COLORADO

Department of Regulatory Agencies

2015 Sunset Review:

Direct-Entry Midwives

Office of Policy, Research and Regulatory Reform

October 15, 2015

COLORADO
Department of
Regulatory Agencies
Executive Director's Office

October 15, 2015

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 mission of the Department of Regulatory Agencies (DORA) is consumer protection. As a part of the Executive Director's Office within DORA, the Office of Policy, Research and Regulatory Reform seeks to fulfill its statutorily mandated responsibility to conduct sunset reviews with a focus on protecting the health, safety and welfare of all Coloradans.

DORA has completed the evaluation of the regulation of direct-entry midwives. I am pleased to submit this written report, which will be the basis for my office's oral testimony before the 2016 legislative committee of reference. The report is submitted pursuant to section 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 Director of the Division of Professions and Occupations and staff, in carrying out the intent of the statutes and makes recommendations for statutory and administrative changes in the event this regulatory program is continued by the General Assembly.

Sincerely,

Joe Neguse
Executive Director

COLORADO
Department of Regulatory Agencies

2015 Sunset Review
Direct-Entry Midwives

SUMMARY

What Is Regulated?
Direct-entry midwives are autonomous practitioners who provide prenatal, childbirth and postpartum care to clients.

Why Is It Regulated?
The purpose of regulatory oversight of direct-entry midwives is to ensure that practitioners have met minimum requirements and have demonstrated competency in prenatal, childbirth and postpartum care.

Who Is Regulated?
In fiscal year 13-14, there were 61 registered direct-entry midwives.

How Is It Regulated?
In order to practice as a direct-entry midwife in Colorado, each practitioner is required to register with the Division of Professions and Occupations (Division). To qualify to register, a candidate must successfully complete the North American Registry of Midwives (NARM) examination. Regulatory oversight is vested with the Director of the Division. The Director is responsible for, among other things, imposing discipline, rulemaking and policymaking.

What Does It Cost?
In fiscal year 13-14, the total expenditures for the oversight of direct-entry midwives were $177,560, and there were 0.15 full-time employees associated with this regulatory oversight.

What Disciplinary Activity Is There?
In fiscal year 13-14, there were eight disciplinary actions taken against direct-entry midwives.

KEY RECOMMENDATIONS

Continue the regulation of direct-entry midwives for seven years, until 2023.
In order to ensure direct-entry midwives are competent to practice midwifery, practitioners are required to obtain certification from NARM. Once certification by NARM is achieved, a candidate is eligible for a direct-entry midwife registration issued by the Director. Regulation ensures competency of direct-entry midwives as well as provides an avenue for the state to formally discipline practitioners for violations of the practice act or applicable rules. This regulatory oversight ensures consumers who use direct-entry midwives in prenatal, labor/birth and postpartum care are insulated from harm, and if harm does occur, the Director has the authority to formally discipline practitioners.

Authorize direct-entry midwives to perform suturing on clients for first- and second-degree perineal tears, and grant them the authority to procure and administer local anesthesia for the procedure.
Direct-entry midwives are required to secure a certification from NARM prior to being registered by the Director. One of the requirements of achieving certification through NARM is for a candidate to demonstrate core competencies, and one of the core competencies is suturing first- and second-degree tears as well as using a local anesthesia injection to lessen discomfort when suturing. As such, direct-entry midwives have demonstrated that they are, by virtue of the NARM certification, competent to suture first- and second-degree tears.

The second sunset criterion asks whether the current regulation is the least restrictive form of regulation consistent with public protection. Authorizing direct-entry midwives to perform suturing for first- and second-degree tears on their clients would achieve the mandate of this criterion. That is, authorizing direct-entry midwives to suture clients' first- and second-degree tears allows mothers who have recently given birth to stay in their homes rather than going to a medical facility for suturing.

METHODOLOGY

As part of this review, staff at the Department of Regulatory Agencies attended a Direct-Entry Midwife Task Force meeting, interviewed Division staff, reviewed Division records including complaints and disciplinary actions, interviewed officials with state and national professional associations, interviewed stakeholders, reviewed Colorado statutes and rules, and reviewed the laws of other states.

MAJOR CONTACTS MADE DURING THIS REVIEW

American Academy of Pediatrics, Colorado Chapter
American College of Nurse Midwives, Colorado Chapter
Children's Hospital Colorado
Colorado Department of Public Health and Environment
Colorado Gynecological and Obstetrical Society
Colorado Medical Society
COPIC
Division of Professions and Occupations
Kaiser Permanente
Members of the Suturing Task Force
North American Registry of Midwives
University of Colorado School of Medicine

What is a Sunset Review?

A sunset review is a periodic assessment of state boards, programs, and functions to determine whether they should be continued by the legislature. Sunset reviews focus on creating the least restrictive form of regulation consistent with protecting the public. In formulating recommendations, sunset reviews consider the public's right to consistent, high quality professional or occupational services and the ability of businesses to exist and thrive in a competitive market, free from unnecessary regulation.

Sunset Reviews are prepared by:
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Background

Introduction

Enacted in 1976, Colorado's sunset law was the first of its kind in the United States. A sunset provision repeals all or part of a law after a specific date, unless the legislature affirmatively acts to extend it. During the sunset review process, the Department of Regulatory Agencies (DORA) conducts a thorough evaluation of such programs based upon specific statutory criteria [1] and solicits diverse input from a broad spectrum of stakeholders including consumers, government agencies, public advocacy groups, and professional associations.

Sunset reviews are based on the following statutory criteria:

- 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;
- 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;
- 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;
- Whether an analysis of agency operations indicates that the agency performs its statutory duties efficiently and effectively;
- 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;
- The economic impact of regulation and, if national economic information is not available, whether the agency stimulates or restricts competition;
- 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;
- Whether the scope of practice of the regulated occupation contributes to the optimum utilization of personnel and whether entry requirements encourage affirmative action;

[1] Criteria may be found at § 24-34-104, C.R.S.

- Whether the agency through its licensing or certification process imposes any disqualifications on applicants based on past criminal history and, if so, whether the disqualifications serve public safety or commercial or consumer protection interests. To assist in considering this factor, the analysis prepared pursuant to subparagraph (i) of paragraph (a) of subsection (8) of this section shall include data on the number of licenses or certifications that were denied, revoked, or suspended based on a disqualification and the basis for the disqualification; and
- Whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest.

