply to take the NARM examination to become a CPM. The NARM examination is currently used in 13 states, including Colorado, as the state licensing examination. An additional 10 states have legislation or regulatory action pending which will require successful completion of this examination prior to state authorization to practice as a direct-entry midwife.

MEAC was formed in April 1991, by the National Coalition of Midwifery Educators, as a not-for-profit corporation. The purpose of MEAC is to accredit direct-entry midwifery educational programs and institutions under the rules of the Department of Education (DOE).[1] MEAC has accredited three institutions nationally, and midwife education programs at two other educational institutions. According to MEAC, there are four other programs currently engaged in the certification process. None of the accredited programs are in Colorado. However, at least one program, the Utah School of Midwifery, has a distance learning program available to Colorado residents.

[1] Website of the Midwives Alliance of North America, http://www.mana.org/meac/

Program Description and Administration

The Division obtains expense efficiencies for the midwife registration program by sharing administration of the program with several allied health professions regulated by the Director. Personal services devoted to the program are estimated for budgetary purposes at .05 full-time equivalent (FTE) Program Administrator and .05 Administrative Assistant. Fees are established annually to cash fund administrative expenses.

Registration Qualifications

There are currently no approved formal educational programs for midwifery in Colorado. The Director has accepted formal education from accredited colleges and universities with credits in related areas as equivalent education for registration in Colorado. The Director has also accepted informal apprentice education provided by supervising midwives. To qualify for registration as a direct-entry midwife an applicant must first meet the statutory requirements in §12-37-103 (5), C.R.S. Among the requirements are:

- At least 19 years of age;
- High school graduate or equivalent;
- Successful completion of a training program approved by the Director;
- Completion of a supervised practical experience apprenticeship;
- Supervised as the primary birth attendant in 30 births;
- Certification in both adult and infant cardiopulmonary resuscitation (CPR); and
- Obtain a satisfactory score on an examination approved by the Director to measure competency in the practice of direct-entry midwifery.

Examination

The first examination for midwife licensure was conducted in December of 1993. Twenty-five applicants attempted the examination with 76 percent, or 19 individuals achieving a passing score. Subsequent examinations were conducted by the Division in April and October of 1994 with an overall pass rate of 66 percent. The Director adopted the NARM examination as a requirement for Colorado registration in 1998. Examination details are contained in Table 2.

Table 2

Midwife Examination Results

	1993	1994	1995	1996	1997	1998	1999
Examinees	25	15	5	1	5	4	7
Passed	19	10	4	1	5	4	6
Percentage	76	66	80	100	100	100	86

Education

The education program approved by the Director must contain nine components defined in §12-37-103 (5)(c), C.R.S.:

- 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 and management of emergency situations;
- Special requirements for home birth;
- Recognition of communicable diseases affecting the pregnancy, birth, newborn, and postpartum periods; and

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

Apprenticeship

Colorado does not require registration of apprentices or have special qualifications for registered direct-entry midwifes who act as preceptors (or trainers) for apprentices. The regulations for standards for education, which include the apprenticeship, are included in Appendix C to this report.

Generally, the preceptor will certify to the Director that an apprentice has obtained the required education under the preceptor's supervision. The preceptor will also certify that the apprentice has experience in the conduct of 100 prenatal examinations on at least 30 different women. Physicians, nurse midwives, and registered direct-entry midwives are all authorized to certify the education portion of the regulatory requirements.

An apprentice must observe at least 30 births performed by a midwife. After meeting this requirement, the apprentice must serve as the primary birth attendant from the prenatal period through the postpartum period for 30 women under the supervision of the preceptor. Births attended in a hospital or birth clinic are not accepted for the experience portion of the apprenticeship.

The statute, in §12-37-105(3), C.R.S., prohibits midwives from caring for women who exhibit signs, symptoms or have a history of high-risk pregnancies. Paragraph (4) of the same section prohibits midwives from providing care to pregnant women whom, according to generally accepted medical standards are likely to deliver a child with a high probability of developing health risks during the postpartum period. The Director is required to establish by rule, procedures for registered midwives to follow to ensure that they make proper referrals to licensed health care providers after initial screenings.

The statute and regulations require emergency transportation of the mother during labor if conditions warrant, as well as emergency transportation of the mother and/or infant after delivery if either party's health is at risk. The regulations also require referrals of women and infants during the postpartum period, if appropriate.

The renewal process for midwives requires each midwife to provide documentation to the Director related to the treatment and deliveries the individual midwife participated in during the past year. This documentation includes information regarding referrals made by the midwife. Additionally, information related to complications occurring during labor, delivery, and the postpartum period is also reported to the Director. Data collected during the renewal process since the last review is summarized in Table 3.

Table 3

Colorado Midwives Statistical Report

	1994	1995	1996	1997	1998	1999	Total
Women Receiving Midwife Care	289	354	396	473	398	546	2,456
Women Receiving Only Midwife Care	189	320	357	398	377	465	2,106
Deliveries Attended by Midwives	253	345	383	465	397	527	2,370
Referred to MD After Screening	23	43	29	29	15	34	173
Referred to MD Before Labor	26	31	38	47	31	37	210
Transferred to Hospital During Labor/Delivery	24	36	42	33	40	48	223
Infants Requiring Consult/Transport Within 24 Hours after Delivery	NA*	4	14	8	7	10	43

*Data not available.

Complaints/Discipline

The program has averaged approximately 10 complaints against midwives each year since the last sunset review. Approximately 25 percent of the complaints filed with the program are related to unregistered practice. It is not unusual for a new regulatory program to have a large number of complaints and disciplinary hearings regarding unregulated practitioners. It is a frequent finding that unlicensed or unregistered practice is a common complaint in the early years of a program. However, as the public and professionals become aware of the regulatory requirements the frequency of this type of complaint should decline.

It is interesting to note that consumers do not file the majority of complaints received by the program. Most complaints are filed by hospital administrators or medical professionals following a transport to a medical facility as required by the statute or regulations. Some complaints are referred to the Director from the Board of Medical Examiners and Board of Nursing. All complaints are reviewed by the program administrator for potential violations of the statute or regulations. Complaints that appear to be violations are referred to the Complaints and Investigations Unit in DORA for a formal investigation into the allegation.

If it is determined that a complaint a violation of the Act or regulations has occurred, disciplinary proceedings begin in accordance with the Colorado Administrative Procedure Act contained in §24-4-104 and 105, C.R.S. Many respondents enter into a stipulated agreement with the Director before going to hearing. This is a cost-effective remedy for both the respondent and the state as it greatly reduces legal expenses for both sides. Stipulated agreements are open to the public and all formal disciplinary actions taken by the Director are available to interested parties.

A summary of the complaints received and disciplinary actions taken by the Director is contained in Table 4. Since unregistered practice as a midwife is also a violation of the Colorado Medical Practices Act, it is common for an injunction in those cases to be jointly sought by the BME.

Table 4

Complaints and Disciplinary Actions

Complaint	94/95	95/96	96/97	97/98	98/99	99/00	Action
Fee Dispute	0	1	0	0	0	0	No action
Fetal Death	0	1	1	1	0	0	No actions
Improper Charting	0	1	0	0	0	0	No action
Maternal Morbidity	3	2	0	1	0	1	1 suspension
Maternal Referral	0	0	0	2	0	0	No actions
Maternal Transport	0	1	0	0	0	2	1 LOA
Newborn Death	3	0	1	1	0	3	1 suspension
Newborn Transport	1	0	1	0	0	0	No actions
Practicing Beyond Scope	1	1	1	1	0	0	1 probation
Substandard Care	0	1	2	0	0	0	1 suspension
Unregistered Practice	1	2	4	2	2	1	8 injunctions
TOTAL	9	10	10	8	2	7	13 actions

Analysis and Recommendations

The regulation of direct-entry midwives is intended to protect the safety of both the mother and the infant. To that end, the General Assembly placed restrictions on the practice of midwifery designed to reduce the likelihood a mother or infant would suffer medical complications during pregnancy, labor, or delivery.

