COLORADO

Department of Regulatory Agencies

Colorado Office of Policy, Research & Regulatory Reform

2020 Sunset Review

Direct-entry Midwives

October 15, 2020

COLORADO
Department of Regulatory Agencies
Executive Director's Office

October 15, 2020

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 General Assembly established the sunset review process in 1976 as a way to analyze and evaluate regulatory programs and determine the least restrictive regulation consistent with the public interest. Pursuant to section 24-34-104(5)(a), Colorado Revised Statutes (C.R.S.), the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) at the Department of Regulatory Agencies (DORA) undertakes a robust review process culminating in the release of multiple reports each year on October 15.

A national leader in regulatory reform, COPRRR takes the vision of their office, DORA and more broadly of our state government seriously. Specifically, COPRRR contributes to the strong economic landscape in Colorado by ensuring that we have thoughtful, efficient and inclusive regulations that reduce barriers to entry into various professions and that open doors of opportunity for all Coloradans.

As part of this year's review, COPRRR has completed an evaluation of the Direct-entry Midwives Program. I am pleased to submit this written report, which will be the basis for COPRRR's oral testimony before the 2021 legislative committee of reference.

The report discusses the question of whether there is a need for the regulation provided under Article 225 of Title 12, C.R.S. The report also discusses the effectiveness of the Director of the Division of Professions and Occupations in carrying out the intent of the statutes and makes recommendations for statutory and administrative changes for the review and discussion of the General Assembly.

To learn more about the sunset review process, among COPRRR's other functions, visit coprrr.colorado.gov.

Sincerely,

Patty Salazar
Executive Director

COLORADO
Department of Regulatory Agencies
Colorado Office of Policy, Research & Regulatory Reform

October 15, 2020

FACT SHEET

Sunset Review: Direct-entry Midwives

Background

What is regulated?

In Colorado, direct-entry midwives (DEMs) attend and assist with the home births of babies. DEM services are not in mainstream of the traditional medicine. A DEM learns midwifery through a midwifery school, apprenticeship, or college program in midwifery. DEMs provide complete prenatal care and attend home births.

Why is it regulated?

The General Assembly began DEM registration to provide an alternative to traditional licensed health care for those who desired an alternative.

Who is regulated?

At the end of fiscal year 18-19, there were 76 DEMs registered with the Director of the Division of Professions and Occupations.

How is it regulated?

Each DEM is required to pass the national North American Registry of Midwives examination. This is the same examination that one must pass to acquire a Certified Professional Midwife credential.

What does it cost?

In fiscal year 18-19 the Director expended $21,274 and allotted 0.10 Full-time Equivalent employees to implement the DEM registration program.

What disciplinary activity is there?

During the period cover for this sunset review, fiscal years 14-15 through 18-19, there were 37 complaints filed, five violations were established, and 10 disciplinary actions were taken against DEM registrants.

Key Recommendations

- Continue the regulation of direct-entry midwives for seven years, until 2028.
- Add the ability to administer Group B Strep prophylaxis to the authorities in the DEM scope of practice.
- Add licensed birth centers to the places where DEMs may assist births.
- Instruct the Director to develop policies governing unregistered birth attendants.
- Clarify that the Director does have the authority to enter into stipulations with a DEM.

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Background

Sunset Criteria

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 Colorado Office of Policy, Research and Regulatory Reform (COPRRR) within 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 guided by statutory criteria and sunset reports are organized so that a reader may consider these criteria while reading. While not all criteria are applicable to all sunset reviews, the various sections of a sunset report generally call attention to the relevant criteria. For example,

- In order to address the first criterion and determine whether a particular regulatory program is necessary to protect the public, it is necessary to understand the details of the profession or industry at issue. The Profile section of a sunset report typically describes the profession or industry at issue and addresses the current environment, which may include economic data, to aid in this analysis.
- To ascertain a second aspect of the first sunset criterion--whether conditions that led to initial regulation have changed--the History of Regulation section of a sunset report explores any relevant changes that have occurred over time in the regulatory environment. The remainder of the Legal Framework section addresses the third sunset criterion by summarizing the organic statute and rules of the program, as well as relevant federal, state and local laws to aid in the exploration of whether the program's operations are impeded or enhanced by existing statutes or rules.
- The Program Description section of a sunset report addresses several of the sunset criteria, including those inquiring whether the agency operates in the public interest and whether its operations are impeded or enhanced by existing statutes, rules, procedures and practices; whether the agency performs efficiently and effectively and whether the board, if applicable, represents the public interest.
- The Analysis and Recommendations section of a sunset report, while generally applying multiple criteria, is specifically designed in response to the tenth criterion, which asks whether administrative or statutory changes are necessary to improve agency operations to enhance the public interest.

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

These are but a few examples of how the various sections of a sunset report provide the information and, where appropriate, analysis required by the sunset criteria. Just as not all criteria are applicable to every sunset review, not all criteria are specifically highlighted as they are applied throughout a sunset review. While not necessarily exhaustive, the table below indicates where these criteria are applied in this sunset report.

Sunset Criteria	Where Applied
(I) Whether regulation by the agency is necessary to protect the public health, safety, and welfare; whether the conditions that led to the initial regulation have changed; and whether other conditions have arisen that would warrant more, less, or the same degree of regulation;	• Profile. • Legal Framework. • Recommendations 1, 2, 3, 4 and 10.
(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;	• Legal Framework. • Program Description and Administration. • Recommendations 1, 2, and 3.
(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;	• Legal Framework. • Program Description and Administration. • Recommendations 1, 4, and 5.
(IV)Whether an analysis of agency operations indicates that the agency performs its statutory duties efficiently and effectively;	• Program Description and Administration. • Recommendation 1.
(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;	• Not Applicable.
(VI) The economic impact of regulation and, if national economic information is not available, whether the agency stimulates or restricts competition;	• Profile. • Program Description and Administration.
(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;	• Program Description and Administration.
(VIII) Whether the scope of practice of the regulated occupation contributes to the optimum use of personnel and whether entry requirements encourage affirmative action;	• Profile. • Program Description and Administration.

(IX) Whether the agency through its licensing or certification process imposes any sanctions or disqualifications on applicants based on past criminal history and, if so, whether the sanctions or disqualifications serve public safety or commercial or consumer protection interests. To assist in considering this factor, the analysis prepared pursuant to subsection (5)(a) of this section must include data on the number of licenses or certifications that the agency denied based on the applicant's criminal history, the number of conditional licenses or certifications issued based upon the applicant's criminal history, and the number of licenses or certifications revoked or suspended based on an individual's criminal conduct. For each set of data, the analysis must include the criminal offenses that led to the sanction or disqualification.	• Program Description and Administration.
(X) Whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest.	• Recommendations 1, 2, 3, 4, and 5.

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 on COPRRR's website at: coprrr.colorado.gov.

The functions of the Director of the Division of Professions and Occupations (Director and Division respectively) related to the Direct-entry Midwife Registration Program, as enumerated in Article 225 of Title 12, Colorado Revised Statutes (C.R.S.), shall terminate on September 1, 2021, unless continued by the General Assembly. During the year prior to this date, it is the duty of COPRRR to conduct an analysis and evaluation of the Director pursuant to section 24-34-104, C.R.S.

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

Methodology

As part of this review, Colorado Office of Policy, Research and Regulatory Reform staff performed an internet search and a literature examination; interviewed the Director and Division staff, Colorado Department of Public Health and Environment staff, officials with state and national professional associations, and individual stakeholders, including direct-entry midwives and medical professionals; reviewed records; and reviewed Colorado rules and laws and the laws of other states.

The major contacts made during this review include but are not limited to:

- American Academy of Pediatrics, Colorado Chapter
- American College of Obstetricians and Gynecologists
- Children's Hospital Colorado
- Colorado Affiliate of the American College of Nurse Midwives
- Colorado Department of Public Health and Environment
- Colorado Medical Society
- Colorado Midwives Association
- Colorado University School of Medicine
- Division of Professions and Occupations
- Elephant Circle and Birth Rights Bar Association
- North American Registry of Midwives
- Office of the Colorado Attorney General

Profile of the Profession

In a sunset review, COPRRR is guided by the sunset criteria located in section 24-34-104(6)(b), C.R.S. The first criterion asks 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.

In order to understand the need for regulation, it is first necessary to understand what the profession does, where they work, who they serve and any necessary qualifications.

Midwifery is a mother-centered model of maternity care practiced all over the world. Midwives are trained to provide expertise and skills to support healthy pregnancies, births, and recoveries. Midwives personalize care to the mother's physical, mental, emotional, spiritual and cultural needs.[2] When parents choose to give birth in settings other than hospitals, hiring a midwife, sometimes called birth attendants, is an important decision. While midwives have been practicing for thousands of years, only nine percent of births in the United States involve a midwife.[3]

Birth Attendants

A birth attendant helps during pregnancy and childbirth. Depending on the nature of training, birth attendants implement basic, emergency, and neonatal care to mothers and babies.

There are multiple types of birth attendants:[4]

[2] Midwife Alliance North America. *What is a Midwife?* Retrieved August 24, 2020, from https://mana.org/about-midwives/what-is-a-midwife
[3] Healthline Parenthood. *Labor and Delivery: Types of Midwives*. Retrieved December 30, 2019, from https://www.healthline.com/health/pregnancy/intrapartum-care-midwife
[4] Ibid.

CERTIFIED NURSE MIDWIFE

These midwives are registered nurses who obtain additional training to acquire a master's degree in nurse midwifery. They are part of the mainstream medical establishment and are certified by the American Midwifery Certification Board.

Nurse midwives work in a wide variety of healthcare settings, including hospitals, physicians' offices, and clinics. Overall employment of nurse midwives is projected to grow 45 percent from 2019 to 2029, much faster than the average for all occupations.[5]

CERTIFIED MIDWIFE

These midwives are similar to certified nurse midwives but they do not obtain an initial degree in nursing. In cases where these individuals are certified by the North American Registry of Midwives (NARM), they have a credential called the Certified Professional Midwife (CPM).