Types of Regulation

Consistent, flexible, and fair regulatory oversight assures consumers, professionals and businesses an equitable playing field. All Coloradans share a long-term, common interest in a fair marketplace where consumers are protected. Regulation, if done appropriately, should protect consumers. If consumers are not better protected and competition is hindered, then regulation may not be the answer.

As regulatory programs relate to individual professionals, such programs typically entail the establishment of minimum standards for initial entry and continued participation in a given profession or occupation. This serves to protect the public from incompetent practitioners. Similarly, such programs provide a vehicle for limiting or removing from practice those practitioners deemed to have harmed the public.

From a practitioner perspective, regulation can lead to increased prestige and higher income. Accordingly, regulatory programs are often championed by those who will be the subject of regulation.

On the other hand, by erecting barriers to entry into a given profession or occupation, even when justified, regulation can serve to restrict the supply of practitioners. This not only limits consumer choice, but can also lead to an increase in the cost of services.

There are also several levels of regulation.

Licensure

Licensure is the most restrictive form of regulation, yet it provides the greatest level of public protection. Licensing programs typically involve the completion of a prescribed educational program (usually college level or higher) and the passage of an examination that is designed to measure a minimal level of competency. These types of programs usually entail title protection – only those individuals who are properly licensed may use a particular title(s) – and practice exclusivity – only those individuals who are properly licensed may engage in the particular practice. While these requirements can be viewed as barriers to entry, they also afford the highest level of consumer protection in that they ensure that only those who are deemed competent may practice and the public is alerted to those who may practice by the title(s) used.

Certification

Certification programs offer a level of consumer protection similar to licensing programs, but the barriers to entry are generally lower. The required educational program may be more vocational in nature, but the required examination should still measure a minimal level of competency. Additionally, certification programs typically involve a non-governmental entity that establishes the training requirements and owns and administers the examination. State certification is made conditional upon the individual practitioner obtaining and maintaining the relevant private credential. These types of programs also usually entail title protection and practice exclusivity.

While the aforementioned requirements can still be viewed as barriers to entry, they afford a level of consumer protection that is lower than a licensing program. They ensure that only those who are deemed competent may practice and the public is alerted to those who may practice by the title(s) used.

Registration

Registration programs can serve to protect the public with minimal barriers to entry. A typical registration program involves an individual satisfying certain prescribed requirements – typically non-practice related items, such as insurance or the use of a disclosure form – and the state, in turn, placing that individual on the pertinent registry. These types of programs can entail title protection and practice exclusivity. Since the barriers to entry in registration programs are relatively low, registration programs are generally best suited to those professions and occupations where the risk of public harm is relatively low, but nevertheless present. In short, registration programs serve to notify the state of which individuals are engaging in the relevant practice and to notify the public of those who may practice by the title(s) used.

Title Protection

Finally, title protection programs represent one of the lowest levels of regulation. Only those who satisfy certain prescribed requirements may use the relevant prescribed title(s). Practitioners need not register or otherwise notify the state that they are engaging in the relevant practice, and practice exclusivity does not attach. In other words, anyone may engage in the particular practice, but only those who satisfy the prescribed requirements may use the enumerated title(s). This serves to indirectly ensure a minimal level of competency – depending upon the prescribed preconditions for use of the protected title(s) – and the public is alerted to the qualifications of those who may use the particular title(s).

Licensing, certification and registration programs also typically involve some kind of mechanism for removing individuals from practice when such individuals engage in enumerated proscribed activities. This is generally not the case with title protection programs.

Regulation of Businesses

Regulatory programs involving businesses are typically in place to enhance public safety, as with a salon or pharmacy. These programs also help to ensure financial solvency and reliability of continued service for consumers, such as with a public utility, a bank or an insurance company.

Activities can involve auditing of certain capital, bookkeeping and other recordkeeping requirements, such as filing quarterly financial statements with the regulator. Other programs may require onsite examinations of financial records, safety features or service records.

Although these programs are intended to enhance public protection and reliability of service for consumers, costs of compliance are a factor. These administrative costs, if too burdensome, may be passed on to consumers.

Sunset Process

Regulatory programs scheduled for sunset review receive a comprehensive analysis. The review includes a thorough dialogue with agency officials, representatives of the regulated profession and other stakeholders. Anyone can submit input on any upcoming sunrise or sunset review via DORA's website at: www.dora.colorado.gov/opr.

The functions of the Director of the Division of Professions and Occupations (Director and Division, respectively) as enumerated in Article 37 of Title 12, Colorado Revised Statutes (C.R.S.), shall terminate on September 1, 2016, unless continued by the General Assembly. During the year prior to this date, it is the duty of DORA to conduct an analysis and evaluation of the administration of this program by the Director pursuant to section 24-34-104, C.R.S.

The purpose of this review is to determine whether the currently prescribed regulation of direct-entry midwives should be continued and to evaluate the performance of the Director and the Division. During this review, the Director must demonstrate that the program serves the public interest. DORA's findings and recommendations are submitted via this report to the Office of Legislative Legal Services.

Methodology

As part of this review, DORA staff attended a Direct-Entry Midwife Task Force meeting, interviewed Division staff, reviewed Division records including complaints and disciplinary actions, interviewed officials with state and national professional associations, interviewed stakeholders, reviewed Colorado statutes and rules, and reviewed the laws of other states.

Profile of the Profession

There are two types of practicing midwives who are regulated in Colorado: direct-entry midwives and certified nurse midwives. The former is the focus of this sunset report, and the latter is subject to a sunset review when DORA conducts its analysis of the Nurse Practice Act. As such, this sunset review will not refer to certified nurse midwives.

In order to practice as a direct-entry midwife in Colorado, a practitioner is required to be registered by the Director. Generally, this sunset review will refer to registered direct-entry midwives as "direct-entry midwives."

Direct-entry midwives, also known as home-birth midwives, are autonomous practitioners who provide prenatal, childbirth and postpartum care. Direct-entry midwives primarily provide services for at-home births. Generally, prenatal care is the care an expecting mother receives from a direct-entry midwife during pregnancy.[2] During prenatal care, direct-entry midwives perform the following duties, including but not limited to:[3]

- Obtain a medical, obstetrical, family and nutritional history;
- Determine the estimated due date and perform a baseline physical examination;
- Arrange or obtain laboratory testing for a variety of potential medical issues (e.g., syphilis and human immunodeficiency virus); and
- Obtain vital signs and weight.

Direct-entry midwives may administer Rho(D) immune globulin, via injection, at 26 to 28 weeks gestation.[4] Direct-entry midwives are also authorized to administer Rho(D) immune globulin to the mother within 72 hours of delivery.