One of the conditions that led to the original regulation was concern that midwifery was being practiced in Colorado, unsafely and without oversight, in violation of the Colorado Medical Practices Act (§12-36-101, et seq., C.R.S.). The number of midwife attended births has increased steadily since the program began. We know from testimony during the sunrise process that there were births attended by midwives prior to the legalization of the profession. However, reliable data as to the number of pre 1993 births is not available so conclusions about the rate of increase can not be accurately evaluated.

One requirement of midwives is completion of a screening process at the initial meeting between the midwife and client. Since 1994, midwives have referred 173, or 7 percent, of prospective clients to a physician subsequent to the initial screening. The bases for referral are contained in statute and regulations and are related to the possibility of complications during pregnancy or delivery of the infant. An example of the screening form used by midwives is contained in Appendix D.

Since 1994, 210 women were referred to a physician before labor began and an additional 223 were transported to medical facilities during labor. This represents 18 percent of the women initially seeking home deliveries by midwives. The standards for physician referral and transportation requirements are contained in Appendix C.

Mortality and morbidity can be used to evaluate the outcomes of home births attended by midwives. Other factors used to evaluate infants are Apgar scores and birth weights. Apgar scores are an evaluation of the infant after delivery. Health care professionals evaluate the infant on a variety of factors including color, respiration, heart rate, reflexes and muscle tone. Each of these factors is rated from 0 to 2, with 10 being a perfect score. Infants are evaluated several times after delivery. If an infant has an Apgar score under seven at the five minute evaluation, the Apgar score is considered low.

Midwives are trained in Apgar evaluation practices and are required to report the scores for the births that they attend. Table 5 compares Apgar scores for infants delivered by direct-entry midwives to those in the general population. Table 6 on the following page compares low birth weights, as reported to the Colorado Department of Public Health and Environment, Health Statistics Section.

Literature promoting home births by direct-entry midwives claim that home births are less stressful for both the mother and infant. Midwives purport that they take a more active and proactive role in the overall well being of the mother during pregnancy. These claims, combined with the fact that midwives are prohibited from providing care to high-risk pregnancies should result in improved outcomes for women and infants cared for by midwives.

As can be seen from Tables 5 and 6, home births by midwives have fewer instances of low birth weights and Apgar scores as compared to hospital births in Colorado. Midwife attended births also have better outcomes than the national average in these categories. This is somewhat surprising since Colorado has historically had a higher risk for low birth weight babies.

Table 5

Low Infant Apgar Scores

YEAR	CO. HOME BIRTHS	ALL CO. BIRTHS
1994	NA	1.3%
1995	.7%	1.3%
1996	2.1%	1.3%
1997	.5%	1.3%
1998	2.2%	1.3%
1999	.4%	1.3%
AVERAGE	1.2%	1.3%

Source: Data compiled from Colorado Department of Health and Environment, Colorado midwife registry statistics, and the National Center for Health Statistics.

Table 6

Low Birth Weight

YEAR	CO. HOME BIRTHS	ALL CO. BIRTHS	UNITED STATES
1994	NA*	8.6%	7.2%
1995	1%	8.5%	7.3%
1996	1.5%	8.9%	7.4%
1997	1%	8.9%	7.5%
1998	1.4%	8.7%	7.6%
1999	1%	NA	NA*
AVERAGE	1.2%	8.8%	7.5%

Source: Data compiled from Colorado Department of Health and Environment, Colorado Midwife Registry Statistics, and the National Center for Health Statistics.
*Data not available.

A major concern of health care professionals and proponents of midwife attended births is the heath and viability of infants. One standard measure used nationally is the infant mortality rate, which averages 7.3 infant deaths per 1000 live births. However, this figure is misleading because infant mortality is calculated using all infant deaths from birth to one year of age. This figure includes infants who die from birth complications and those who die from other causes, such as automobile accidents.

Another standard measure is neonatal deaths. A neonatal death is one that occurs in the first month of life. While this also includes deaths from all causes, not just complications from birth, it is more likely that a death within the first month of life is related to birth issues. Table 7 below compares the neonatal deaths of midwife attended births to those in the general population in Colorado and nationally. As the data demonstrates, midwife attended births show a much lower death rate than the general population. To some extent, this is expected, since midwife attended births are lower risk and should have fewer complications.

Table 7

Neonatal Deaths

Year	Midwife Attended	Colorado	National
1993	0	4.2	5.3
1994	3.4	4.2	5.1
1995	0	4.2	4.9
1996	0	4.5	4.8
1997	0	4.9	4.8
1998	0	4.6	4.3*
1999	2.6	4.5	NA**
Average	.9	4.5	4.7

*Preliminary data from National Center for Health Statistics6 ** Data not available.

Colorado is one of only eight states that require the reporting of early term spontaneous fetal deaths. Spontaneous fetal deaths, commonly called miscarriages, occur most frequently in the early stages of pregnancy. Fetal deaths are divided into two categories, those that occur at less than 20 weeks of pregnancy (early term) and those that occur at over 20 weeks of pregnancy (late term). Nationally, only data on fetal deaths over 20 weeks is maintained. According to the Colorado Department of Public Health and Environment early stage miscarriages are under reported, since many women may not even know they are pregnant when they miscarry in the early stages of pregnancy.

The midwife program collects data on fetal deaths but does not differentiate between late term and early term deaths. In addition, while reviewing the data collected, it was noticed that some midwives incorrectly included fetal deaths in the infant death reporting. This required some adjusting of the data provided by the program. Table 8 compares overall reported fetal deaths for midwife attended pregnancies with the Colorado population as a whole.

Table 8

Fetal Demise Per 1,000 Live Births

Year	Midwife Attended*	All Colorado Births**
1994	Not Available	36.2
1995	17.4	33.5
1996	5.2	33.5
1997	4.3	29.6
1998	7.6	28.3
1999	15.2	Not Available

* Provided by the Midwives Registration Program
** Provided by the Health Statistics Section, CDPHE

Interviews with midwives and women who have experienced home births found strong support for continuation of the program. Advocates for midwife attended births believe it is a right of women to choose home births over hospital births and cite a belief that hospital births are frequently an impersonal experience where a physician controls the process with little or no input from the mother. They also expressed concern that some physicians encourage unnecessary medical intervention during hospital births.

Midwives and supporters claim that there is bias in the medical community against midwife attended births. They cite difficulties in obtaining required lab reports from medical facilities. Many midwives report difficulties in obtaining recommended medical backup from physicians. Midwives and physicians assert that major medical malpractice carriers threaten to withdraw a physician's insurance if they formally provide support to midwives.

These contentions are difficult to document. However, interviews with individual physicians and communications with the BME, the Colorado Medical Society and the Colorado Gynecological and Obstetrical Society clearly show that there is little or no collaboration between physicians and midwives. Most medical organizations either declined to take a formal position or opposed midwife attended births. This combined with the fact that most complaints against midwives are brought by physicians or hospital administrators could lead one to conclude there is at least informal resistance in the medical community to recognizing midwives as health care professionals.