DIRECT-ENTRY MIDWIFE

Direct-entry midwives (DEM) operate outside of the traditional medical mainstream. A DEM learns midwifery through a midwifery school, apprenticeship, or college program in midwifery. DEMs provide complete prenatal care and attend home births or deliveries in birth centers. However, in Colorado they are only able to attend home births. DEMs and the training that they are required to complete is the subject of this sunset review.

Also, in Colorado, the requirements to become a DEM are virtually the same as those to become a CPM.

LAY MIDWIFE

A lay midwife is not a medical professional. The training, certification, and ability of lay midwives varies. Generally, lay midwives do not deliver babies in hospitals, are not viewed as part of the mainstream medical community, and often work with people who practice alternative medicine. They usually help with deliveries at home or in birth centers. DEMs and CPMs are often referred to as lay midwives.

[5] U.S. Bureau of Labor and Statistics. *Occupational Outlook Handbook, Nurse Anesthetists, Nurse Midwives, and Nurse Practitioners.* Retrieved December 30, 2019, from https://www.bls.gov/ooh/healthcare/nurse-anesthetists-nurse-midwives-and-nurse-practitioners.htm

DOULA

Doulas usually help during pre-birth, labor, and delivery. They provide emotional and physical support and can help educate the parents. They provide no medical care but they may help devise a birth plan and answer questions.

During childbirth, a doula could provide comfort and help with breathing and relaxation, provide a massage, or help with labor positions. After childbirth, doulas help mothers with breastfeeding and other postpartum matters.

According to the Colorado Midwives Association, an organization that represents DEMs and advocates for home birth in Colorado:[6]

> The decision to birth at home is a matter of choice. Parents-to-be look at the options available to them and for some, the possibility of welcoming their baby into the world in their own home seems most appealing. In Colorado, parents have the option of hiring a [DEM] to provide prenatal care to the mother, attend the birth, and oversee the health of the mother and baby for [six] weeks postpartum. [DEMs] in Colorado:
>
> - Monitor the physical, psychological and social wellbeing of the mother throughout the childbearing cycle;
> - Provide the mother with individualized education, counseling and prenatal care, continuous hands-on assistance during labor and delivery, and extensive postpartum support;
> - Minimize technological interventions; and
> - Identify and refer women who require obstetrical attention.
>
> Some positive aspects of homebirth midwifery care include:
>
> - Informed choice,
> - Parents experience a strong sense of involvement in their care,
> - Freedom of movement—mom chooses positions for labor and birth,
> - Low Cesarean section rate,
> - Very low episiotomy rate,
> - Strong support for breastfeeding,
> - Waterbirth option, and
> - Referral to appropriate medical care when needed.

[6] Colorado Midwives Association. *About Homebirth*. Retrieved February 20, 2020, from https://coloradomidwives.org/about/about-homebirth/

Midwife Regulation in the United States

The sixth sunset criterion requires COPRRR to evaluate the economic impact of regulation. One way this may be accomplished is to review the expected salary of the profession.

Entry into the profession is ranked as the fourth most burdensome in the United States by the Institute for Justice. DEMs are regulated in 28 states and in nine states, the practice is or appears to be prohibited. Fees vary greatly, from $822 in New York to $2,600 in Wyoming.[7] Initial registration fees in Colorado for fiscal year 18-19 were $400, renewal was $304, and reinstatement was $319.

The U.S. Bureau of Labor Statistics *Occupational Handbook* classifies nurse midwives with other types of Master degree level, advance practice nurses. It reports that the annual salary is approximately $115,800.[8] This is much higher than the approximately $40,000 per year that members of the Colorado Midwife Association, an association of DEMs, maintains its members earn annually.

In the United States during 2017, there were 28,994 planned home births, approximately 0.8 percent of total births. A physician, a certified nurse midwife, or a certified midwife attended in approximately 30 percent of the planned home births. CPMs, DEMs, or otherwise licensed midwives, attended in approximately 51 percent of the planned home births which amounts to 0.4 percent of the total births in the United States.[9] These numbers do not include hospital transfers before or during labor.

Colorado Statistics

According to the Colorado Department of Public Health and Environment, during 2018, there were 62,871 total live births in Colorado.[10] The Director's records indicate that the same year, DEMs provided 1,175 women some level of midwifery care and only 802 received care solely from a DEM.[11] These numbers represent approximately two percent and one percent, respectively, of Colorado's 2018 total live births.

[7] Institute for Justice. *License to Work, A National Study of Burdens from Occupational Licensing*. Retrieved May 14, 2020, from https://ij.org/report/license-work-2/ltw-occupation-profiles/ltw2-midwife-direct-entry/
[8] U.S. Bureau of Labor and Statistics. *Occupational Outlook Handbook, Nurse Anesthetists, Nurse Midwives, and Nurse Practitioners*. Retrieved June 29, 2020 from https://www.bls.gov/ooh/healthcare/nurse-anesthetists-nurse-midwives-and-nurse-practitioners.htm
[9] Macdorman et al., "Trends and State Variations in Out-of-Hospital Births in the United States, 2014-2017," p.8. *Birth* 46(2). HHS Public Access Published online 2018 Dec 10.
[10] CDPHE. *Vital Statistics program, Live births by method of delivery and maternal characteristics, 2018 summary*. Retrieved February 20, 2020, from https://drive.google.com/file/d/16PymZ2ZRnRJgXd5aUtgLpCWPeZ7xDxj_/view
[11] DORA. *Office of Direct-Entry Midwife Registration: Program information, 2018 CO Midwifery Statistical Summary*. p.1. Retrieved February 19, 2020, from https://drive.google.com/file/d/1C9Q1CCzWD5xsW4wViBalUHobval__mkw/view

Legal Framework

History of Regulation

In a sunset review, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) is guided by the sunset criteria located in section 24-34-104(6)(b), Colorado Revised Statutes (C.R.S.). The first sunset criterion questions 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 that would warrant more, less or the same degree of regulation.

One way that COPRRR addresses this is by examining why the program was established and how it has evolved over time. The Direct-entry midwife (DEM) registration program has undergone sunset review on three previous occasions, in 1995, 2010, and 2015. This 2020 sunset review constitutes the third review of the program in 10 years.

The State of Colorado began registering DEMs in 1993. Initial registration directed the Director of what is now the Division of Professions and Occupations (Director and Division respectively) to promulgate standards for education and training.

A 1995 sunset review recommended, among other things, adding grounds for discipline other than revocation and a mandatory waiting period of two years for reapplication following a revocation. The General Assembly adopted these recommendations.

Following a 2010 sunset review, the General Assembly granted DEMs limited authority to procure and administer vitamin K to newborns.

In adopting the most significant recommendation in the 2015 sunset review, the General Assembly authorized DEMs to suture first-degree and second-degree perineal tears and administer local anesthetics in conjunction with the sutures.

Also, during the 2019 legislative session, the General Assembly recodified Title 12, C.R.S. At that time, Article 37 was repealed and reenacted as Article 225 (Act). Though there were changes in the manner in which the law reads and many provisions of law were combined with common elements of other laws, none of those changes effected the implementation or enforcement of the Act.

Legal Summary

The second and third sunset criteria question:

> 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; and

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.

A summary of the current statutes and rules is necessary to understand whether regulation is set at the appropriate level and whether the current laws are impeding or enhancing the agency's ability to operate in the public interest.

A DEM advises, attends to, and assists a client during pregnancy, labor, and birth in the home without the use of instruments, surgical procedures, or prescription drugs. He or she also advises, attends to, and assists during the six weeks after birth.[12]

The General Assembly created DEM registration as an alternative to traditional licensed health care. Regulation under the Act, Article 225, of Title 12, C.R.S. applies only to DEMs and not professionals otherwise licensed in Colorado if midwifery is within the scope of that license.[13] However, any person who practices or attempts to practice as a DEM without being registered under the Act commits a class 2 misdemeanor for a first offense and a class 6 felony for subsequent offenses.[14]

The Act requires that every DEM apply for registration and be registered with the Director.[15] It is not permissible for a DEM to represent himself or herself as a nurse-midwife or a certified nurse-midwife.[16]

The Director is empowered by the Act to:[17]

- Adopt rules to implement the Act,
- Establish and receive registration and renewal fees,
- Adopt education standards and registration requirements,
- Adopt a registration examination,
- Seek an injunction to halt violations of the Act,
- Suspend a registration for failing to comply with an order of the Director, and
- Develop a risk assessment procedure to be followed by every DEM and to be placed in every client's record.[18]

[12] §§ 12-225-103(3), 103(4), and 103(6), C.R.S.
[13] §§ 12-225-101((1)(a) and 101(1)(c), C.R.S.
[14] § 12-225-110, C.R.S.
[15] § 12-225-104(1), C.R.S.
[16] § 12-225-101(1)(b)(II), C.R.S.
[17] § 12-225-108(1), C.R.S.
[18] § 12-225-106(11), C.R.S.

There are multiple ways for an individual to qualify for DEM registration. One may qualify through education and examination,[19] go through an evaluation of experience and pass an examination,[20] or acquire substantially equivalent education, training, or service in the military, as determined by the Director.[21]

To be eligible, a person must be at least 19 years old, procure a high school diploma, and hold a certification in infant cardio pulmonary resuscitation.[22]

Beyond those basics, an applicant must complete practical, supervised experience including 100 prenatal examinations on at least 30 different women, observe 30 births,[23] act as a birth attendant from prenatal through postpartum care, in connection with at least 30 births,[24] and successfully complete training that includes care during labor and delivery as well as antepartum and postpartum periods.[25]

The required qualifying examination is developed and administered by the North American Registry of Midwives (NARM). It is the same examination that is required to become a Certified Professional Midwife (CPM) [26] and one must meet NARM's qualifications to sit for the examination. In essence, a registered Colorado DEM fulfils the requirements to become a CPM and if a midwife holds a current CPM, then that person has satisfied the educational and training requirements necessary for registration.