Rho(D) immune globulin is a sterilized solution made from human blood. Rh is a substance that most people have in their blood (Rh-positive) but some people do not (Rh-negative).[5] A person who is Rh-negative can be exposed to Rh-positive blood through a mismatched blood transfusion or during pregnancy when the baby has the opposite blood type.[6] When this exposure happens, the Rh-negative blood will respond by making antibodies that will try to destroy the Rh-positive blood cells.[7] This can cause medical problems such as anemia (loss of red blood cells), kidney failure or shock.[8]

[2] Planned Parenthood. *What is Prenatal Care?* Retrieved August 11, 2015, from http://www.plannedparenthood.org/learn/pregnancy/prenatal-care
[3] 4 CCR § 739-1-5B-1-2-3 and 5C-1, Colorado Midwives Registration Rules.
[4] 4 CCR § 739-1-17C-2 and 5C-1, Colorado Midwives Registration Rules.
[5] RXList. *Rhogam.* Retrieved August 26, 2015, from http://www.rxlist.com/rhogam-drug/patient-images-side-effects.htm
[6] RXList. *Rhogam.* Retrieved August 26, 2015, from http://www.rxlist.com/rhogam-drug/patient-images-side-effects.htm
[7] RXList. *Rhogam.* Retrieved August 26, 2015, from http://www.rxlist.com/rhogam-drug/patient-images-side-effects.htm
[8] RXList. *Rhogam.* Retrieved August 26, 2015, from http://www.rxlist.com/rhogam-drug/patient-images-side-effects.htm

Direct-entry midwives also assist in labor and in the birth of the child. During labor, the direct-entry midwife, among other duties, continually assesses the mother's and the baby's condition. This is accomplished through duties such as monitoring the mother's and the baby's heart rates, the mother's blood pressure (at least every four hours in the early stages of labor and hourly during the active phase of labor) and the positioning of the baby.

During the postpartum period, which is defined as the period of six weeks after birth,[9] direct-entry midwives provide care to the mother and baby. Specifically, direct-entry midwives, among other things, perform a physical assessment on the infant to assess the presence of femoral pulses. Femoral pulses are the beat of the heart as felt through the walls of a peripheral artery, such as the radial artery at the wrist.[10]

Direct-entry midwives also measure the weight of the infant, measure the height and circumference of the head and check for normal reflexes.[11]

Direct-entry midwives may administer eye prophylaxis to the infant within one hour after birth.[12] Newborn eye prophylaxis refers to the practice of eye drops or ointment containing an antibiotic medication being placed on the newborn's eyes after birth.[13] The administration of eye prophylaxis protects the baby from an unknown gonorrhea or chlamydia infection in the mother's body.[14]

Additionally, direct-entry midwives are authorized to administer Vitamin K, via injection, to newborns within 72 hours after birth to prevent a type of bleeding called Vitamin K deficiency bleeding (VKDB), formally known as hemorrhagic disease. VKDB can range from bruising of the skin to bleeding inside the baby's brain.[15]

Direct-entry midwives are also authorized to administer antihemorrhagic drugs to women for control of postpartum bleeding.

During the postpartum period, direct-entry midwives are required to arrange or obtain the required newborn screenings. Newborn screenings include:

- Newborn blood spot, and
- Newborn hearing.

[9] § 12-37-102(7), C.R.S.
[10] Medical Dictionary. *Femoral pulse.* Retrieved August 14, 2015, from http://medical-dictionary.thefreedictionary.com/femoral+pulse
[11] 4 CCR § 739-1-8A-4, Colorado Midwives Registration Rules.
[12] 4 CCR § 739-1-8A-3, Colorado Midwives Registration Rules.
[13] Motherlandmidwivery.com *Newborn Vitamin K and Eye Prophylaxis.* Retrieved August 14, 2015, from http://www.motherlandmidwifery.com/newborn-eye-prophylaxis/
[14] Motherlandmidwivery.com *Newborn Vitamin K and Eye Prophylaxis.* Retrieved August 14, 2015, from http://www.motherlandmidwifery.com/newborn-eye-prophylaxis/
[15] Doernbecher Children's Hospital – Oregon Health and Science University. *Why Does My Newborn Need a Vitamin K Shot?* Retrieved August 14, 2015, from http://www.ohsu.edu/blogs/doernbecher/2012/06/26/why-does-my-newborn-need-a-vitamin-k-shot/

The purpose of the newborn blood spot screening is to screen for inherited disorders. The screening allows for early diagnosis and treatment of disorders that may negatively affect a child's mental and physical health.[16] This screening can identify many disorders, including, but not limited to cystic fibrosis. Cystic fibrosis is an inherited disease where secretory glands produce abnormally thick mucus; the mucus can cause problems in digestion, breathing and body cooling.[17]

Newborn hearing screenings can detect if a child has any issues associated with hearing.

Direct-entry midwives are required to report the number of births performed to the Division. Table 1 highlights the total number of deliveries performed by direct-entry midwives in calendar years 2010 through 2014.

Table 1
Total Number of Births Performed by Direct-Entry Midwives in Calendar Years 2010 through 2014

Calendar Year	Deliveries
2010	736
2011	719
2012	733
2013	574
2014	771

[16] Colorado Department of Public Health and Environment. *Newborn Blood Spot Screening.* Retrieved August 14, 2015, from https://www.colorado.gov/pacific/cdphe/newborn-blood-spot-screening
[17] PubMed Health. *Cystic Fibrosis.* Retrieved August 14, 2015, from http://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0022782/

Legal Framework

History of Regulation

In 1993, the State of Colorado began regulating direct-entry midwives through a registry program. The General Assembly created the registry in House Bill 93-1051 and mandated the establishment of suitable standards for education and training.

In 1995, the Department of Regulatory Agencies (DORA) completed a sunset review of the registration of direct-entry midwives program. One of the changes to the statute was to implement a mandatory waiting period of two years for reinstatement for direct-entry midwives who have their registrations revoked.

In 2010, DORA completed another sunset review of the direct-entry midwives statute. One salient recommendation, which was passed by the General Assembly, was to grant direct-entry midwives limited authority to procure and use Vitamin K through injection on newborns.

Legal Summary

The regulation of direct-entry midwives is created in section 12-37-101, *et seq.,* Colorado Revised Statutes. The authority to regulate direct-entry midwives is vested with the Director of the Division of Professions and Occupations (Director and Division, respectively).