During the course of this sunset review, DORA interviewed and requested input from a variety of licensed health providers and their professional associations, including the Colorado Board of Medical Examiners, the Colorado Medical Society, the Colorado Gynecological and Obstetrical Society and individual physicians. The majority of these organizations and individuals indicated a lack of knowledge regarding the role of a midwife, midwife regulation, and midwife qualifications. Many of the complaints by medical professionals are not found to be violations of the Act. In one instance, a physician complained that a midwife failed to administer Pitocin (an anti-hemoragic drug) following a home delivery. This "failure" allegedly led to excessive blood loss, potentially placing the mother's life in jeopardy. In fact, the Act prohibits midwives from administering any pharmaceuticals except oxygen and prophylactic eye treatment.

The enabling legislation for midwife registration contains provisions that protect physicians and insurance carriers from liability when a physician provides assistance to a mother or infant who are under the care of a midwife. Section 12-37-109, C.R.S., states that no medical facility, licensed physician, nurse, or emergency medical personnel can be held liable for any act or omission resulting from care rendered by a registered direct-entry midwife. In fact, individuals and facilities identified in this section are only liable for willful and wanton acts committed by themselves or their employees. This is an extremely difficult standard to meet in a liability claim and virtually renders physicians and hospitals safe from any claims resulting from supporting a registered midwife. Midwives are required to inform all prospective clients of this liability provision.

The statute also requires midwives to carry liability insurance when the Director finds that such insurance is available at an affordable price. To date, the Director has not found insurance carriers to market a liability product to midwives at an economically feasible price. This is despite the fact that the use of midwives is increasing, creating a larger market for an insurance product. The General Assembly has established public policy allowing midwifery services to be available to the citizens of Colorado. It appears there is some validity to charges by midwife supporters that the insurance industry has a policy counter to that supported by the elected officials of the state. In a similar situation, the State of Washington created a Joint Underwriting Association in 1993 to ensure that licensed midwives have access to malpractice insurance. Washington State legislation requires certain insurance carriers offering malpractice insurance in health care fields to offer malpractice insurance to midwives.

Recommendation 1 - Continue the Regulation of Direct-Entry Midwives Until July 1, 2006; Continue the Midwife Exemption to the Medical Practice Act Contained in §12-36-106(1)(f)(II), C.R.S.; and Change Legislative References from Registered to Licensed.

In April of 1999, the Pew Health Professions Commission and the University of California, San Francisco Center for the Health Professions issued a joint report entitled "The Future of Midwifery." This report made some interesting findings. As an example, although the United States spends more per capita on health care than any other country, 24 nations have lower infant mortality rates. The report also found large disparities in the costs of births at hospitals compared to birthing centers. The report found that the costs for hospital births were not justified by the outcomes in most cases.

Worldwide, the use of hospitals and physicians for births is the exception rather than the rule. According to the Pew report, only the United States and Canada use physicians more extensively than midwives in the care of pregnant women. The use of midwives for routine deliveries is the norm in most industrialized countries.

According to the National Association of Childbearing Centers (NACC), in 1995, a typical vaginal delivery in a hospital cost an average of $6,378. Approximately 60 percent of this cost was for the use of the hospital facility. Approximately 40 to 45% of the delivery cost was attributed to the professional services of the physician. Birthing center deliveries, usually attended by nurse midwives, averaged almost half the cost at $3,241. Nationally, reliable data on costs for direct-entry midwives is not available. However, registrants contacted for this report indicated fees substantially less than those reported by the NACC for physicians and nurse midwives.

All indications are that when properly educated, trained, and regulated, direct-entry midwives provide a safe birthing experience for those women who choose this alternative. Infants born in traditional home birth settings with a midwife in attendance have similar outcomes as those born in hospitals under the supervision of a qualified physician, provided that proper qualification criterion is used to restrict home births to those women who are at low risk for complications.

The State of Washington has over 20 years experience in regulating direct-entry midwives. The PEW report cited several Washington studies. One study indicated that the only statistical difference in outcomes found between low-risk hospital births and home deliveries by midwives was that midwife attended births had fewer instances of low birth weight babies. Another study reported positive results for Medicaid eligible women choosing home births attended by direct-entry midwives. [2]

Midwife attended births are not universally embraced by the medical community. However, there is a segment of the population that desires the option of a home birth attended by a midwife. That population will obtain the services of a midwife whether the medical community approves or not, and, whether the practice is legal or not.

The review of the midwife program found that the regulation of midwives is necessary to protect the public. While childbirth is a natural event, it does have risks to both the mother and infant and should be attended by qualified professionals. This report recommends continuing the regulation of midwives. The continued regulation of midwives also requires an extension of the exemption to the Medical Practice Act, contained in §12-36-106(1)(f)(II), C.R.S.

[2] Dower CM, Miller JE, O'Neil EH and the Taskforce on Midwifery. *"Charting a Course for the 21st Century: The Future of Midwifery*". San Francisco, CA: Pew Health Professions Commission and UCSF Center for the Health Professions. April, 1999. (p 25)

Registered vs. Licensed

The Colorado direct-entry midwife registration program is in fact a licensing program. In the regulatory scheme, registration is the least restrictive form of regulation. A true registration program requires no education or experience standards. The purpose of the registration is merely to alert the public to the correct address of the registered individual for purposes of process serving in the event it is necessary for a civil action.

When a regulatory requirement contains qualifications or standards for individuals before registration, it is more accurately termed a certification program. Certifications in the true sense are like high school or college diplomas, where an organization certifies that an individual has obtained a specific level of training or education.

Only a licensing program requires applicants to meet minimum standards before being allowed to practice a profession and the ability of the state to remove or restrict (discipline) the ability of the individual to practice. In reality, the current direct-entry midwife registration program is a licensing program and should correctly be referred to as such. Thirteen of the 15 states with formal regulatory programs for direct entry midwifery license midwives. Nine of these 13 states authorize licensed midwives to be reimbursed by Medicaid and other third-party insurers.

Recommendation 2 - The General Assembly Should Increase the Educational Standards for Licensure, Increase the Minimum Practical Experience Requirement, and Allow Greater Flexibility to Grant Credit for Actual Experience.

A formal apprenticeship is an accepted method of entering many professions. As recently as 30 years ago, pharmacists were attaining licensure in Colorado without formal college education. However, most health care professions currently require formal education to be combined with practical experience in the form of an internship or apprenticeship as a standard for licensure.

When Colorado began regulating midwives in 1993 there were few national standards for midwives, and almost no formal educational programs. The North American Registry of Midwives (NARM) now has a nationally recognized certification for midwives. This certification accepts approved education and training in areas such as medication administration. In addition, the Midwives Education Accreditation Commission (MEAC) now approves formal education programs for midwives. It is in the public interest to require direct entry midwives in Colorado to obtain nationally recognized education and training to practice in this state.

It may be argued that requiring formal education in Colorado places an undue burden on persons seeking to enter the profession. It is true there are no MEAC accredited educational programs available in the state. However, there are programs in nearby states such as New Mexico, Arizona and Utah, and, according to MEAC, more programs are being developed.

The availability of local, approved educational programs should not be a determining factor in the requirement. It is common for states to require education not available locally in order to obtain a license. For example, every state requires graduation from an accredited veterinary school as a condition for licensure as a veterinarian. However, few states actually have a veterinary medicine school within its borders. Further, the State of Colorado did not have an accredited dental school until fairly recently. Therefore, dentists attended schools in other states prior to being licensed in Colorado.

Licensure as a midwife should require some formal education in the health care field. The Director should be allowed the flexibility to accept college education in related fields, such as nursing, or other health care fields. Applicants should still be required to obtain field experience through an internship or apprenticeship with a midwife. Formal education does not replace the benefit of practical experience with actual patients but does establish a foundation of knowledge deemed necessary to practice safely.