The Act also lays out some very specific prohibitions and mandates for DEMs, such as:

- No DEM may dispense or administer medication, perform any operative or surgical procedure, including sutures, or administer oxygen unless he or she has the specific training to do so;[27]
- No DEM may provide care to any pregnant woman with a high risk of complications to the mother or baby;[28]
- Every DEM must retain applicable records of all related activity;[29]
- Every DEM must prepare an emergency plan for transportation to the nearest facility capable of providing treatment that exceeds the limits of registration;[30]
- Every DEM must collect newborn screening specimens in accordance with section 25-4-1004, C.R.S., and refer newborns for evaluation to a licensed healthcare provider with expertise in pediatric care, within seven days of birth;[31]

[19] 4 CCR 739-1 § 1.2 (A), Colorado Midwives Registration Rules.
[20] 4 CCR 739-1 § 1.2 (B)(2), Colorado Midwives Registration Rules.
[21] 4 CCR 739-1 § 1.2 (B)(4), Colorado Midwives Registration Rules.
[22] §§ 12-225-104(4)(a), (4)(b), and (4)(f), C.R.S.
[23] § 12-225-104(4)(d), C.R.S.
[24] § 12-225-104(4)(e), C.R.S.
[25] § 12-225-104(4)(c), C.R.S.
[26] 4 CCR 739-1 § 1.2(b)(1), Colorado Midwives Registration Rules.
[27] §§ 12-225-106(1), 106(2), 106(13), and 12-225-107, C.R.S.
[28] §§ 12-225-106(3), and 106(4), C.R.S.
[29] § 12-225-106(5), C.R.S.
[30] § 12-225-106(6), C.R.S.
[31] § 12-225-106(7), C.R.S.

- Every DEM must make sure that appropriate laboratory testing is completed for each client;[32]
- Every DEM must provide eye prophylactic therapy according to Colorado law to every newborn in his or her care;[33]
- Every DEM must be skilled in aseptic procedures and the use of universal precautions and employ them with every client;[34] and
- Every DEM must keep data and submit it to the Director upon renewal. The data include:[35]
    - The number of women to whom care was provided since the previous registration;
    - The number of deliveries performed;
    - The Apgar scores of delivered infants, in groupings established by the Director;
    - 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.

Each DEM must make certain disclosures to each client when they first meet, including business location and contact information, education and experience information (including any healthcare-related licensure that has been suspended or revoked), a copy of the emergency plan, and whether the DEM carries liability insurance.

Beyond the fundamental practice-related information, the disclosure must also communicate that the practice is regulated and include the telephone number of the Office of Midwifery Registration. There must be notification that a violation of the Act may result in revocation of the authority to practice direct-entry midwifery in Colorado. Finally, the disclosure must inform the client whether the DEM will administer vitamin K or Rho(D) immune globulin when necessary. If not, a list of qualified health-care practitioners who can provide such services must be provided.[36]

DEMs may obtain some specific prescriptions to administer to patients,[37] including:[38]

- Vitamin K to newborns by intramuscular injection,
- Rho(D) immune globulin to Rh-negative mothers by intramuscular injection,
- Postpartum antihemorrhagic drugs to mothers,
- Eye prophylaxis, and
- Local anesthetics when needed to perform sutures.[39]

[32] § 12-225-106(8), C.R.S.
[33] § 12-225-106(9), C.R.S.
[34] § 12-225-106(10), C.R.S.
[35] § 12-225-106(12), C.R.S.
[36] § 12-225-105(1), C.R.S.
[37] § 12-225-107(1), C.R.S.
[38] § 12-225-107(2), C.R.S.
[39] § 12-225-107(6), C.R.S.

When a client refuses vitamin K or Rho(D) immune globulin, the DEM must give her an informed consent form explaining the benefits of the medications and the risks of refusal. The DEM must keep a copy of the client's acknowledged and signed form.[40]

If a client experiences uncontrollable postpartum hemorrhage and refuses treatment with antihemorrhagic drugs, the DEM must immediately initiate transport according to the emergency plan.[41] Further, each emergency plan must inform the client that if she experiences uncontrollable postpartum hemorrhage, the DEM is required by Colorado law to initiate emergency medical treatment, which may include the administration of an antihemorrhagic drug to mitigate the postpartum hemorrhaging during transportation. It must also explain that if there is a postpartum hemorrhage, the DEM is prepared and equipped to administer intravenous fluids to restore volume from bleeding. [42]

If a DEM violates the registration and disclosure provisions of the Act, the Director is empowered take disciplinary action or seek an injunction to stop a DEM from practicing. The Act allows the Director to issue a letter of admonition, suspend or revoke a registration, place a registrant on probation, or issue a fine up to $5,000 for various violations.[43] It also allows the Director to accept any disciplinary action taken against a registrant in another jurisdiction as *prima facie* evidence of a violation of the Act.[44] Violations include:[45]

- Not providing necessary information or paying a registration fee;
- Providing false, deceptive, or misleading information to the Director;
- Not responding to a complaint in an honest, materially responsive, and timely manner;
- Failing to comply with an order of the Director;
- Attempting to obtain a registration through fraud, deceit, misrepresentation, misleading omission, or material misstatement of fact;
- Having any government credential to practice as a DEM or any other health care profession suspended or revoked;
- Violating any law or regulation governing DEMs in another state or jurisdiction. (A plea of *nolo contendere* or its equivalent may be considered to be the same as a finding of violation);
- Being convicted of a felony or entering a plea of *nolo contendere* to a felony;
- Aiding or knowingly permitting any person to violate any provision of the Act; and
- Advertising that a DEM will perform any prohibited action.

[40] § 12-225-107(3)(a), C.R.S.
[41] § 12-225-107(3)(b), C.R.S.
[42] § 12-225-107(4), C.R.S.
[43] §§ 12-225-109(1) and 109(2), C.R.S.
[44] § 12-225-109(5), C.R.S.
[45] § 12-225-109(3), C.R.S.

There are also violations that pertain directly to an individual's fitness to practice safely as a DEM:

- Engaging in any act or omission that does not meet generally accepted standards of safe care for women and infants;[46]
- Falsifying or failing to make essential entries in, or in a negligent manner making incorrect entries in client records;[47]
- Abuse or habitual or excessive use of a habit-forming drug, a controlled substance, or alcohol;[48] and
- Failing to notify the Director, act within limitations, or comply with agreed upon limitations concerning a physical illness, physical condition, or behavioral, mental health, or substance use disorder that renders the registrant unable, or limits the registrant's ability, to practice direct-entry midwifery with reasonable skill and safety.[49]

The Act provides that the Director may keep investigation files and information confidential until a complaint is dismissed or notice of hearing and charges are served to the subject of the investigation.[50]

[46] § 12-225-109(3)(e), C.R.S.
[47] § 12-225-109(3)(j), C.R.S.
[48] § 12-225-109(3)(f), C.R.S.
[49] § 12-225-109(3)(n), C.R.S.
[50] § 12-225-113, C.R.S.

Program Description and Administration

In a sunset review, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) is guided by sunset criteria located in section 24-34-104(6)(b), Colorado Revised Statutes (C.R.S.). The third, fourth and fifth sunset criteria question:

> Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, rules, procedures 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; and
>
> 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;

In part, COPRRR utilizes this section of the report to evaluate the agency according to these criteria. The fifth criterion does not apply in this case as there is no regulatory board or commission.

The Director of the Division of Professions and Occupations (Director and Division, respectively) implements the Direct-entry Midwife (DEM) registration program. Among the duties of the Director are verifying qualifications of DEMs (including qualifying the DEMs for additional authorities to administer oxygen, medication, intravenous fluids, and sutures), rulemaking, and acting on complaints and disciplinary matters.

Table 1 contains program-associated expenditures for the time cohort examined for this sunset review, fiscal years 14-15 through 18-19.

Table 1
Program Expenditures

Fiscal Year	Expenditures	FTE
14-15	$95,089	0.15
15-16	$60,133	0.10
16-17	$43,435	0.10
17-18	$33,628	0.10
18-19	$21,274	0.10

Table 1 notes that very few personnel resources are expended on the program. The Division allots only 0.10 full-time equivalent (FTE) employees to its administration and that is split between two positions. Additionally, the FTE listed does not include employees in the centralized offices of the Division, which provide management, licensing, administrative, technical, and investigative support to the program. The 0.10 FTE are allocated as follows:

- Technician IV, 0.05 FTE – This position handles case management, correspondence, case summary preparation, practice monitoring, packet preparation, follow-up, initial decision follow-up, expedited settlement procedure and Attorney General referrals.
- Administrative Assistant III, 0.05 FTE – This position handles complaint intake, correspondence, case summary preparation, final action processing.

Table 1 also illustrates that one major expense can drastically affect the overall expenditures in multiple years. One court case caused expenditures to triple from the average in fiscal year 14-15 and approximately double in fiscal year 15-16, before normalizing in subsequent fiscal years.

Registration

The eighth sunset criterion questions whether the scope of practice of the regulated occupation contributes to the optimum utilization of personnel and whether entry requirements encourage affirmative action.

In part, COPRRR utilizes this section of the report to evaluate the program according to this criterion.

The Act expressly forbids the issuance of reciprocal registration.[51] Nonetheless, there are multiple ways to qualify for registration:

- Graduating from a program accredited by the Midwifery Education and Accreditation Council and passing the national North American Registry of Midwives (NARM) examination;[52]
- Possessing a current NARM Certified Professional Midwife (CPM) credential and passing the NARM examination;[53]
- Possessing a certificate under NARM's entry-level Portfolio Evaluation Process that illustrates an education substantially equivalent to that required by Colorado and passing the NARM examination;[54]
- Passing a credential review performed by the International Credentialing Associates or the International Consultants of Delaware (both organizations

[51] § 12-225-104(6), C.R.S.
[52] 4 CCR 739-1 § 1.2 (A), Colorado Midwives Registration Rules.
[53] 4 CCR 739-1 § 1.2 (B)(1), Colorado Midwives Registration Rules.
[54] 4 CCR 739-1 § 1.2 (B)(2), Colorado Midwives Registration Rules.

evaluate international training/education) determining a substantially equivalent education as that required in Colorado and passing the NARM examination;[55] or
- Possessing a substantially equivalent education, training, or service in the military, as determined by the Director.[56]

Prior to sitting for the NARM examination, NARM requires that a candidate be at least as qualified as these registration requirements. When a person passes the NARM examination, he or she becomes a CPM. In essence, a CPM is required for DEM registration unless a person is qualified through military service. No person has qualified through military service.