The practice of direct-entry midwifery is defined as the advising, attending or assisting a woman during pregnancy, labor and natural childbirth at home, and during the postpartum period.[18] Natural childbirth is defined as the birth of a child without the use of instruments, surgical procedures or prescription drugs, other than those for which the direct-entry midwife has specific authority to use.[19] In fact, Colorado Midwife Registration Rules prohibit direct-entry midwives from utilizing forceps, vacuum extraction or other instruments or mechanical means to facilitate birth.[20]

In order to practice as a direct-entry midwife in Colorado, each practitioner is required to register with the Division.[21] To qualify to register, a candidate must successfully complete the North American Registry of Midwives examination.[22] The examination tests a candidate's competency in the practice of direct-entry midwifery.

[18] § 12-37-102(3), C.R.S.
[19] § 12-37-102(6), C.R.S.
[20] 4 CCR § 739-1-4B-2, Colorado Midwives Registration Rules.
[21] § 12-37-103(1), C.R.S.
[22] § 12-37-103(5), C.R.S.

An applicant for registration must also:[23]

- Be at least 19 years of age;
- Have earned a high school diploma or equivalent;
- Successfully complete training approved by the Director in areas such as:
    - The provision of care during labor and delivery and during the antepartum and postpartum periods;
    - Parenting education for prepared childbirth;
    - Aseptic techniques and universal precautions;
    - Management of birth and immediate care of the mother and the newborn;
    - Recognition of early signs of possible abnormalities;
    - Recognition and management of emergency situations;
- Acquire practical experience with a minimum of 100 prenatal examinations of at least 30 different women, as well as observe a minimum of 30 births;
- Participate as a birth attendant, including rendering care from the prenatal period through the postpartum period in connection with at least 30 births; and
- File documentation with the Director demonstrating that the applicant possesses a current certification by the American Heart Association or the American Red Cross to perform adult and infant cardiopulmonary resuscitation.

Also, an applicant for registration must graduate from an accredited midwifery educational program or obtain a substantially equivalent education that is approved by the Director.[24]

When the aforementioned prerequisites are satisfied, an applicant is eligible for registration as a direct-entry midwife in Colorado. An applicant must complete an application for registration and pay the applicable fee to the Division.

Once practicing as a direct-entry midwife in Colorado, practitioners are required to provide mandatory disclosure information to clients. The information includes:[25]

- The name, business address and business phone number;
- A listing of education, experience, degrees and membership in any professional organizations;
- A statement indicating whether the direct-entry midwife possesses liability insurance;
- A listing of any license, certificate or registration in the health care field previously held by the direct-entry midwife and whether it has been suspended or revoked;
- A statement that direct-entry midwives are regulated by DORA;
- A copy of the emergency plan;
- A statement indicating whether the direct-entry midwife will administer Vitamin K to the newborn, and if not, provide a list of qualified health care individuals who can provide the service; and

[23] § 12-37-103(5), C.R.S.
[24] § 12-37-103(6), C.R.S.
[25] § 12-37-104(1), C.R.S.

- A statement indicating whether the direct-entry midwife will administer Rho(D) immune globulin to the client if she is Rh-negative, and if not, provide a list of qualified health care professionals who can provide the service.

Direct-entry midwives are prohibited from providing care to clients who exhibit signs or symptoms of increased risk of medical or obstetric or neonatal complications or problems.[26] The conditions include, but are not limited to:[27]

- Signs or symptoms of diabetes,
- Multiple gestation (two or more embryos present in the uterus),
- Hypertension disorder or abnormal presentation of the fetus, or
- Signs or symptoms of increased risk that the child may develop complications or problems during the first six weeks of life.

Additionally, prior to providing services to a client, a direct-entry midwife must provide an informed consent form to the client, which includes, but is not limited to:

- The nature and scope of care to be rendered, including the possibility of transport of the client to a hospital,
- A description of alternatives to direct-entry midwife care, and
- A description of the risks of birth, including those of a hospital birth.

Direct-entry midwives are required to prepare an emergency plan for clients in the event that emergency situations arise. The plan must include procedures to follow in situations where the time required for transportation to the nearest facility to provide treatment exceeds 30 minutes.[28]

Also, as part of the emergency plan, the direct-entry midwife must inform the client that if she experiences uncontrollable postpartum hemorrhage, treatment may be initiated, which may include the administration of an antihemorrhagic drug.[29] The administration of the drug will be immediately followed by transport to a medical facility.[30]

A direct-entry midwife must prepare and transmit appropriate specimens for newborn screening, and refer every newborn for evaluation by a licensed health care provider with expertise in pediatric care within seven days of birth.[31]

[26] § 12-37-105(3), C.R.S.
[27] §§ 12-37-105(3) and (4), C.R.S.
[28] § 12-37-105(6), C.R.S. and 4 CCR § 739-1-10A, Colorado Midwives Registration Rules.
[29] § 12-37-105.5(4)(a), C.R.S.
[30] § 12-37-105.5(4)(a), C.R.S.
[31] § 12-37-105(7), C.R.S.

The Director is authorized to, among other things, impose discipline on registered direct-entry midwives. Specifically, the Director may deny, revoke, suspend, issue a letter of admonition, place a registered direct-entry midwife on probation or apply for a temporary or permanent injunction against a direct-entry midwife.[32]

The Director also has fining authority for violations of the practice act. Fines cannot exceed $5,000. [33]

There are a variety of violations that are grounds for discipline, including, but not limited to:[34]

- Engaging in any act or omission that does not meet generally accepted standards of safe care for women or infants, whether or not actual injury occurs;
- Procuring or attempting to procure a registration by fraud, deceit, misrepresentation, misleading omission or material misstatement of fact; or
- Falsifying or failing to make essential entries in a client's records.

[32] § 12-37-107(1), C.R.S.
[33] § 12-37-107(2)(a)(I), C.R.S.
[34] §§ 12-37-107(2)(e)(g), and (j), C.R.S.

Program Description and Administration

The regulation of direct-entry midwives is created in section 12-37-101, *et seq.,* Colorado Revised Statutes (C.R.S.). The regulatory authority over direct-entry midwives is vested with the Director of the Division of Professions and Occupations (Director and Division, respectively).

The Director is responsible for, among other things, rulemaking, policymaking and, when necessary, imposing formal discipline on practitioners.

In fiscal year 14-15, the Division devoted 0.15 full-time equivalent (FTE) employees to provide regulatory oversight of direct-entry midwives. The FTE are as follows:

- General Professional VI, and
- Technician IV.