The requirements in the registration provision of the Act should be amended to read:

12-37-103(5)(c) Graduation from an accredited educational program or obtain substantially equivalent education approved by the Director. Such education must include training 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;

(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); and

(X) Medication administration.

Very few of the currently registered midwives in Colorado have graduated from an accredited program. Those midwives without the necessary education should be allowed two years to meet the new standard. Until these registrants obtain the necessary education, they should be prohibited from exercising the medication privileges contained in recommendation 3. This will result in the temporary existence of two tiers of regulation for the profession, similar to the various levels of licensure contained in the Optometrists regulations. However, once the two year grace period has expired, there will be a single standard for licensure.

The current regulatory requirements for registration as a midwife include a provision for assisting 30 home births as an apprentice and then performing an additional 30 home births as primary attendant under supervision. This is a very low number of births attended before becoming licensed. The General Assembly should consider increasing the minimum number of births attended as a secondary and primary attendant in the apprenticeship program. Both Washington and Florida require 50 supervised births as a condition for licensure.

In addition, this language does not allow for credit to be given for births attended in settings other than a home birth. A strict interpretation would not allow any birth experience credit to a licensed Certified Nurse Midwife with years of experience and attendance at thousands of births in regulated facilities. The General Assembly should allow the Director to promulgate regulations accepting attendance at births other than home births attended by a midwife for credit in the experience category.

Recommendation 3 - Update §12-37-105, C.R.S., to Permit the Administration of Approved Medications to Infants and Mothers During the Labor, Delivery, and Postpartum Periods and to Suture First and Second Degree Tears of the Peritoneum.

A concern of many women who chose home births by midwives is the alleged overuse of medical intervention in the birth process. Physicians have been accused of intervening in the natural birth process for reasons other than to protect the health and safety of the mother or infant. *Healthy People 2000* is a series of health care goals established by a consortium of health care organizations, staffed by the Federal Department of Health and Human Services. This consortium established a goal for cesarean deliveries of fewer than 15 percent of all deliveries. While Colorado is close to achieving that goal according to recent statistics, nationally, over 20 percent of all births are still being performed via cesarean.

Cesarean deliveries may represent the extreme of medical intervention. However, it is not the only form of intervention that many view as unnecessary. It has been alleged that some physicians have induced or stimulated labor when it is not medically necessary. The percentage of induced labor increased from 9 percent in 1989 to 16.9 percent in 1996. During this same time period labor stimulation increased from 10.9 percent to 16.9 percent according to the National Center for Health Statistics.

Even though minimum medical intervention is a goal of most midwives and their clientele, medical intervention is sometimes necessary to protect the patients involved in the delivery. Currently, midwives are required by §25-4-303, C.R.S., to administer prophylactic eyewash to newborn infants. Midwives who have undergone approved training may administer oxygen when necessary to women in labor. Since these procedures have been adopted by the General Assembly there have been no reported incidences of abuse or misuse by midwives.

The majority (13 of 15) of states that regulate direct entry midwives authorize regulated midwives to purchase, posses, and administer approved medications. These states require approved training prior to permitting midwives to incorporate medication privileges into their practice. These states report there have not been issues of diversion or complaints about misuse of the medications. Table 9 identifies the authorized medication administration practices in states with midwifery regulatory programs.

TABLE 9

COMPARISON OF MEDICATION AUTHORIZATIONS

STATE	Eye Prophylaxis	Pitocin	Methergine	Vitamin K	Rhogam	o2	IV	Local Anesthesia	Suturing
AK	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
AR	No	No	No	No	No	No	No	No	Yes
AZ	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
CA	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No
CO	Yes	No	No	No	No	Yes	No	No	No
FL[1]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	yes	Yes
LA	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes
MN[1]	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes
MT[1]	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes
NH	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
NM	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
OR	Yes	Yes	Yes	Yes	No	Yes	No	No	No
SC	Yes	Yes	No	No	No	Yes	No	No	No
TX[1]	Yes	No	No	No	No	Yes	No	No	No
WA[2]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

1 Other medications authorized by a physician
2 The director may authorize additional medications by rule, Epinephrine, Magnesium Sulfate, Rubella Vaccine have been authorized.

To protect the safety of mothers and infants, Colorado should expand the ability for licensed midwives to carry and administer medications, provided they have demonstrated through education and examination that they are qualified to do so. If the education requirements contained in recommendation 2 are adopted, newly licensed midwives will have the necessary medication training since it is part of the accredited program.

Currently, registered midwives who obtained their training through an apprenticeship program should have the option of attending a training program approved by the Director to be authorized to expand their practice to include medication administration. This would create a two-tiered licensing program similar to that currently in place for optometrists. In the optometrist program, licensees who have undergone an approved training program described in §12-40-109.5(1), C.R.S., are granted an expanded practice certification which authorizes them to diagnose and treat ocular conditions.

There are situations that are considered part of the normal birth process in which medical intervention is not only desirable, but also necessary. Women whose blood type are RH negative and carry an RH positive fetus are at high risk for developing antibodies which will severely affect subsequent RH positive fetuses. An injection of a medication known as Rhogam within 72 hours of delivery will prevent the formation of these antibodies and protect future infants. Rhogam is routinely administered in hospital deliveries when an RH incompatibility exists. A mother in a home delivery situation would have to travel to a physician to have Rhogam prescribed and administered. Physicians are reluctant to prescribe for women who are not their patients. This puts future children of RH negative women at unnecessary risk.

Another routinely administered medication in hospital deliveries is Vitamin K. Vitamin K is administered to infants after delivery to stimulate the natural blood clotting functions of the body. Hemorrgagic Disease of the Newborn (HDN) is found in approximately 1 in 100,000 live births. Oral forms of Vitamin K, available without a prescription, have been found to reduce the incidence of HDN to .44 per 100,000 births. Prescription Vitamin K injections have been found to virtually eliminate the risk of HDN. Although HDN is not a common problem, the ease of eliminating any risk to a newborn warrants the use of Vitamin K by injection in home deliveries.

The third medication the General Assembly should permit midwives to administer is more controversial. Vitamin K and Rhogam have very specific uses and would not be administered for any other purpose. Pitocin is a synthetic oxytocin, which stimulates uterine contractions. Depending on when and how Pitocin is administered it can be used to induce or stimulate labor or to treat postpartum hemorrhage.

The use of Pitocin to stimulate or induce labor should only be done under the supervision of a physician when medically necessary. However, the use of the drug to prevent hemorrhaging is a life saving measure that should not be limited to use in a medical facility.

If it were possible to accurately predict which women were likely to hemorrhage following a delivery it would be practical to consider these women high risk and include them in the list of women that should be screened from home births. However, an accurate screening mechanism for this condition does not exist.

Therefore, midwives should be authorized to carry and dispense Pitocin intravenously to treat postpartum hemorrhage. However, if the hemorrhaging is severe enough to require the administration of Pitocin, transportation to a medical facility should be mandatory. It is interesting to note that at least one complaint to the Director was by a physician who believed that the failure of the midwife to administer Pitocin placed a mother's life at risk.

The General Assembly should also authorize midwives to suture first and second degree tears of the peritoneum. A local anesthetic while not necessary for this type of repair is typically used. Therefore, the General Assembly should authorize qualified midwives to carry and use a local anesthetic for repairs of first and second degree tears only. To implement this provision §12-37-105, C.R.S., should be amended to read:

(14) Direct-entry midwives, for purposes of repairing first and second degree tears of the peritoneum, are authorized to carry and administer a local anesthetic.