DEM registrations expire on November 30 every year and must be renewed. However, DEMs who are issued a registration within 120 days of the upcoming renewal expiration date obtain a registration with the next year's expiration date.[57] In conjunction with registration renewal, every DEM is required to report to the Director:[58]

- The number of women to whom care was provided since the previous registration;
- The number of deliveries performed;
- The Apgar scores of delivered infants, in groupings established by the Director;
- 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.

The complete 2019 Statistical Summary may be found in Appendix A.

Table 2 enumerates registration data compiled by the Division during the period examined for this sunset review.

Table 2
Registrations

Fiscal Year	Initial Registration	Renewal	Reinstated	Total (June 30)
14-15	5	63	3	67
15-16	5	67	1	66
16-17	8	66	2	66
17-18	3	69	7	69
18-19	9	71	2	76

[55] 4 CCR 739-1 § 1.2 (B)(3), Colorado Midwives Registration Rules.
[56] 4 CCR 739-1 § 1.2 (B)(4), Colorado Midwives Registration Rules
[57] Department of Regulatory Agencies. *Office of Direct-Entry Midwifery Registration: Applications and Forms.* Retrieved March 26, 2020, from https://dpo.colorado.gov/Midwives/Applications
[58] §-225-106(12), C.R.S.

Table 2 shows that there are very few DEMs registered in Colorado. For perspective, the estimated population of the state was 5.6 million people in 2018[59] and the number of births, according to the Colorado Department of Public Health and Environment, was 63,455. Of those total births, 617, approximately one percent, were attended by a DEM.

As is the case for most licensure programs, regulatory activities for the DEM registration program are funded through registration fees. Table 3 illustrates that registration fees for DEMs are quite high. The fee to become a DEM in fiscal years 16-17 and 17-18 was $1,200, up from $200 in fiscal year 15-16. This is mainly due to the small population of DEMs and fees are set to cover the direct and indirect costs of program implementation. In fiscal year 18-19, the fees were reduced as expenses became more normalized.

Table 3
DEM Registration Fees

Fiscal Year	Initial	Renewal	Reinstatement
FY 14-15	$ 200	$ 954	$ 969
FY 15-16	$ 200	$ 954	$ 969
FY 16-17	$ 1,200	$ 1,215	$ 1,230
FY 17-18	$ 1,200	$ 454	$ 469
FY 18-19	$ 400	$ 304	$ 319

According to Division staff, original registration and renewal fees had to be raised in fiscal year 16-17 because the program's legal funds were exhausted in the previous fiscal years. Covering expenses required the Division to increase all DEM fees to alleviate the severe fund deficit. Since that time, due to the increase in fees and lower legal costs, the program achieved a positive fund balance and registration fees were lowered. Nonetheless, because there are so few registrants, one major legal case could again result in a negative fund balance and increased fees.

Special Authorities

DEMs also may acquire special practice authorities to administer oxygen, administer medication, administer intravenous (IV) fluids, and to perform sutures. The CPM credential verifies that a DEM is proficient in these skills whether the DEM performs them or not. NARM sets the fundamental standards for CPM education and proficiency, regardless of the individual circumstances in which the CPM/DEM practices.[60] The

[59] United States Census Bureau. *Quick Facts, Colorado*. Retrieved March 26, 2020, from https://www.google.com/search?rlz=1C1GCEU_enUS821US822&ei=OO58XqaFEpHb-gS7xpWACg&q=colorado+population+2018&oq=colorado+population+2018&gs_l=psy-ab.3..0j0i22i30l9.3440.4421..4872...0.2..0.181.316.0j2.....0....1..gws-wiz.....0i71j0i131i67j0i67.BYE1EEzNVGY&ved=0ahUKEwimgcrP3LjoAhWRrZ4KHTtjBaAQ4dUDCAs&uact=5

[60] *Certified Professional Midwife (CPM), Candidate Information Booklet*, North American Registry of Midwives. p.20.

General Healthcare Skills section of the NARM examination requires an examinee to demonstrate knowledge of the benefits, risks, and appropriate administration of:

- Local anesthetic for suturing;
- Medical oxygen;
- Methergine (methylergonovine maleate);
- Prescriptive ophthalmic ointment;
- Pitocin for postpartum hemorrhage;
- Rho(D) immune globulin;
- Vitamin K;
- Antibiotics for Group B Strep (GBS);
- Intravenous fluids;
- Cytotec (misoprostol); and
- Epinephrine.

The Director has established, in rule, that each DEM has met the minimum training requirements for the safe administration of oxygen because they are included in the entry-level education and training requirements.[61] There are no fees for a special authority to administer oxygen.

MEDICATION AIDE AUTHORITY

To obtain a Medication Aide Authority, a DEM must have passed an accredited course in pharmacology, a program or course approved by the Midwifery Education and Accreditation Council (MEAC), or a program or course otherwise approved by the Director within the six months prior to submitting an application for that authority. The course must be eight clock hours in duration and include basic pharmacotherapeutic principles and administration of medications as well as specific administration practices and procedures itemized in rule, including:[62]

- Mechanism of Pharmacological Action,
- Indications,
- Therapeutic Effects,
- Side Effects/Adverse Reactions,
- Contraindications,
- Incompatibilities/Drug Interactions,
- Drug administration,
- Administration of medications through injection,
- Appropriate injection sites,
- Procedures for drawing up and administering drugs,
- Proper disposal of hazardous and other contaminated materials, and

[61] 4 CCR 739-1 § 1.3 Colorado Midwives Registration Rules.
[62] 4 CCR 739-1 § 1.17, Colorado Midwives Registration Rules.

- Student demonstration of competence in administering medications.

The fees to obtain a medication administration authority in fiscal year 18-19 were $108 for the initial authority and $38 to renew.

Table 4 enumerates the number of medication aide authorities issued by the Director during the sunset review period.

Table 4
Medication Aide Authorities

Fiscal Year	Initial Authorities Issued	Authorities Renewed
14-15	5	53
15-16	7	56
16-17	3	56
17-18	5	51
18-19	8	55

When comparing the number of total registrations and the medication aide authorities, one sees that a majority of DEMs also obtain the authority to administer medications.

INTRAVENOUS AUTHORITY

To acquire the authority to administer intravenous (IV) fluids to restore fluid volume lost due to dehydration, fatigue, or postpartum hemorrhage, a DEM must pass an accredited course in IV therapy, a course approved by MEAC, or a program or course otherwise approved by the Director within the six months prior to submitting an application for that authority. The course must be six clock hours in duration and include basic principles and elements of the administration of medications intravenously, including 0.9 percent sodium chloride in sterile water and Lactated Ringer's solution.[63] The fees to obtain an IV authority in fiscal year 18-19 were $108 for the initial authority and $38 to renew.

Table 5 enumerates the IV authorities issued by the Director during the period examined for this sunset review.

[63] 4 CCR 739-1 § 1.18, Colorado Midwives Registration Rules.

Table 5
IV Authorities

Fiscal Year	Initial Authorities Issued	Authorities Renewed
14-15	8	31
15-16	5	37
16-17	2	40
17-18	10	34
18-19	7	43

Table 5 shows that fewer DEMs obtain the authority to administer IV fluids than to administer medication. Still, more than half of all DEMs choose to obtain the authority.

SUTURING AUTHORITY

To obtain an authority to suture first-degree and second-degree perineal tears, a DEM must pass an eight-hour MEAC accredited live class or workshop that teaches the identification of muscles and anatomy of the vagina and perineum including the affected nerves, the selection of appropriate instruments, the suture material and needle types required for suturing, and appropriate techniques for basic repair. The live class or workshop must also teach identification of third- and fourth-degree perineal tears and the proper referral of such tears.[64] There are no fees to obtain a suturing authority though the Act allows the Director to impose one. The Act also states that this authority need not be renewed as long as the DEM holds a valid registration.[65]

Very few DEMs obtained the authority to suture once it was established in fiscal year 17-18. There were three authorities issued in fiscal year 17-18 and one issued in fiscal year 18-19. Division staff explained that as with all of the authorities, acquiring one is a choice, not mandatory, and many DEMs do not see the need to add this authority to their practice.

Examinations

The Division does not examine DEMs, but the Director does require that every DEM pass the NARM examination. The NARM examination is written and reviewed according to standards set for accreditation by the National Commission for Certifying Agencies.[66]

[64] 4 CCR 739-1 § 1.20, Colorado Midwives Registration Rules.
[65] § 12-225-107(6)(b), C.R.S.
[66] North American Registry of Midwives. *NARM Written Examination Questions and Scoring*. Retrieved April 1, 2020, from http://narm.org/testing/written-exam-questions-and-scoring/

The examination takes seven hours, it is given in two parts, and each part contains 150 multiple choice questions.[67] Candidates submit a form to the NARM Test Department along with a $900 testing fee. Once the information and payment are collected, NARM will forward information regarding scheduling the examination.[68] Those who are eligible to take the examination, choose a date and a PROV computer-testing center at which to take the examination. A list of test sites is sent to each candidate when they are qualified for the examination.

The examination contains 300 multiple choice questions in several subject areas. A passing score is determined using a modified Angoff Method. Subject matter experts determine how likely a competent, entry-level, midwife would answer each question correctly. Each question is assigned a score centered on how many competent midwives out of 100 would choose the correct answer. The NARM Board is the ultimate authority in determining a passing score.[69] Official test results are mailed approximately two weeks after the test date.[70]

The examination covers the following subject areas:[71]

- Professional Issues, Knowledge, and Skills,
- General Healthcare Skills,
- Maternal Health Assessment,
- Prenatal,
- Labor, Birth, and Immediate Postpartum,
- Postpartum, and
- Well Baby Care.