The aforementioned FTE do not include staffing in the centralized offices of the Division, which include the following:

- Director's Office,
- Office of Investigations,
- Office of Expedited Settlement,
- Office of Examination Services,
- Office of Licensing, and
- Office of Division-Wide Systems and Programs.

Table 2 highlights the total expenditures for the regulation of direct-entry midwives in fiscal years 09-10 through 13-14.

Table 2
Total Program Expenditures in Fiscal Years 09-10 through 13-14

Fiscal Year	Total Expenditures
09-10	$57,606
10-11	$58,587
11-12	$87,117
12-13	$98,880
13-14	$177,560

The total expenditures were the highest in fiscal year 13-14. One of the reasons for the overall increase was an increase in legal services expenditures. In fact, more than $107,000 was expended on legal services during this fiscal year.

Registration

In order to practice as a direct-entry midwife, the State of Colorado requires candidates to secure a registration from the Division. To be eligible for a registration, a candidate must, among other things, either have graduated from an accredited educational program approved by the Midwifery Education and Accreditation Council (MEAC) or obtained substantially equivalent education and passed an examination.

The first option entails completing a MEAC-accredited program. MEAC's mission is to promote excellence in midwifery education through accreditation. It creates standards and criteria for the education of midwives. MEAC standards incorporate the nationally recognized core competencies and guiding principles set by, among others, the Midwives Alliance of North America. The core competencies are numerous and comprehensive and include areas such as:[35]

- Suturing first- and second-degree perineal or vaginal tears,
- Performing manual removal of placenta,
- Inserting intravenous lines and administering fluids and drawing blood for laboratory testing,
- Administering Vitamin K, and
- Administering eye prophylaxis.

During the process of completing a MEAC-accredited program, there is a clinical phase, which entails serving as an apprentice/student to a preceptor (registered direct-entry midwife). The clinical phase requires students to attend a minimum number of prenatal appointments, assisting the registered direct-entry midwife with labor and childbirth and assisting the direct-entry midwife during the postpartum period. The clinical portion of training as a direct-entry midwife is similar to the requirements of North American Registry of Midwives' (NARM) Portfolio Evaluation Process (PEP), which is highlighted below.

[35] Midwifery Education Accreditation Council. *Curriculum Checklist of Essential Competencies.* Retrieved August 18, 2015, from http://meacschools.org/wp-content/uploads/2014/12/Curriculum-Checklist-of-Essential-Competencies-rev-2014.pdf

The second registration option is for candidates who have not completed a MEAC-accredited education program. Under this option, the candidate apprentices with a qualified direct-entry midwife and completes the PEP and NARM's Skills, Knowledge, and Abilities Essential for Competent Practice. The PEP and NARM's process serve as an educational evaluation process, which includes verification of knowledge and skills by qualified preceptors.[36] In order to fulfill the PEP requirements, a candidate must attend the following:[37]

- A minimum of 10 births as an observer;
- A minimum of 20 births as an assistant to the preceptor;
- A minimum of 25 prenatal visits as an assistant, including three initial examinations;
- A minimum of 20 newborn examinations as an assistant; and
- A minimum of 10 postpartum visits as an assistant.

A candidate participating in the PEP must also serve as the primary provider, under the supervision of a preceptor, for the following:[38]

- 25 births;
- 75 prenatal visits, including 20 initial prenatal examinations;
- 20 newborn examinations; and
- 40 postpartum examinations.

Upon completion of the requirements highlighted above, a candidate must also attend five additional births serving as the primary practitioner while under the supervision of the preceptor.[39]

PEP candidates must also possess certification in cardiopulmonary resuscitation and neonatal resuscitation.[40]

[36] North American Registry of Midwives. *Entry-Level Applicants.* Retrieved August 27, 2015, from http://narm.org/entry-level-applicants/
[37] North American Registry of Midwives. Entry-Level Applicants. Retrieved August 27, 2015, from http://narm.org/entry-level-applicants/
[38] North American Registry of Midwives. *Entry-Level Applicants.* Retrieved August 27, 2015, from http://narm.org/entry-level-applicants/
[39] North American Registry of Midwives. *Entry-Level Applicants.* Retrieved August 27, 2015, from http://narm.org/entry-level-applicants/
[40] North American Registry of Midwives. *Entry-Level Applicants.* Retrieved August 27, 2015, from http://narm.org/entry-level-applicants/

The Skills, Knowledge, and Abilities Essential for Competent Midwifery Practice consist of an extensive set of skills and knowledge in the following areas:[41]

- Midwifery Counseling, Education and Communication;
- General Health Care Skills;
- Maternal Health Assessment;
- Prenatal;
- Labor, Birth and Immediate Postpartum;
- Postpartum Period; and
- Well-Baby Care.

A candidate is required to work with a qualified preceptor to complete all of the prerequisites in the Skills, Knowledge, and Abilities Essential for Competent Practice, and both the candidate and the preceptor must acknowledge proficiency in each content area.

Once a candidate completes the PEP process and the Skills, Knowledge, and Abilities Essential for Competent Practice, he/she is eligible to take the NARM examination. Generally, it takes a candidate approximately four to six years to complete all of the requirements.

Table 3 highlights the total number of registered direct-entry midwives in fiscal years 09-10 through 13-14.

Table 3
Total Number of Registered Direct-Entry Midwives in Fiscal Years 09-10 through 13-14

Fiscal Year	Original Direct-Entry Midwife Registrations	Direct-Entry Midwife Registration Renewals	Reinstatement of Direct-Entry Midwives' Registration	Total Number of Registered Direct-Entry Midwives
09-10	11	51	3	65
10-11	6	56	0	62
11-12	8	56	5	69
12-13	9	57	2	65
13-14	7	54	0	61

As Table 3 illustrates, the total number of registered direct-entry midwives has remained fairly consistent in the past five fiscal years.

In fiscal year 13-14, the fee to obtain an initial direct-entry midwife registration from the Director was $200. Once registered, a direct-entry midwife is required to renew his/her registration annually. In fiscal year 13-14, the renewal fee was $954.

[41] NARM. *Instructions for Comprehensive Skills, Knowledge, and Abilities Essential for Competent Midwifery Practice Verification Form 201a, 201b, and 201c.* Retrieved August 21, 2015, from http://narm.org/pdffiles/AppForms/Form201a.pdf

Registered direct-entry midwives must pay additional fees for the authorization to use intravenous (IV) therapy and/or medications while practicing.

In fiscal year 13-14, the original fees for IV therapy and medication authority were $100 each.