The Act already requires the Director to approve training for midwives using oxygen. The training program can be expanded to include instruction on the administration of these other medications. The pharmacist statute should be amended to insert language absolving them of any liability for the misuse of any medications dispensed to a licensed midwife. The provision could be modeled after the language used in the Washington statute.

The practice standards provisions of the Act should be amended at §12-37-105(13), C.R.S., to read:

> It shall be lawful for a registered direct-entry midwife to purchase, possess, carry, and administer oxygen, prophylactic ophthalmic medication, vitamin K, Rho Immune globulin (Rhogam), and may administer such other drugs or medications as prescribed by a physician. A licensed midwife may administer oxytocic, (Pitocin) postpartum if the administration is followed by transport to a licensed medical facility in accordance with the approved emergency plan. A pharmacist who dispenses such drugs to a licensed midwife shall not be liable of any adverse reactions cased by any method of use by the midwife. The department of regulatory agencies shall promulgate rules concerning minimum training requirements for direct-entry midwives with respect to the safe administration of medications to patients. Each direct-entry midwife registered pursuant to this article shall complete the minimum training requirements and submit proof of having completed such requirements to the director before administering medication to any patient.

Adoption of this language will require a change to §12-37-105 (1), C.R.S., to allow midwives to administer these medications. This provision should be amended to read:

> A direct-entry midwife shall not dispense or administer any medication except those authorized by this section or prescribed by a licensed physician or advanced practice nurse.

Recommendation 4 - Eliminate the Prohibition Against Dual Licensure for Direct-Entry Midwives.

Colorado initially prohibited licensed health care professionals from registering as direct-entry midwives. This prohibition was loosened as a result of the 1995 sunset to allow acupuncturists to register as midwives. There is no data to support continuation of this prohibition as a public protection measure.

An argument used to support the prohibition was the potential for licensees in other fields to avoid discipline by using the midwife registration as a shield, claiming, for example, the Board of Nursing has no jurisdiction over actions of a licensed nurse while performing midwife services. In fact, the standards of care for a midwife are based on the same standards used in the medical models. Any violations of these standards would also be violations of the standards for other health care licenses. In addition, the fact that the Board of Medical Examiners has sought joint status in some midwife disciplinary actions indicates that there can be cooperation between the midwife and other health care regulatory programs.

Continuing this prohibition can only perpetuate the negative attitude prevailing with some licensed health care professionals. This will continue to inhibit collaboration between midwives and other health care professionals. Experiences in other countries, supported by the findings in the Pew report, are that the most beneficial birthing experience is when midwifes, physicians, and other health care professionals work together. The General Assembly should repeal §12-37-101(1), C.R.S. and renumber the remaining subparagraphs of this section.

Recommendation 5 -The General Assembly Should Eliminate the Reporting Requirements Contained in §12-37-105(12), C.R.S.

It appears to be the intent of the General Assembly to monitor the overall effectiveness of the midwife program by requiring the collection of data from midwife attended births. However, the data collected by the program on renewal notices has been found to be inaccurate, and not useful in analyzing the program.

For data to have use, it should have some statistical basis for comparison purposes. The Colorado Department of Public Health and Environment (CDPHE) collects information on all births and deaths statewide. The statistics collected by CDPHE are not in the same format as those collected by the program, making comparisons impractical.

The CDPHE has the ability to separate midwife attended birth information from the overall birth records in a format that allows comparisons. Much of the data collected by the midwife program is also collected by CDPHE, in a more useful format. Therefore, the majority of the midwife program data is duplicative and unnecessary.

CDPHE does not collect data regarding the number of women who received midwife care, only midwife attended births. In addition, the number of physician referrals is not recorded. However, since other states do not collect this data either, it is not possible to compare the Colorado program with other states in this area. Therefore, the usefulness of the information is questionable.

Other licensed health care providers are not required to report proprietary practice information in order to renew their professional license. The collection of this information is not necessary to protect the health and safety of the public and is inconsistent with sunset criterion II "…whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest…"

Recommendation 6 - The General Assembly Should Amend §12-37-109, C.R.S., to Eliminate Unnecessary Restrictions on the Recognition of Midwifery as a Health Care Profession.

Section 109 contains conflicting provisions that do not represent clear public policy regarding the regulation of midwifery. Paragraph (1)(a) relieves other health care licensees from liability in treating patients of midwives except in instances of extreme negligence. The last sentence of the paragraph allows licensed health care professionals to enter into a consultation arrangement with a midwife without establishing a business relationship, further protecting the licensee from liability. This could be interpreted to encourage physicians and other health care providers to work collaboratively with midwives without fear of personal or professional liability.

However, paragraph (1)(b) states that the General Assembly is not going to recognize midwifery as a licensed health care profession for purposes of the medical liability provisions of §13-64-302, C.R.S. The medical liability provision provides a cap on tort claims for individuals licensed in the healing arts, except midwives. Midwives are regulated as licensed health care providers and should be recognized as such by all applicable state statutes. This exclusion in this provision does not serve a public protection purpose.

Paragraph (2) of this section goes on to state that midwives should not be considered licensed health care providers for the purposes of reimbursement by insurers and third party payers of government health care programs. As previously discussed, costs for home births are significantly less than those for hospital births. It makes economic sense to allow direct entry midwife attended home birth as an option for consumers who are eligible for Medicaid and other third party insurance. In addition, midwife attended births have fewer instances of low birth weight babies, which present the potential for increased medical expenses.

The state expends large amounts of resources on low income births and low birth weight infants. It would seem to be in the best interest of the state to utilize a safe, effective, low cost alternative to physician attended births in low risk pregnancies rather than legislating against such a practice.

Recommendation 7 - Allow the Director to Issue Cease and Desist Orders.

Currently the Director may seek a court injunction against individuals who are engaged in prohibited activities. This is a time consuming and expensive activity. It is more cost effective and provides a more immediate consumer protection to allow the Director to issue a cease and desist order. If the individual ignores the cease and desist order the Director may proceed with an injunction.

Recommendation 8 - Technical Housekeeping Amendments to Improve the Efficiency of the Program.

The following proposed amendments to the Act were agreed upon by the program staff, the Attorney General staff, and industry representatives as meeting the intent of sunset criterion IX "…statutory changes are necessary to improve agency operations to enhance the public interest."

8a Delete the phrase "for compensation" from the definition of direct-entry midwife in §12-37-102(1), C.R.S.

The Director has received complaints against unregistered individuals practicing midwifery that have not resulted in disciplinary actions because the individuals do not receive compensation. In one situation, the midwife claimed to have performed the service for members of her church as a ministry. Church members who make contributions to the church are eligible for free midwifery services.

Religious exemptions are routinely given for certain services performed by trained, recognized clergy members. For example, the mental health statutes exempt clergy from licensure as marriage counselors. It is also common to allow people to refuse some medical procedures on religious grounds, certain inoculations required for admission to public schools for example. However, the public is not protected by allowing individuals to practice midwifery without oversight simply because the practitioner is affiliated with a religious organization.

8b Amend §12-37-105, C.R.S., to include:

(15) A direct entry midwife is prohibited from practicing beyond the scope of education and training or from practicing with a mental or physical impairment sufficient to render the licensee unable to perform midwifery services with reasonable skill and with safety to the patient.

These are standard prohibitions in health care practice acts designed to protect the public from unsafe practices by regulated professionals. It is reasonable to include these safeguards in the Midwives Practice Act.

8c Remove the prima facie provisions from §12-37-107 (3)(f), C.R.S.