NARM does not publish examination passing rates.

Complaint and Disciplinary Activity

The seventh sunset criterion requires COPRRR to examine 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.

[67] North American Registry of Midwives. *The Day of the Exam*. Retrieved July 24, 2020, from http://narm.org/testing/the-day-of-the-exam/
[68] North American Registry of Midwives. *Registering for the Exam*. Retrieved, July 24, 2020,from http://narm.org/testing/registering-for-the-exam/
[69] North American Registry of Midwives. *NARM Written Examination Questions and Scoring*. Retrieved April 1, 2020, from http://narm.org/testing/written-exam-questions-and-scoring/
[70] North American Registry of Midwives. I*ssuance of the Certified Professional Midwife Credential*. Retrieved July 24, 2020, from http://narm.org/testing/issuance-of-the-certified-professional-midwife-credential/
[71] *Certified Professional Midwife (CPM), Candidate Information Booklet*, North American Registry of Midwives. p.33.

In part, COPRRR utilizes this section of the report to evaluate the program according to this criterion.

Given the small number of registrants, the number of complaints filed appears to be somewhat high. Table 6 lists the number of complaints received by the Director, the number of founded violations, and the number of actions taken by the Director during the sunset review period.

Table 6
Complaint Data

Fiscal Year	Complaints	Violations	Actions
14-15	7	0	3
15-16	5	2	1
16-17	3	0	2
17-18	9	2	2
18-19	13	1	2
Total	**37**	**5**	**10**

Not all complaints are resolved in the same fiscal year they are received. Therefore, the number of actions does not line up with the complaints and violations. Table 6 illustrates that few of the complaints actually result in a violation, approximately 27 percent. However, the number and type of actions taken by the Director indicate that the violations are serious. In fact, of the 10 total actions taken, eight were practice stipulations. A stipulation is a condition placed on a registrant that somehow restricts that person's ability to practice.

In fiscal year 14-15, the Director took three actions. One individual was issued a practice stipulation for substandard practice and unregistered practice. The other two actions were practice stipulations issued to DEMs for substandard practice. In fiscal year 15-16, one midwife received a practice stipulation for multiple issues that included: substandard practice, inappropriate care of child/client, misdiagnosis, poor communication, and failure to release records. Two stipulations were issued in fiscal 16-17 for substandard practice. The Director issued two stipulations in fiscal year 17-18, one for substandard practice and one for inappropriate care of child/client. In fiscal year 18-19, two cease and desist orders were issued for unregistered practice.

Fining Activity

The seventh sunset criterion requires COPRRR to examine 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.

In part, COPRRR utilizes this section of the report to evaluate the program according to this criterion.

The Act grants the Director the ability to issue a fine up to $5,000 per violation. No fines were issued during the period examined for this sunset review.

Collateral Consequences – Criminal Convictions

The ninth sunset criterion requires COPRRR to examine whether the agency under review, through its licensing processes, imposes any sanctions or disqualifications based on past criminal history, and if so, whether the disqualifications serve public safety or commercial or consumer protection interests.

In part, COPRRR utilizes this section of the report to evaluate the program according to this criterion.

Section 12-225-109(3)(k), C.R.S., states that a DEM may be disciplined for conviction, or a plea of guilty or *nolo contendere* to a felony. No DEM was disciplined and no registration was denied during the period examined for this sunset review based on this provision.

Analysis and Recommendations

The final sunset criterion questions whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest. The recommendations that follow are offered in consideration of this criterion, in general, and any criteria specifically referenced in those recommendations.

Recommendation 1 – Continue the regulation of direct-entry midwives for seven years, until 2028.

The first sunset criterion directs analysis to determine if regulation is necessary to protect consumers.

Direct-entry midwives (DEMs) attend to women who desire to give birth at home. Childbirth can be risky to both mother and child. Choosing to give birth at home presents a unique set of issues with which mother, child, and birth attendants must contend.

Article 12-225 of Title 12, Colorado Revised Statutes (C.R.S.) (Act) empowers the Director of the Division of Professions and Occupations (Director and Division, respectively) to regulate DEMs. Each DEM must register with the Division prior to practicing. The Director is also responsible for, among other things, rulemaking, policymaking and, when necessary, disciplining DEMS. DEM registration ensures that a practitioner is competent to practice and provide care throughout pregnancy and during the postpartum period.

Division records indicate that in 2018, DEMs provided 1,175 women some level of midwifery care and 802 received care solely from a DEM.[72] That same year there were 62,871 total live births in Colorado.[73] Therefore, approximately one percent of 2018 Colorado total live births occurred solely under DEM care.

To become registered, a DEM must 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 and passing the NARM/Certified Professional Midwife (CPM) certification examination. Once that has been completed, NARM signifies that the individual has established a minimum level of competency to be eligible for registration in Colorado.

[72] Department of Regulatory Agencies. *Office of Direct-Entry Midwife Registration: Program information, 2018 CO Midwifery Statistical Summary*. Retrieved February 19, 2020, from https://drive.google.com/file/d/1C9Q1CCzWD5xsW4wViBalUHobval__mkw/view

[73] CDPHE. *Vital Statistics program, Live births by method of delivery and maternal characteristics, 2018 summary*. Retrieved February 20, 2020, from https://drive.google.com/file/d/16PymZ2ZRnRJgXd5aUtgLpCWPeZ7xDxj_/view

In most cases, prenatal care consists of monitoring the well-being of the mother and unborn child during pregnancy and developing a contractual birth plan. In a home birth, the DEM monitors the mother's and child's vital signs and how things progress throughout labor and the birth. If there are any issues concerning the health of mother and/or baby, the DEM is required to act based on a previously agreed upon emergency plan and transport them to a medical facility. In fact, 107 times there was a transport during labor, indicating that DEMs take their professional obligations seriously.

During the postpartum period, DEMS have many duties including, among other things, ensuring that the baby receives a vitamin K injection. Vitamin K injections ensure that a newborn's blood is able to clot properly.

DEMs are expressly forbidden to assist with any high-risk pregnancies and births. Traditional medical practitioners express concern that DEMs perform beyond the scope of their training and work with high-risk pregnancies. They point to DEMs working with mothers who desire a vaginal birth after caesarian section, or VBAC. Concerning all types of care in Colorado during 2018, 12 percent of the total pregnancies involved a mother who had a previous caesarian section and the VBAC rate was 21 percent of total pregnancies. Colorado is the state with the fourth highest VBAC rate in the United States.[74] It is far less common for a pregnant woman who has had a caesarian section to attempt to use a DEM, four percent of the total clients. However, during 2019, of the 68 VBAC mothers who received DEM care, 51, or 75 percent, delivered at home and another mother delivered vaginally at a hospital. This indicates that more than 76 percent of the VBAC DEM clients were able to accomplish a vaginal delivery though not all in the home setting.

Data also indicate that during 2019, 81 prenatal women transferred out of the care of a DEM to physician care prior to birth. This number illustrates that DEMs understand their responsibilities concerning high-risk clients.

Although most mothers deliver at home safely while under the care of a midwife, some women develop serious complications after labor begins. Many obstetric complications occur quickly and require prompt treatment by a doctor. Because of this, few doctors in mainstream American medicine recommend home birth.[75]

In part, because of concerns such as these, the Act instructs the Director to discipline practitioners for violations of the Act or applicable rules. The data analyzed for this sunset review illustrates that violations come with serious consequences. Of the 12 total actions taken against DEMs, nine required the DEMs to modify their practices or risk further discipline. Practice modifications, also called practice stipulations, require a registrant to change the manner in which he or she practices and often require oversight by another more experienced DEM. The abilities to sanction registrants and ensure best practices provide necessary consumer protections. Regulation also ensures that birth

[74] Caesareanrates.org. *VBAC Rates by State*. Retrieved February 20, 2020, from https://www.cesareanrates.org/vbac

[75] Healthline Parenthood. *Labor and Delivery, Types of Midwives.* Retrieved July 24, 2020, from https://www.healthline.com/health/pregnancy/intrapartum-care-midwife#outlook

attendants are qualified to help in such a unique situation. The program is essential to protecting life and wellbeing and is necessary. The DEM registration program satisfies the first sunset criterion.

To continue to ensure the competency of practitioners and the safety of consumers, and because there are no outstanding issues to warrant sooner scrutiny, the General Assembly should continue the regulation of direct-entry midwives for seven years, until 2028.

Recommendation 2 - Add the ability to administer Group B Strep prophylaxis to the authorities in the DEM scope of practice.

Group B Strep (GBS) bacteria can cause miscarriages, stillbirths, and premature deliveries. GBS disease may lead to long-term problems, such as deafness and developmental disabilities in babies. Two to three of every 50 babies who contract GBS disease die.[76] The American College of Obstetricians and Gynecologists and American College of Nurse-Midwives recommend that pregnant women get tested for GBS bacteria at 36 to 37 weeks of pregnancy. Women who test positive are at increased risk for passing the bacteria to their babies during birth. The Centers for Disease Control and Prevention recommends testing and giving antibiotics, during labor, to women with a higher risk.[77]

DEMS are required to pass the NARM examination. To sit for the examination a candidate must be trained and qualified to administer the antibiotics to treat GBS. This is an important procedure and DEMs should be authorized to treat their clients when the need arises.

Still, not every practicing DEM has received the training that is currently mandated by NARM. NARM has only been requiring training and testing around GBS for approximately 20 years. The Director should verify the qualifications of those credentialed before the year 2000 prior to granting initial authority and charge a fee for the service. However, once a DEM is qualified, there is no need for a renewal or a renewal fee.

The first sunset criterion ask the analysis to consider if regulation is necessary to protect public health and safety. Granting the authority to administer GBS antibiotics, when necessary, will protect the health and safety of both mother and baby. Therefore, the General Assembly should add the ability to administer Group B Strep prophylaxis to the authorities in the DEM scope of practice.