Examination

Once a candidate has completed the required MEAC-accredited education or the PEP and the Skills, Knowledge, and Abilities Essential for Competent Practice, a candidate is eligible to take the NARM examination. The NARM examination consists of 300 multiple-choice questions and must be completed in three and one half hours.

The NARM examination can be taken in Denver and Colorado Springs, and the cost of the examination is $900.

The examination utilizes seven domains to test a candidate's competency. The seven domains are:[42]

- Midwifery counseling, education and communication (12-18 questions);
- General health care skills (12-18 questions);
- Maternal health assessment (24-36 questions);
- Prenatal (69-81 questions);
- Labor, birth and immediate postpartum (99-111 questions);
- Postpartum (39-51 questions); and
- Well-baby care (12-18 questions).

Department of Regulatory Agencies (DORA) staff requested pass rates for Colorado candidates who took the examination in the past five fiscal years. NARM staff was unable to provide the information.

Once a candidate passes the examination, he/she has fulfilled the requirements to be a Certified Direct-Entry Midwife through NARM. Then a direct-entry midwife is eligible to obtain a registration from the Director.

[42] The North American Registry of Midwives. *Candidate Information Booklet (CIB).* Retrieved August 17, 2015, from http://narm.org/pdffiles/CIB.pdf

Complaints/Disciplinary Actions

There have been relatively few complaints filed against registered direct-entry midwives in the past five fiscal years. Table 4 highlights the total number of complaints filed with the Director in fiscal years 09-10 through 13-14.

Table 4
Total Number of Complaints Filed with the Director in Fiscal Years 09-10 through 13-14

Nature of Complaints	FY 09-10	FY 10-11	FY 11-12	FY 12-13	FY 13-14
Failure to Meet Generally Accepted Standards of Practice	4	5	5	12	1
Practicing Without a Registration	0	0	1	4	0
Failure to Document Treatment	2	2	5	2	1
Other	1	0	0	3	1
Total	**7**	**7**	**11**	**21**	**3**

The most common category of complaints was "Failure to Meet Generally Accepted Standards of Practice." This is a fairly general category, and complaints include direct-entry midwives failing to transport a mother or baby to a hospital in a timely manner.

Additionally, Table 5 illustrates the total number of disciplinary actions the Director imposed on registered direct-entry midwives in fiscal years 09-10 through 13-14.

Table 5
Total Number of Final Agency Actions in Fiscal Years 09-10 through 13-14

Type of Action	FY 09-10	FY 10-11	FY 11-12	FY 12-13	FY 13-14
Revocations/Relinquishments	0	2	0	1	2
Suspensions	1	0	0	0	0
Revocations/Suspensions Held in Abeyance or Stayed	0	0	0	0	0
Stipulations	0	0	1	2	5
Letters of Admonition	0	0	0	0	0
Cease and Desist Orders	0	0	0	0	1
Total Disciplinary Actions	**1**	**2**	**1**	**3**	**8**
Dismissals	0	4	3	2	4
Letters of Concern	0	1	4	1	1
Total Dismissals	**0**	**5**	**7**	**3**	**5**

As Table 5 delineates, the highest number of disciplinary actions imposed on direct-entry midwives were stipulations. The stipulations varied, but one example includes a direct-entry midwife who failed to refer the patient to a qualified health care provider for a suspected breech position before and during labor. The direct-entry midwife also falsified and failed to make accurate entries in the patient's records as to the baby's position.

On another occasion, in the same year, the direct-entry midwife failed to evaluate the progression of labor and to timely transport the patient when the labor did not progress appropriately.

The direct-entry midwife entered into a Stipulation and Order to permanently relinquish her registration to practice.

Collateral Consequences – Criminal Convictions

Section 24-34-104(9)(b)(VIII.5), C.R.S., requires DORA to determine whether the agency under review, through its licensing processes, imposes any disqualifications on applicants or licensees based on past criminal history, and if so, whether the disqualifications serve public safety or commercial or consumer protection interests.

The Director has the authority, in section 12-37-107(1)(k), C.R.S., to deny, revoke or suspend a direct-entry midwife registration if the candidate is convicted of a felony or if a court accepts a plea of guilty or *nolo contendere* to a felony. During the past five fiscal years, the Director did not deny, revoke or suspend any direct-entry midwife registrations based on past criminal history.

Analysis and Recommendations

Recommendation 1 – Continue the registration of direct-entry midwives for seven years, until 2023.

There are many risks associated with childbirth and as such, regulatory oversight is necessary to ensure competent practitioners are providing services to pregnant women as well as children.

In order to ensure direct-entry midwives are competent to practice midwifery, the State of Colorado regulates them through the Director of the Division of Professions and Occupations (Director and Division, respectively). Specifically, direct-entry midwives are required to secure a registration from the Director prior to practicing. The Director is also responsible for, among other things, rulemaking, policymaking and, when necessary, imposing discipline on practitioners.

In order to become a registered direct-entry midwife, a candidate is required to complete the requirements for certification through the North American Registry of Midwives (NARM). Certification requirements include graduating from a Midwifery Education and Accreditation Council-accredited school or obtaining a substantially equivalent education. A candidate must also pass an examination administered by NARM.

Once a candidate passes the NARM examination, he/she has demonstrated a minimum level of competency to practice in Colorado. As such, the candidate is then eligible to secure a registration through the Director and begin practicing.

Securing a direct-entry midwife registration provides two important functions. First, it ensures that a practitioner is competent to practice, thereby providing protection to consumers who choose to utilize direct-entry midwives during pregnancy. In fact, direct-entry midwives are competent to provide care in various stages of pregnancy including: prenatal, labor and birth and postpartum.

Generally, prenatal care consists of, among other things, monitoring the well-being of the mother and unborn child during pregnancy.

Direct-entry midwives also assist in labor and childbirth. Some of the duties include monitoring the mother's heart rate and blood pressure to ensure that the mother is safely progressing through labor. Direct-entry midwives also assist the mother in delivering the child through monitoring the mother's and child's condition and assisting in birth.

During the postpartum period, direct-entry midwives ensure, among other things, that the baby receives a Vitamin K injection. Vitamin K injections ensure that a newborn's blood is able to clot properly.

The direct-entry midwife registration also enables the Director to formally discipline practitioners for violations of the practice act or applicable rules. As evidenced in this sunset review, specifically Table 5 on page 17, the Director has imposed discipline on practitioners. For example a direct-entry midwife permanently relinquished her registration to practice for various violations, such as failing to transport a client who failed to progress appropriately during labor. This practitioner's registration was permanently relinquished so that she is unable to practice in Colorado. Doing so provides protection to consumers from the unfortunate and dangerous actions (or inactions) of the direct-entry midwife.