The language in the Act stating that disciplinary actions in other states against a midwife's credentials, health care license, or the conviction of a criminal act may be grounds for discipline in Colorado is consistent with other health care license acts. However, the phrase that these actions constitute prima facie evidence has resulted in unnecessary legal proceedings and expenses by the Director to prove a case that has already been adjudicated. The language should be changed to be consistent with other professional licensing acts.

8d Provide that appeals of final agency actions should be heard in the Colorado Court of Appeals.

The disciplinary provisions of the Act require that all disciplinary actions utilize the processes of the Administrative Procedure Act (APA). Due process provisions of the APA provide for appeals of final agency actions. However, the APA does not specify that appeals should be made to the Colorado Court of Appeals. This means that appeals could be made in a district court, with a subsequent appeal to the Appellate Court. This creates the potential for unnecessary expense for the licensee and the program and delays in final decisions being rendered. It would be consistent with other programs to require all appeals to be made directly to the Court of Appeals.

Appendix A - 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 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 not 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; and

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

Appendix B - Midwives Practice Act

ARTICLE 37

Midwives

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, but a health care provider who is registered under article 29.5 of this title may 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) (Deleted by amendment, L. 96, p. 395, § 2, effective April 17, 1996.)

(4.5) A person who has had his or her registration revoked shall not apply for reregistration until at least two years have elapsed since the date of the revocation.

(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 nineteen 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) 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) 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:

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

(D) 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;

(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, 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.

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

(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 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) (a) (II).

(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.

(13) It shall be lawful for a registered direct-entry midwife to 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 to patients. Each direct-entry midwife registered pursuant to this article shall complete the minimum training requirements and submit proof of having completed such requirements to the director before administering oxygen to any patient.

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 education standards for applicants and to adopt a registration 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 - grounds for discipline. (1) If a direct-entry midwife has violated any of the provisions of section 12-37-103, 12-37-104, 12-37-105, or 12-37-109 (3), 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, 12-37-105, or 12-37-109 (3). 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.

(3) The director has the power to deny, revoke, or suspend any registration or to issue a letter of admonition or place a registrant on probation for any of the following acts or omissions:

(a) Any violation of the provisions of section 12-37-103, 12-37-104, 12-37-105, or 12-37-109 (3) or any rule promulgated pursuant to section 12-37-106 (1) (a);

(b) Failing to provide any information required pursuant to or to pay any fee assessed in accordance with section 12-37-103, or providing false, deceptive, or misleading information to the division of registrations that the direct-entry midwife knew or should reasonably have known was false, deceptive, or misleading;

(c) Engaging in any act or omission that does not meet generally accepted standards of safe care for women and infants, whether or not actual injury to a patient is established;

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

(e) Has procured or attempted to procure a registration in this or any other state or jurisdiction by fraud, deceit, misrepresentation, misleading omission, or material misstatement of fact;

(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.

(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 agency of another state or jurisdiction may be considered to be the same as a finding of violation for purposes of a proceeding under this article.

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

(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.

(j) Has violated any provision of this article or has aided or knowingly permitted any person to violate any provision of this article; 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.

(4) Any proceeding to deny, suspend, or revoke a registration or place a registrant on probation 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 of article 30 of title 24, C.R.S.

(5) The director may accept as prima facie evidence of grounds for disciplinary action any disciplinary action taken against a registrant by another jurisdiction if the violation that prompted such disciplinary action would be grounds for disciplinary action under this article.

(6) To aid the director in any hearing or investigation instituted pursuant to this section, the director shall have the power to issue subpoenas commanding the appearance of persons and the production of copies of 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 provider of such copies shall prepare the copies from the original record and shall delete the name of the patient, to be retained by the custodian of the records from which the copies were made, but shall identify the patient by a numbered code. Upon certification by the custodian that the copies are true and complete except for the patient's name, the copies 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 respect to such copies and no liability shall lie against the director or the custodian or the director's or custodian's authorized employees for furnishing or using such copies in accordance with this 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 the director finds that liability insurance is available at an affordable price, the direct-entry midwife shall be required to carry such insurance.

12-37-109.5. Immunity. 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 ascertain the facts of the matter as to which he or she acts, and acts in the reasonable belief that the action taken by him or her is warranted by the facts. The immunity provided by this section shall also extend to any person participating in good faith in any investigative proceeding pursuant to this article.

12-37-109.7. Confidential files. The director may keep confidential all files and information concerning an investigation authorized under this article until the results of such investigation are provided to the director and either the complaint is dismissed or notice of hearing and charges are served upon the registrant.

12-37-110. Repeal of article. (1) This article is repealed, effective July 1, 2001.

(2) Prior to such repeal, the registering of direct-entry midwives by the division of registrations shall be reviewed as provided in section 24-34-104, C.R.S.

Appendix C - Rules and Regulations

MINIMUM PRACTICE REQUIREMENTS
General Authority C.R.S. 12-37-106
Section 12-37-105

1. RESTRICTIONS

1.1 The registered direct-entry midwife shall not provide care to any woman whose medical history shows the following:

a. Diabetes mellitus or gestational diabetes;

b. Hypertensive disease (BP greater than 140/90 at rest);

c. Pulmonary disease or cardiac disease which interferes with activities of daily living;

d. A history of thrombophlebitis or pulmonary embolism;

e. Blood dyscrasia, for example sickle cell anemia;

f. Seizures controlled by medication if the mother has seized within the last year;

g. Hepatitis B, HIV positive or AIDS;

h. Current use of psychotropic medications;

i. Current substance abuse (drugs or alcohol);

j. Rh sensitization (positive antibody titre), an incompetent cervix; or previous uncontrollable postpartum hemorrhage; or

k. The midwife shall not provide care to any woman who has had a previous cesarean section whose emergency plan does not include the ability to transport, within 30 minutes, to a facility able to perform a cesarean section or,

l. Infants who were premature, stillborn, or neonatal deaths associated with maternal health or genetic anomaly without an intervening normal pregnancy

1.2 The registered direct-entry midwife shall not:

a. Perform any operative or surgical procedures;

b. Utilize any instruments or mechanical means of delivery, other than hemostats to clamp the cord;

c. Perform versions; or

d. Administer any medications except for eye prophylaxis of the newborn.

2. ANTEPARTUM CARE

2.1 The registered direct-entry midwife shall schedule patient visits at least once a month from the first trimester through 28 weeks; every 2 weeks from 28 weeks through 35 weeks; and weekly from 36 weeks to delivery.

2.2 At the time of the initial visit for care the registered direct-entry midwife shall, at a minimum:

a. Obtain a medical, obstetrical, family and nutritional history;

b. Determine the EDC and perform a baseline physical examination;

c. Arrange to or obtain laboratory testing to include: blood group and Rh type, if unknown; Coombs test for all Rh negative mothers; CBC with differential; rubella titre; serology for syphilis; hepatitis B screen, urine for protein and glucose, culture if indicated; GC screen and/or Chlamydia culture if needed based on social history, offer HIV testing;

d. Discuss home birth, options to home birth, risk assessment and referral procedures; and

e. Provide the client the Mandatory Disclosure form and obtain informed consent on forms provided by the Director. Complete the emergency plan.

2.3 Care consistent with generally accepted standards of safe care for women and infants during each prenatal visit shall include, at a minimum, but not be limited to:

a. Vital signs and weight;

b. Urine dipstick for protein and glucose;

c. Assessing for:

(1) Edema, headaches, visual disturbances, dizziness or sharp pains in legs, abdomen, chest or head and reflexes if indicated;

(2) Mother’s psychological and emotional status;

(3) Nutritional status;

(4) Fundal height and

(5) Fetus for gestational age, presentation and position; estimated fetal weight; fetal activity, listen for fetal heart tones and record when first audible;

d. Chart all findings, interventions and outcomes including the quickening date;

e. Provide teaching, guidance and referral as appropriate;

f. Discuss the emergency plan and revise if needed.