[76] Centers for Disease Control and Prevention. *Group B Strep (GBS), Complications*. Retrieved June 15, 2020, from https://www.cdc.gov/groupbstrep/about/diagnosis.html
[77] Centers for Disease Control and Prevention. *Group B Strep (GBS), Prevention*. Retrieved June 15, 2020, from https://www.cdc.gov/groupbstrep/about/prevention.html

Recommendation 3 – Add licensed birth centers to the places where DEMs may assist births.

Birth centers are health-care facilities established specifically for childbirth. In birth centers midwives provide care and assist mothers through labor and childbirth. Colorado Department of Public Health and Environment (CDPHE) rule defines a birth center as:[78]

> [A] freestanding facility licensed by [CDPHE] that is not a hospital, attached to a hospital, or in a hospital which provides prenatal, labor, delivery and postpartum care to low risk pregnant persons and the newborns. Care during delivery and immediately after delivery shall be generally less than [24] hours.

According to NARM and the American Association of Birth Centers, many of the birth centers in the United States are owned and/or staffed by DEMs/CPMs. In Colorado, DEMs are not allowed to practice in birth centers because of section 12-225-103(3), C.R.S., which states that the practice of direct-entry midwifery, "is the advising, attending, or assisting of a woman during pregnancy, labor and natural childbirth at ***home***." (Emphasis added). In Colorado, only nurse midwives are allowed to work in birth centers even though DEMs are qualified to do so.

Birth centers offer mothers different options compared to a home birth or a birth in a hospital. The principles of prevention, sensitivity, safety, appropriate medical intervention and cost-effectiveness are central to operations. A birth center allows a mother the ability to make informed choices concerning her and her baby's health based on her personal values and beliefs.[79] This is in line with the legislative intent for regulating DEMs. In part, the intent of the General Assembly in adopting the registration program was because it is, "an alternative to traditional licensed health care."[80] Birth centers encourage family involvement and provide a safe environment for families to experience birth while attending to the possibility that a problem may arise that will require medical intervention or care in the acute care setting of the hospital.[81]

The second sunset criterion directs analysis to consider if regulation is the least restrictive option necessary to protect the public. The prohibition disallowing DEMS from practicing in the home-like setting of a birth center is overly restrictive because it is not a "home." In fact, a birth center birth offers greater consumer protection than what may be available with a home birth.

Therefore, the General Assembly should add licensed birth centers to the places where a DEM may assist a birth.

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[78] 6 CCR 1011-1 Chapter 22 § 2.1
[79] American Association of Birth Centers. *What is a Birth Center?* Retrieved June 15, 2020, from https://www.birthcenters.org/page/bce_what_is_a_bc
[80] § 12-225-101(1)(c), C.R.S.
[81] American Association of Birth Centers. *What are the Benefits to Families? Retrieved* June 15, 2020, from https://www.birthcenters.org/page/bc_experience

Recommendation 4 – Instruct the Director to develop policies governing unregistered birth attendants.

The Act requires that all DEMs pass the NARM examination prior to registration. NARM requires that any person who wants to sit for the examination must first demonstrate essential competencies through an apprenticeship under a NARM Registered Preceptor or clinical training through a Midwifery Education Accreditation Council-approved program. The clinical component is at least two years and the average apprenticeship lasts three to five years.[82]

A NARM Registered Preceptor is a CPM, Certified Nurse Midwife, Certified Midwife, or a licensed practitioner legally recognized by a jurisdiction to provide maternity care. A preceptor has additional experience above initial CPM requirements of 50 primary births, 10 continuity of care births, and a minimum of 10 out-of-hospital births in the previous three years. The preceptor mentors and verifies the competency of the CPM candidate prior to examination and certification.[83] NARM is clear that it expects the preceptor to be hands on:

> NARM Registered Preceptors who sign off on experiences they did not witness risk losing their ability to sign as a preceptor in the future and also risk losing their CPM certification.[84]

The Act also stipulates that prior to registration a candidate must have,

> Participated as a birth attendant, including rendering care from the prenatal period through the postpartum period, in connection with at least thirty births;[85]

The definition of direct-entry midwifery includes, "the advising, attending, or assisting of a woman during pregnancy, labor and natural childbirth at home."[86] It is unclear what role, if any, unregistered birthing attendants or apprentices may play during a woman's pregnancy, labor, or postpartum period. Because there is no other provision for an apprenticeship in the Act, the Director has investigated three complaints over the last seven years for DEMs practicing without a registration. In the most recent case, the individual in question explained that she was delivering babies under a preceptor. Still, there are no laws or policies in place in Colorado to accommodate such a situation.

The first sunset criterion asks the General Assembly to consider if:

> regulation by the agency is necessary to protect the public health, safety and welfare; whether the conditions which led to the initial regulation

[82] *Certified Professional Midwife (CPM), Candidate Information Booklet*, North American Registry of Midwives. p.6.
[83] North American Registry of Midwives. Preceptors. Retrieved September 23, 2020, from http://narm.org/preceptors/
[84] North American Registry of Midwives. *Guidelines for Documentation of Clinical Experience*. Retrieved September 23, 2020, from http://narm.org/preceptors/guidelines-for-documentation-of-clinical-experience/
[85] § 12-225-104(4)(e), C.R.S.
[86] § 12-225-103(3), C.R.S.

have changed; and whether other conditions have arisen which would warrant more, less or the same degree of regulation;

The third sunset criterion asks the General Assembly to consider whether agency operations are, "impeded or enhanced by existing statutes, rules, procedures and practices and any other circumstances."

Under these circumstances, the General Assembly should instruct the Director to develop policies and protocols to provide for unregistered birth attendants. The Director should adapt and adopt the NARM practices to fit Colorado's circumstances. Making the changes will protect Colorado consumers and enhance agency operations.

Recommendation 5 – Clarify in the Act that the Director does have the authority to enter into stipulations with a DEM.

In 2019, House Bill 1172 (HB-1172) recodified and reorganized Title 12, which included the creation of a common provisions section. Individual practice acts typically include references to common provisions and the common provisions section also specifically lists any professions to which the common provisions are not applicable.

Stipulations are included in a common provision under section 12-20-405(3), C.R.S. While this section is not referenced in the Act, the common provisions also does not list the profession under the exclusions to this authority, which seems to indicate that the Director does have the authority to enter into stipulations.

The third sunset criterion questions whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes.

Prior to recodification, the Director did have clear authority to enter into stipulated agreements.[87] The authority for stipulations is commonly granted to regulatory entities and necessary for the Board to effectively regulate the practice of pharmacy.

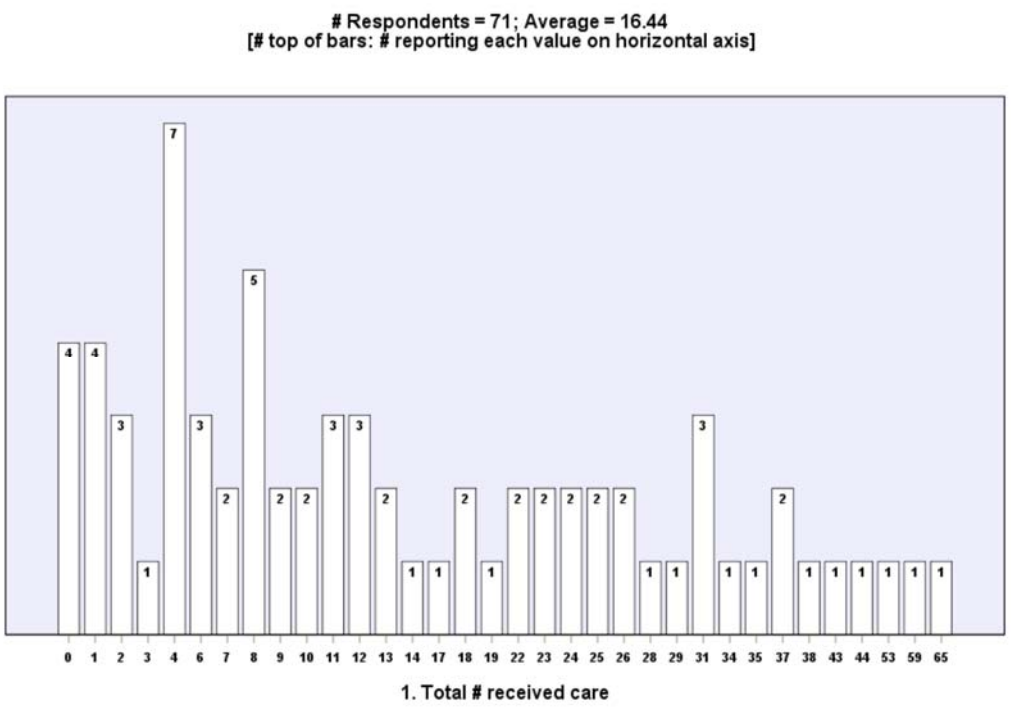
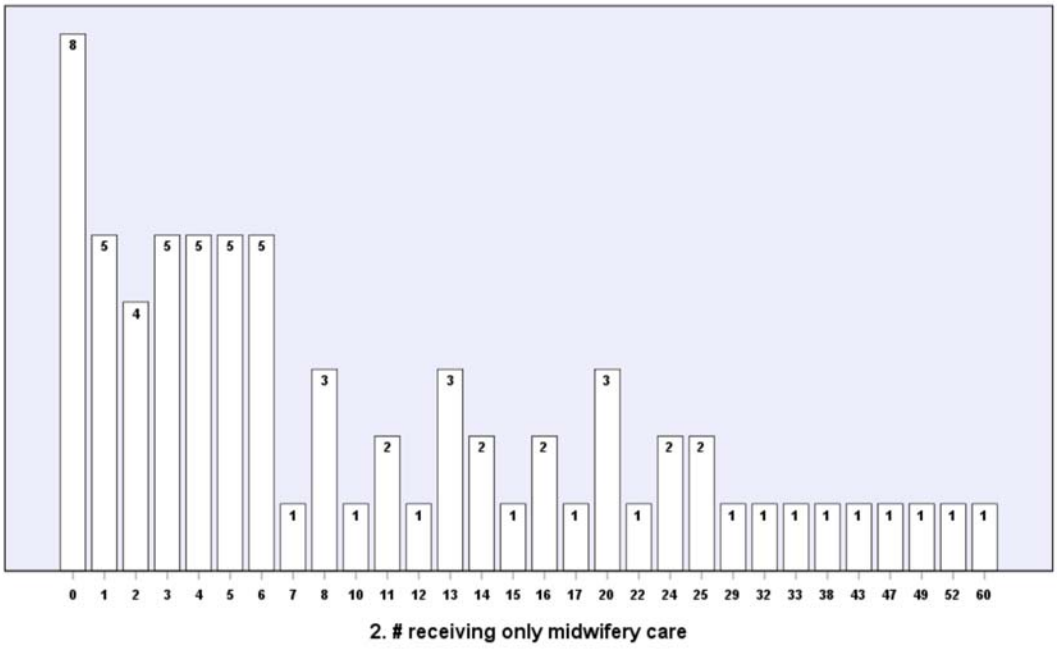
For this reason, the General Assembly should clarify in the Act that the Director does have the authority to enter into stipulations according to section 12-20-405(3), C.R.S.