Importantly, regulation ensures competency of direct-entry midwives, and also provides an avenue for the state to formally discipline practitioners for violations of the practice act or applicable rules. This mechanism serves to enhance consumer protections for those who use direct-entry midwives in prenatal, labor/birth and postpartum care.

In order to ensure the safety of mothers and, ultimately unborn children and newborns, the General Assembly should continue the regulation of direct-entry midwives for seven years, until 2023.

Recommendation 2 – Authorize direct-entry midwives to perform suturing on clients for first- and second-degree perineal tears, and grant them authority to procure and administer local anesthesia for the procedure.

Between 2004 and 2009, approximately 41 percent of women who gave birth vaginally, under the care of direct-entry midwives, sustained first- or second-degree perineum lacerations.[43]

A first-degree tear is a small tear in the perineum and only involves the skin.[44] A second-degree tear involves the skin and some of the muscles in the perineum.[45] These are often stitched to help with healing.[46]

Currently, section 12-37-101, *et seq.,* Colorado Revised Statutes (C.R.S.), does not authorize direct-entry midwives to perform suturing of first- or second-degree perineal or vaginal tears that occur to mothers during childbirth.

[43] Journal of Midwifery and Women's Health. *Outcomes of Care for 16,924 Planned Home Births in the United States: The Midwives Alliance of North America Statistics Project, 2004 to 2009.* Retrieved August 26, 2015, from http://onlinelibrary.wiley.com/doi/10.1111/jmwh.12172/full
[44] Pregnancy Birth and Beyond. *Perfecting the Perineum.* Retrieved August 27, 2015, from http://www.pregnancy.com.au/resources/topics-of-interest/labour-and-birth/perfecting-the-perineum.shtml
[45] Pregnancy Birth and Beyond. *Perfecting the Perineum.* Retrieved August 27, 2015, from http://www.pregnancy.com.au/resources/topics-of-interest/labour-and-birth/perfecting-the-perineum.shtml
[46] Pregnancy Birth and Beyond. *Perfecting the Perineum.* Retrieved August 27, 2015, from http://www.pregnancy.com.au/resources/topics-of-interest/labour-and-birth/perfecting-the-perineum.shtml

As previously mentioned, direct-entry midwives are required to secure a certification from NARM prior to being registered by the Director. One of the requirements of achieving certification through NARM is for a candidate to demonstrate core competencies, and one of the core competencies is suturing first- and second-degree tears as well as using a local anesthesia (e.g., lidocaine) injection to lessen discomfort when suturing. As such, direct-entry midwives have demonstrated that they are, by virtue of the NARM certification, competent to suture first- and second-degree tears.

The issue of midwives suturing first- and second-degree tears is not without precedent. There are currently 28 states that regulate direct-entry midwives, and 26 of those states allow their regulated, direct-entry midwives to suture. All of the 26 states authorize suturing first- and second-degree tears. Department of Regulatory Agencies (DORA) staff contacted some states to determine whether direct-entry midwives have had complaints filed against them or whether formal discipline had been imposed concerning suturing. Two states responded to DORA's request for information (Utah and Washington). Regulators from both states stated that they had not received complaints or imposed discipline on direct-entry midwives for suturing, including the administration of local anesthesia.

In 2013, a task force was created by the Director, consisting of stakeholders from a variety of disciplines, including the medical community. A report was issued recommending direct-entry midwives be authorized to perform suturing for first-degree perineal tears on their clients. Consensus was not reached on second-degree tears.

During sunset reviews, DORA utilizes statutory criteria to evaluate programs. The second sunset criterion asks whether the current regulation is the least restrictive form of regulation consistent with public protection. Authorizing direct-entry midwives to perform suturing for first- and second-degree perineal tears on their clients would achieve the mandate of this criterion. That is, authorizing direct-entry midwives to perform suturing and administering local anesthesia on clients allows them to stay in their home after childbirth rather than going to a medical facility to suture their first- or second-degree tears. Doing so provides an important option for mothers who have recently given birth.

Importantly, this recommendation does not mandate that clients utilize the services of direct-entry midwives to suture first- and second-degree perineal tears. Instead, it provides an option for clients to have the procedure completed shortly after childbirth in their home without going to a medical facility to have the procedure performed. Clients may still choose to be transported to a medical facility to have the procedure completed.

Direct-entry midwives possess the skill (competency) to perform suturing for first- and second-degree tears on their clients. In fact, in order to become registered by the Director, direct-entry midwives must demonstrate these competencies by becoming certified through NARM. The vast majority of other states that regulate midwives allow this practice and as discussions with other state regulators attest, consumer safety has not been compromised. In Colorado, a task force consisting of various professionals recommended allowing direct-entry midwives to suture first-degree perineal tears.

As such, the General Assembly should authorize registered direct-entry midwives to suture first- and second-degree tears on their clients and to procure and administer local anesthesia.

Recommendation 3 – Require direct-entry midwives to perform or to make arrangements for the newborn pulse oximetry screening.

House Bill 15-1281 requires that, on or after January 1, 2016, children born in general hospitals or birthing centers be tested for critical congenital heart defects using pulse oximetry. House Bill 1281 does not require this screening to be performed on newborns delivered by direct-entry midwives, which are primarily delivered in at-home settings.

The newborn pulse oximetry screenings check for a set of serious, life-threatening heart defects known as critical congenital heart disease.[47] Newborns with these heart problems may have low blood oxygen levels. If detected early, it can often be treated with surgery or other medical interventions.[48]

In order to provide appropriate care and ensure that newborns who are born through the services of direct-entry midwives are receiving the same standard of care related to newborn screenings, the General Assembly should require direct-entry midwives to perform, if properly trained, or arrange for newborn pulse oximetry screenings.

Recommendation 4 – Authorize the Director to transmit letters of admonition to direct-entry midwives by means other than certified mail.

Sections 12-37-107(7)(a) and (b), C.R.S., require the Director to send a letter of admonition to a direct-entry midwife via certified mail.

Certified mail is a service offered by the U.S. Postal Service, and its purpose is to provide a delivery confirmation. For example, when the Director sends a letter of admonition to a direct-entry midwife via certified mail, the Director receives confirmation that a delivery attempt was made. However, certified mail does not ensure that the addressee actually receives the letter. Also, the addressee can choose to decline or refuse to sign for the letter, and then claim he/she did not receive the letter.