2.4 Laboratory studies are repeated during pregnancy including Indirect Coombs test at 28 and 36 weeks, if indicated; Hemoglobin and/or Hematocrit at 28 and 36 weeks; and a one Hour Glucose Tolerance Test with a minimum of a 50 Gram glucose loading dose shall be offered to the patient at 26-28 weeks;

2.5 At least one home visit shall be made during the third trimester to assure that environmental conditions are appropriate, supplies are procured and birth participants are prepared for the home birth.

2.6 The registered direct-entry midwife shall refer mothers for evaluation by a qualified licensed health care provider and shall not continue as the care provider when a multiple gestation or a presentation other than vertex at the onset of labor are noted.

2.7 The registered direct-entry midwife shall refer mothers for evaluation by a qualified licensed health care provider and shall not continue as the primary care provider without the mother's consultation with a health care provider when the following conditions are noted until the mother has been assessed by the licensed health care provider and that provider has determined, based upon generally accepted medical standards, the pregnant woman is not exhibiting signs or symptoms of increased risk of medical or obstetrical or neonatal complications or problems during the completion of her pregnancy, labor, delivery or the post partum period, and is not exhibiting signs and symptoms of increased risk that her child may develop complications or problems during the first 6 weeks of life:

a. Urine glucose of 2+ or greater on two sequential visits or if other signs or symptoms of gestational diabetes occur with the urine glucose;

b. Hyperemesis beyond the 24th week of gestation;

c. Hypertension - BP greater than 140/90 or an increase from the baseline of greater than 30 mm Hg in the systolic or 15 mm Hg in the diastolic pressure;

d. Signs and symptoms of preeclampsia including but not limited to persistent edema, increased blood pressure or proteinuria, increased reflexes, persistent headaches, epigastric pain or, visual disturbances;

e. Seizures;

f. Vaginal bleeding after 20 weeks;

g. Signs and symptoms of urinary infections or sexually transmitted disease;

h. Oral temperature in excess of 101. 0 F for more than 24 hours accompanied by other signs or symptoms of clinically significant infection, or, which does not resolve within 72 hours;

i. Laboratory results indicating need for medical treatment, for example, a positive culture;

j. Anemia not responding to over the counter iron therapy as measured by Hemoglobin below 11 grams or Hematocrit below 34% at term;

k. Signs and symptoms of polyhydramnios or oligohydramnios;

l. Suspected fetal demise - lack of fetal movement, inability to auscultate fetal heart tones;

m. Decreased fetal movements;

n. Gestation longer than 42 weeks;

o. Rupture of membranes for longer than 12 hours without labor;

p. Premature labor - less than 37 weeks gestation;

q. Active herpes;

r. Intrauterine growth retardation; or

s. Suspected abnormality of pelvis;

2.8 The Registered Direct-Entry Midwife shall perform pervimetry by 36 weeks gestation.

3. INTRAPARTUM CARE

3.1 The direct-entry midwife is responsible for making arrangements to be with the patient by the time labor has been established as determined by contractions occurring every 5 minutes or cervical dilation of 5 cm or more, once labor has been so established, the registered direct-entry midwife shall remain with the mother.

3.2 When membranes rupture, the registered direct-entry midwife shall perform a sterile vaginal exam for prolapsed cord if the presenting part is not engaged and record fetal heart tones. In the case of rupture of the membranes without labor, no further vaginal checks shall be made.

3.3 Aseptic technique and universal precautions will be used while rendering care.

3.4 The registered direct-entry midwife is responsible for monitoring the status of the mother and baby during labor and delivery including:

a. Maternal vital signs and physical well being

(1) Maternal temperature, pulse and respirations shall be measured at least every 4 hours, and;

(2) Maternal blood pressure shall be measured at least every four hours in early labor and hourly during the active phase of labor;

(3) Check for bladder distention, signs of maternal fatigue, and hydration status.

b. Fetal vital signs and well being:

(1) Fetal heart tones in response to contractions as well as when the uterus is at rest. These shall be assessed, at a minimum, every hour during early labor, every half hour during active labor and every 5-10 minutes during the second stage of labor;

(2) Normality of fetal lie, presentation, attitude and position

c. Progress of labor including cervical effacement and dilation, station, presenting part and position;

d. Coaching the birthing family;

e. Obtaining a cord blood specimen, if feasible, which shall accompany the infant in case of transport;

f. Checking the placenta and blood vessels and estimating blood loss;

g. Checking the perineum and vaginal vault for tears; and

h. Checking the cervix for tears and, if present, making appropriate referral.

3.5 The registered direct-entry midwife shall arrange for immediate consultation and transport according to the emergency plan if the following conditions exist:

a. Bleeding other than capillary bleeding ("show") prior to delivery;

b. Signs of placental abruption including continuous lower abdominal pain and tenderness;

c. Prolapse of the cord;

d. Any meconium staining without reassuring fetal heart tones, moderate or greater meconium staining regardless of status of fetal heart tones;

e. Significant change in maternal vital signs;

(1) Temperature greater than 101^{o}F

(2) Pulse over 100 with decrease in blood pressure,

(3) Increase in blood pressure greater than 140/90 or an increase of 30 mm Hg systolic or 15 mm Hg diastolic;

f. Failure to progress in labor:

(1) Lack of steady progress in dilation and descent after 24 hours in the primipara or 18 hours in the multipara,

(2) Second stage of labor without steady progress of descent through the mid-pelvis and/or pelvic outlet longer than two hours in the primipara or one hour in the multipara,

(3) Third stage of labor longer than one hour;

g. Fetal heart rate below 120 or above 160 between contractions;

h. Protein or glucose in the urine;

i. Seizures;

j. Atonic uterus;

k. Retained placental fragments;

l. Vaginal or cervical lacerations requiring repair; or

m. Client requests transport.

4. POSTPARTUM CARE

4.1 The direct-entry midwife shall remain with the mother and infant for a minimum of two hours after the birth or until the mother and infant are stable, whichever is longest.

4.2 The direct-entry midwife shall make a follow up visit within 72 hours to assess the progress of the mother and infant. Such visit shall include an assessment of, at a minimum, fundus, lochia, perineum, breasts, nutrition, hydration, elimination, emotional adjustment and bonding.

4.3 The direct-entry midwife shall instruct the mother and family in self care until the follow up visit is done.

4.4 The direct-entry midwife shall refer all Rh negative mothers for Rhogam within 72 hours of the birth.

4.5 The direct-entry midwife shall arrange for consultation and/ or transport when:

a. There is maternal blood loss of more than 500 cc;

b. The mother has a fever of greater than 101^{o}F on any of the second through 10th days postpartum;

c. The mother cannot void within 6 hours after birth;

d. The lochia is excessive, foul smelling, or otherwise abnormal; or

e. There are signs of clinically significant depression (not the "baby blues").

5. NEWBORN CARE

5.1 The direct-entry midwife will perform the following care for the newborn:

a. Apgar scores at one minute and five minutes after birth and at 10 minutes if the 5 minute score is below 7;

b A physical assessment including assessing presence of femoral pulses. Upper and lower extremity blood pressures should be obtained if equipment is available;

c. Eye prophylaxis within 1 hour after birth as provided by CRS 25-4-303;

d. Weigh the infant and measure height and head circumference, check for normal reflexes;

e. Perform a gestational age assessment; and

f. Arrange to or obtain laboratory testing on the infant of an Rh negative mother to include blood type and Coombs test.