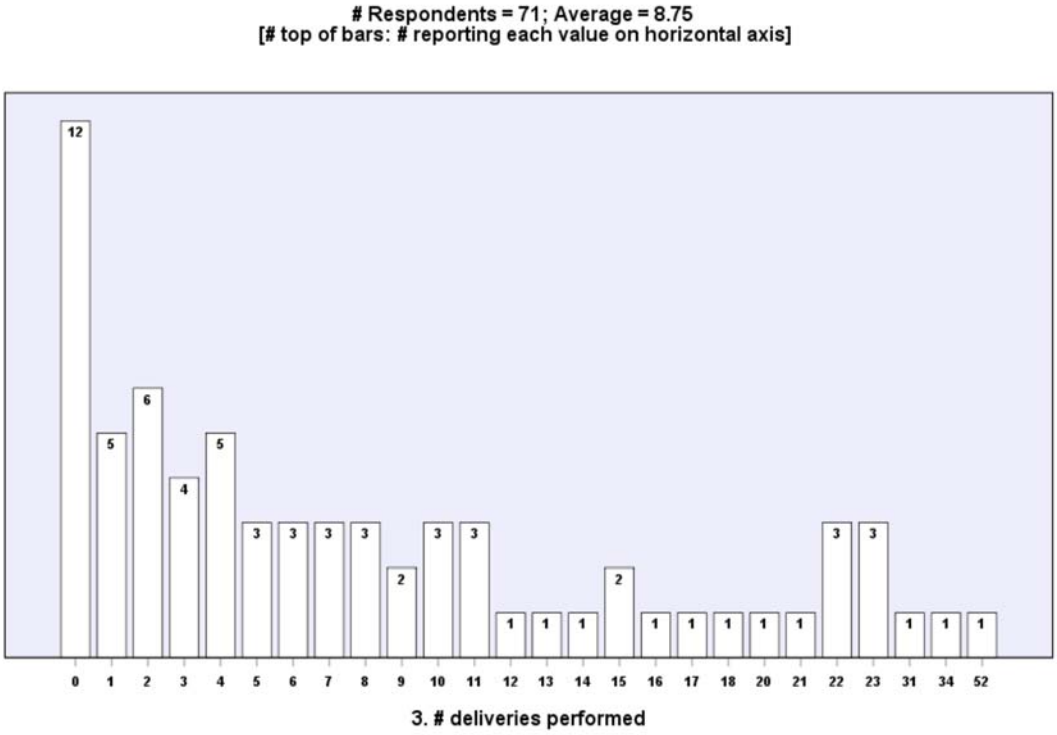
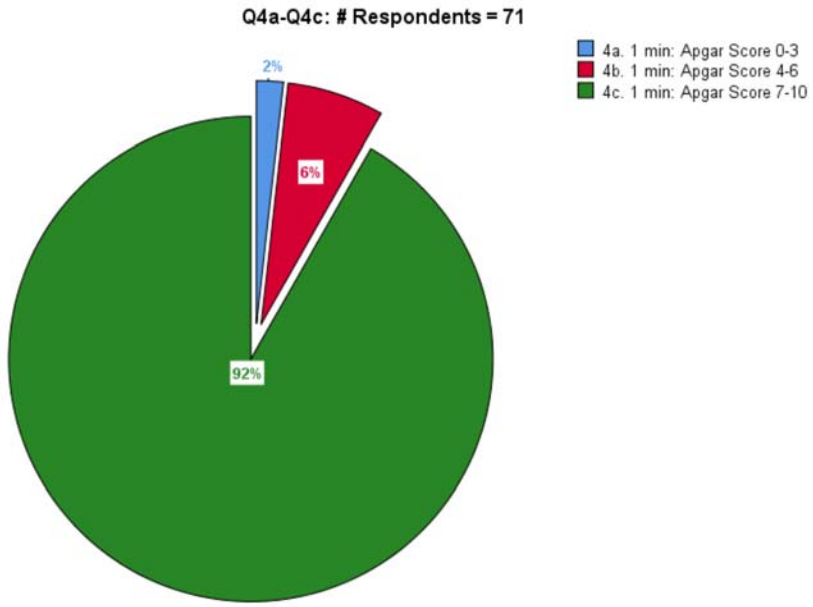
[87] *See Colorado Revised Statutes 2018*: § 12-37-107(11) C.R.S.

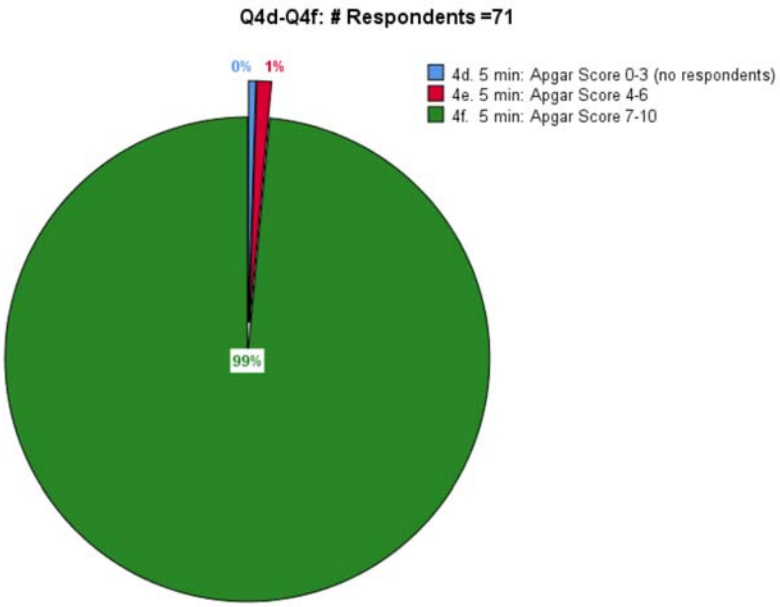
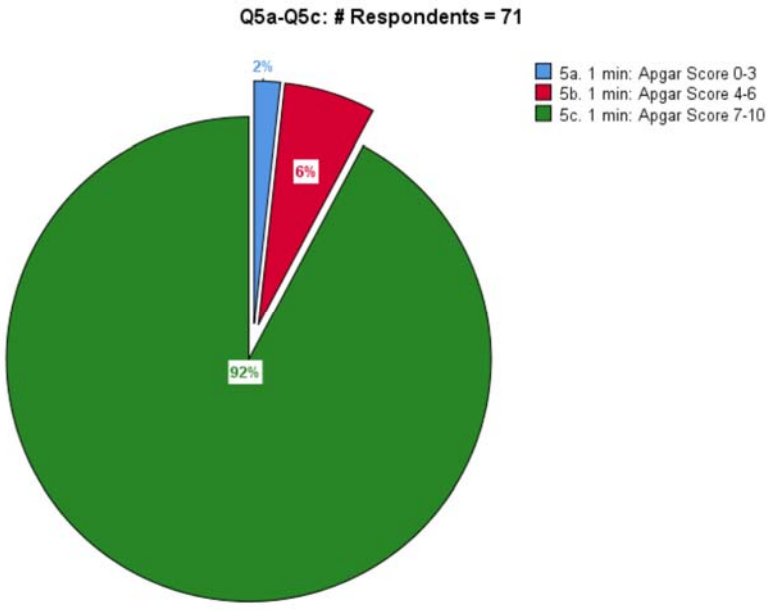
Appendix A – Direct-Entry Midwife Registration 2019 Statistical Summary