Sending a letter of admonition to a direct-entry midwife via certified mail is more costly than sending letters via first class or priority mail with no greater assurance that the addressee will actually receive it.

Also, many practice acts, via sunset reviews, have removed this requirement because it is more costly and unnecessary.

[47] Colorado Department of Public Health and Environment. *Newborn Pulse Oximetry Screening.* Retrieved August 14, 2015, from https://www.colorado.gov/pacific/cdphe/newborn-screening-pulseox

[48] Colorado Department of Public Health and Environment. *Newborn Pulse Oximetry Screening.* Retrieved August 14, 2015, from https://www.colorado.gov/pacific/cdphe/newborn-screening-pulseox

As such, the General Assembly should repeal the requirement that letters of admonition be sent via certified mail. Doing so would serve to streamline the administrative process for mailing letters of admonition, be a cost saving mechanism for the Division and would not compromise the Director's enforcement authority.

Recommendation 5 – Establish failure to properly address the direct-entry midwives' own physical or mental condition as grounds for discipline and grant the Director the authority to enter into confidential agreements with direct-entry midwives.

One of the Director's critical responsibilities is to take disciplinary action against direct-entry midwives who pose a threat to the clients under their care. The Director may take disciplinary action against any direct-entry midwife who has:[49]

> A mental or physical impairment sufficient to render the registrant unable to perform midwifery services with reasonable skill and with safety to the client.

The intent of this provision is clear: to protect the public from unsafe practitioners. But in many cases, direct-entry midwives with such conditions could continue to practice safely, under certain defined circumstances. Moreover, this provision could arguably violate federal law.

Under the current system, even a practitioner who is able to accommodate any physical or mental condition he or she has may be subject to discipline simply by virtue of having such a condition. This is typically accomplished by way of entering into a stipulation that limits the direct-entry midwife's practice. Such a stipulation is public discipline.

Thus, the practitioner is able to continue to practice, but his or her condition is made public and he or she has been disciplined. Being injured in a car accident, suffering a stroke or receiving a diagnosis of a physical or mental impairment is fundamentally different from committing an act that constitutes grounds for discipline. While these conditions might temporarily or permanently affect a direct-entry midwife's ability to treat clients, it is illogical for a direct-entry midwife who successfully manages a health condition to be included in the same category as a direct-entry midwife who has harmed a client while practicing midwifery.

Current law presents direct-entry midwives who have a physical or mental condition that might affect their practice with a stark choice: violate the law by continuing to practice without disclosing the condition, stop practicing entirely or enter into a public disciplinary order.

[49] § 12-37-105(14), C.R.S.

Disciplining a direct-entry midwife for having a physical or mental condition does nothing to protect the public and punishes the practitioner. A more effective approach would be to revise the grounds for discipline such that failing to accommodate a physical or mental condition is grounds for discipline.

To ensure that practitioners adequately manage their conditions, the Director should be authorized to enter into confidential agreements with such registrants. These agreements would articulate the measures the registrant will take to manage the condition. If the practitioner fails, the Director could then pursue discipline.

This approach protects the public by ensuring that direct-entry midwives are safe to practice, and it protects the practitioner from unnecessary discipline and unnecessarily publicizing the registrant's condition.

Therefore, the General Assembly should establish failure to properly address the direct-entry midwife's own physical or mental condition as grounds for discipline and grant the Director the authority to enter into confidential agreements with direct-entry midwives.

Administrative Recommendation 1 – The Director should convene a task force to review the efficacy of reporting data required in section 12-37-105(12), C.R.S.

Currently, direct-entry midwives are required to submit, on an annual basis as part of their registration renewal, data to the Division concerning the following:[50]

- The number of women to whom care was provided;
- The number of deliveries performed;
- The Apgar scores of delivered infants;
- The number of prenatal transfers;
- The number of transfers during labor, delivery and immediately following birth;
- Any perinatal deaths, including the cause of death and a description of the circumstances; and
- Other morbidity statistics as required by the Director.

This reporting requirement was established when the General Assembly originally created the registration program for direct-entry midwives in 1993.

Since 1993, the reporting requirements have expanded to more than 30 questions.

The usefulness of these data has been questioned by a number of stakeholders, including Division staff. The Division only collects these data; it does not provide any meaningful analysis. Further, in the past five fiscal years, no registration renewal was denied based on the information reported by direct-entry midwives.

[50] §§ 12-37-105(12)(a-g), C.R.S.

Essentially, the Division serves only as a collector of these data.

Some stakeholders argue that reporting these data is essential to identifying any trends related to the practice of midwifery. Although this assertion may have some validity, in its current form, these data are not utilized as a meaningful tool to improve, or even perhaps properly identify, issues associated with the practice of midwifery.

Thus, the Director should create a task force, consisting of stakeholders from the medical community, direct-entry midwife profession and members of the public, to review the data reporting requirement in statute. First, the task force should determine whether reporting information is necessary. Also, the task force should identify ways to not only enhance the data, but provide alternatives to reporting the information, such as the Midwives Alliance of North America data registry.

Administrative Recommendation 2 – The Director should promulgate rules concerning direct-entry midwives supervising students.

One of the required competencies for student midwives is to obtain practical, clinical training. Clinical training occurs when a student works under the direct supervision of a registered direct-entry midwife, observing, assisting and, when appropriate, providing prenatal, childbirth and postpartum care.

In fiscal years 09-10 through 13-14, there were three instances where student midwives allegedly provided care to clients without the direct supervision of direct-entry midwives. The first instance resulted in a complaint that was dismissed by the Director due to lack of evidence that the student provided services without direct supervision of a direct-entry midwife.

In the second instance, the Director issued a cease and desist order to the student midwife, and her application for registration was denied.

In the final instance, a complaint was filed against a student midwife. While the complaint was being reviewed by the Division, the student was issued her direct-entry midwife registration. At the conclusion of the complaint review, the Director issued a confidential letter of concern, which is not considered formal discipline, to the newly registered direct-entry midwife.

Clearly, there have been issues associated with unregulated student midwives in the recent past. However, the rules that govern the regulatory oversight of direct-entry midwives do not contain direction for the proper supervision of students.

As such, there may be confusion in the direct-entry midwife profession concerning the roles and responsibilities of supervised direct-entry midwives and their students.

To address this issue, the Director should promulgate rules that highlight the responsibilities, including proper supervision practices, of both direct-entry midwives and student midwives.