5.2 The direct-entry midwife shall arrange for or obtain the required newborn screenings required by CRS 25-4-1004.

5.3 The direct-entry midwife shall recommend that the mother arrange for the administration of Vitamin K by a licensed health care provider soon after birth.

5.4 The direct-entry midwife shall arrange for immediate transport for the infant who exhibits the following signs:

a. Apgar of 7 or less at ten minutes;

b. 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;

c. Inability to maintain body temperature;

d. Medically significant anomaly;

e. Seizures;

f. Fontanel full and bulging;

g. Suspected birth injuries;

h. Cardiac irregularities;

i. Pale, cyanotic, gray newborn; or

j. Lethargy or poor muscle tone.

5.5 The direct-entry midwife will arrange for consultation and/or transport for an infant who exhibits the following:

a. Signs of hypoglycemia including Jitteriness;

b. Abnormal cry;

c. Passes no urine in 12 hours or meconium in 24 hours;

d. Projectile vomiting;

e. Inability to suck;

f. Pulse greater than 180 or less than 80 at rest;

g. Jaundice within 24 hours of birth; or

h. Positive Coombs test.

5.6 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.

6. RECORD KEEPING

6.1 The direct-entry midwife shall keep appropriate records on all patients. All records shall:

a. Be accurate, current, and comprehensive, giving information concerning the condition and care of the client and associated observations;

b. Provide a record of any problems that arise and the actions taken in response to them;

c. Provide evidence of care required, interventions by professional practitioners and patient responses;

d. Include a record of any factors (physical, psychological or social) that appear to affect the patient;

e. Record the chronology of events and the reasons behind decisions made;

f. Provide baseline data against which improvement or deterioration may be judged;

g. Have a signature and date for each entry; and

k. All records shall be made available to the receiving health care provider in the event of transfer of care or the transport of mother and/or newborn.

6.2 The patient records shall include, at a minimum:

a. Risk assessment;

b. Mandatory disclosure form;

c. Informed consent form and emergency plan;

d. Assessments, interventions and recommendations for each prenatal visit;

e. Progress of labor and maternal assessments during labor;

f. Fetal assessments during labor;

g. Apgar scores and newborn examination;

h. Administration of eye prophylaxis;

i. Refusal of care by the mother;

j. Filing the birth certificate as required by CRS 25-2-112;

k. Follow-up postpartum visits; and

l. Statement of verification that one copy of the record was provided to the mother or the health care provider of her choice.

m. Baseline blood pressure determined prior to the end of the second trimester or upon the initial visit if such visit occurs subsequent to the second trimester.

7. EMERGENCY PLAN

The time required for transportation to the nearest facility capable of providing appropriate treatment shall not exceed 30 minutes, unless the emergency plan prepared by the direct-entry midwife and the client, on the form prescribed by the Director, includes an estimate of time for transportation for appropriate treatment for the conditions listed in sections 2.7, 3.5, 4.5, 5.4 and 5.5 and such plan is consented to by both the patient and the direct-entry midwife. A copy of such plan shall be given to the client.

STANDARDS FOR EDUCATION

Each applicant for registration shall submit proof of education meeting the following minimum criteria.

1. The apprenticeship/clinical practice shall be for a minimum of one calendar year.

2. The theoretical/tutorial content shall include, at a minimum:

(A) Basic knowledge and skills:

(1) Basic sciences to include anatomy and physiology, genetics, and microbiology;

(2) Aseptic technique and universal precautions;

(3) Infant and adult CPR; and

(4) Basic care skills;

B. Antepartum care

(1) Physical assessment skills;

(2) Psychological changes during pregnancy;

(3) Normal pregnancy, including growth and development of the embryo and fetus;

(4) Laboratory test interpretation;

(5) Risk factor assessment for referral including, but not limited to, recognition of early signs of abnormalities;

(6) Childbirth education; and

(7) Recognition and management of emergency situations.

(8) Nutrition for mother and newborn;

C. Intrapartal care

(1) Physical assessment skills;

(2) Psychological changes during labor and delivery;

(3) Physical care skills;

(4) Normal process of labor;

(5) Normal vaginal delivery;

(6) Risk factor assessment for referral;

(7) Recognition and management of emergency situations; and

(8) Special requirements for home birth.

D. Postpartal care

(1) Physical assessment skills;

(2) Psychological changes in adapting to motherhood;

(3) Physical care skills;

(4) Normal involution;

(5) Risk factor assessment for referral;

(6) Breast feeding; and

(7) Recognition and management of emergency situations.

E. Care of the Newborn

(1) Apgar scoring;

(2) Physical assessment;

(3) Physiological adjustment to extrauterine life;

(4) Risk factor assessment for referral;

(5) Nutritional needs;

(6) Physical care skills including administration of eye prophylaxis; and

(7) Recognition and management of emergency situations.

(8) Growth and Development - Birth to one year;

F. Legal issues

(1) Minimum standards for midwifery practice;

(2) Required laboratory testing for newborns;

(3) Charting of care;

(4) Vital statistics forms/reporting; and

(5) Liability and informed consent.

3. Apprenticeship/clinical instruction

A. In a home setting the student shall, as a minimum, have experience with the conduct of 100 prenatal examinations on at least 30 different women. The apprenticeship/clinical supervisor must be present during the examinations.

B. In a home setting the student will observe at least 30 births performed by a primary birth attendant qualified to serve as a preceptor/clinical instructor.

C. The student shall be the primary birth attendant from prenatal care through the post partum period for a minimum of 30 women under the personal and responsible supervision of a qualified midwifery instructor . A birth attendant qualified to serve as a preceptor/clinical instructor shall also be in attendance at the first 10 births.

4. Qualified individuals to verify the education of the applicant shall include:

A. A physician whose license is in good standing in the jurisdiction in which the training was conducted and who has at least 5 years experience in the care of mothers and infants during the prenatal through the postpartum period.

B. A nurse-midwife whose license is in good standing in the jurisdiction in which the training was conducted and who has at least 5 years experience in the care of mothers and infants during the prenatal thorugh the postpartum period.

C. A direct-entry midwife whose authorization to practice was in good standing in the jurisdiction in which the training was conducted and who has been responsible as the primary birth attendant from the prenatal through the postpartum period of a minimum of 60 women. Birth experiences during the supervising midwife's apprenticeship or supervised clinical practice are not applicable.

EDUCATIONAL STANDARDS FOR THE ADMINISTRATION OF OXYGEN

Prior to administering oxygen the direct-entry midwife shall submit to the director proof of having completed education in the administration of oxygen to women in labor and infants. Such education shall include content and practice with the use of equipment to administer oxygen by nasal canula, mask and bag and mask. The topics and areas to be included, at a minimum, are:

1. Basic anatomy of the respiratory and circulatory system in adults and fetal/newborn differences

2. Indications for the use of oxygen (maternal and infant)
3. Selection of method for oxygen administration for mother and/or infant
4. Determination of airway status
5. Clearing the infant airway by use of bulb and DeLee suctioning
6. Flow rate selection for mother or infant
7. Assessment of effectiveness of the oxygen administration to mother and/or infant
8. Indications for discontinuing the use of oxygen
9. Setting up and maintaining the oxygen equipment, including changing tanks and regulators and cleaning and disinfecting bags and masks between patients.

In order to receive the Director's approval of the sufficiency of such training the direct-entry midwife must submit proof that the instructor was qualified to present the class, including proof of appropriate education and a minimum of one year's experience with infants and mothers.

Appendix D - Midwife Patient Screening Form