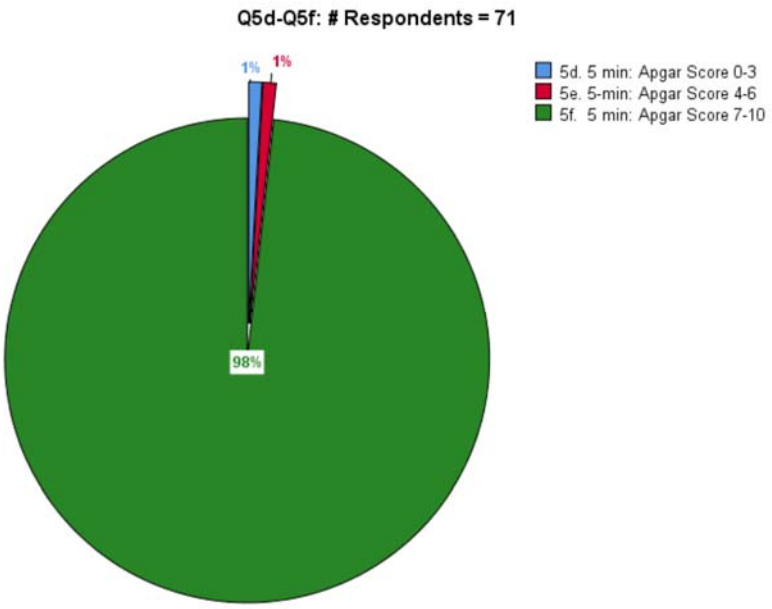
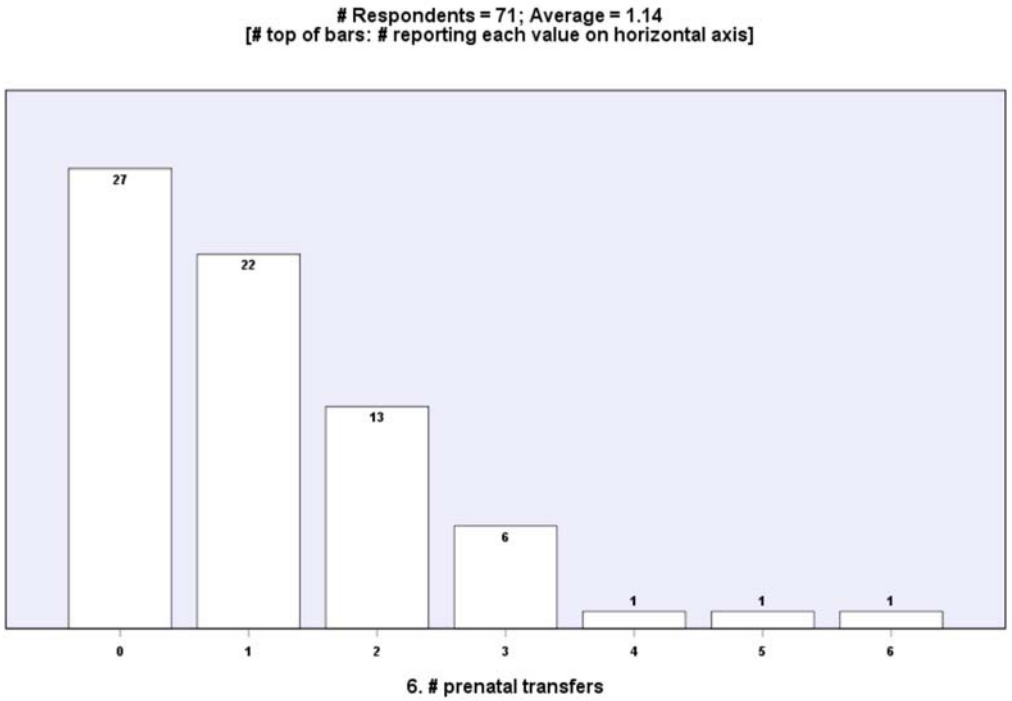
Section 12-225-106(12), Colorado Revised Statutes, requires each direct-entry midwife, when renewing a registration, to submit practice and birth statistics to the Director of the Division of Professions and Occupations. Appendix A contains the "COLORADO MIDWIFERY REGISTRATION 2019 STATISTICAL SUMMARY," the aggregated data for the entire program.

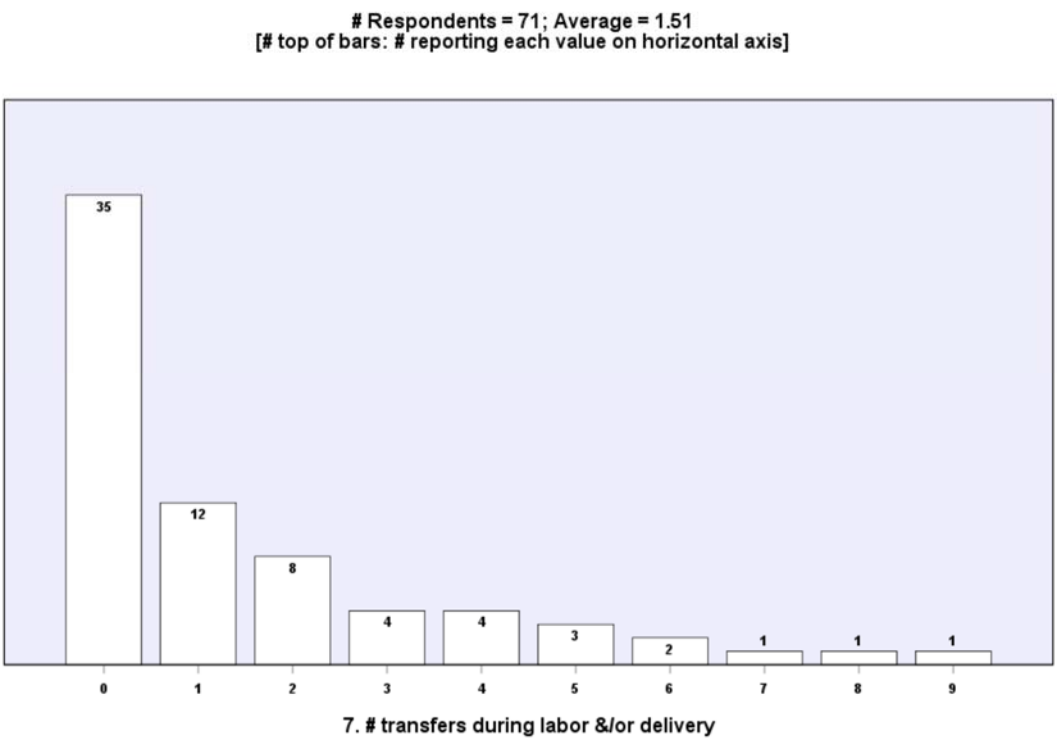
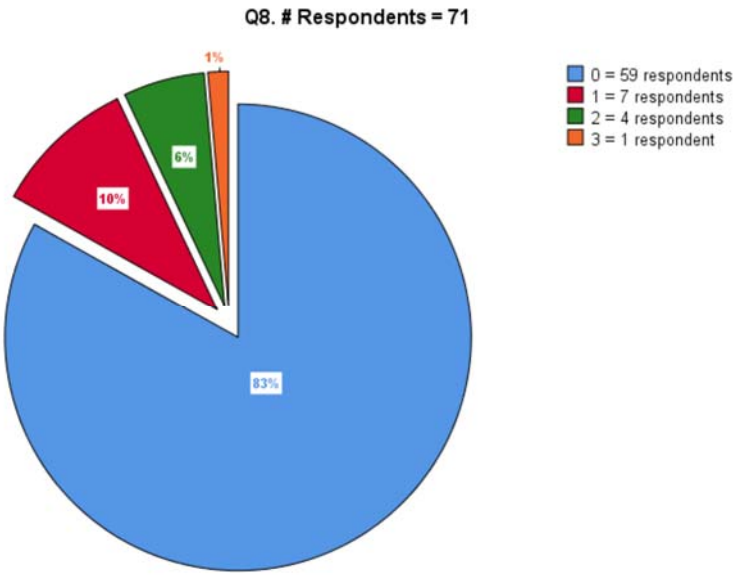
Registered Direct-Entry Midwives answered the following questions by submitting their data during the 2019 renewal cycle. Respondents entered a value of "0" if their answer to any question was "zero".

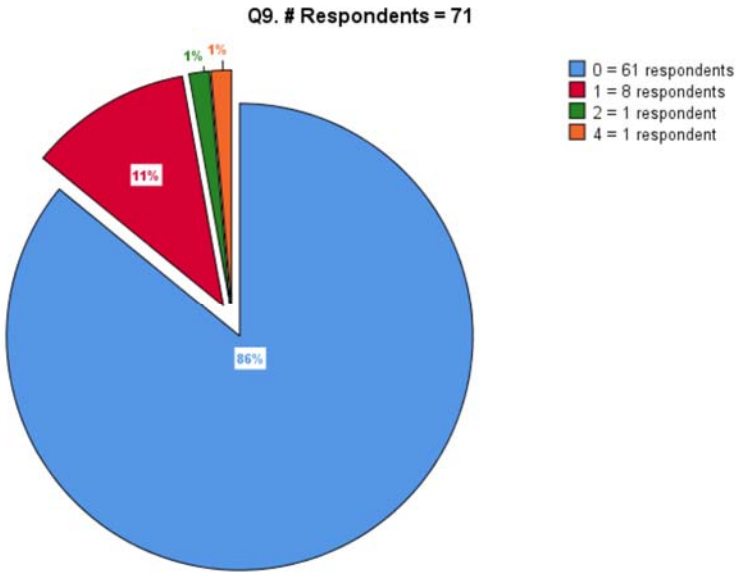
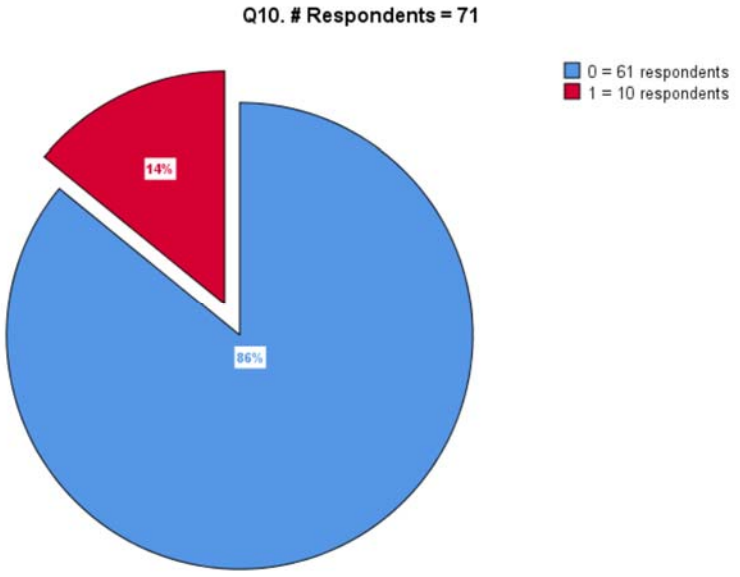
1. The number of women to whom midwifery care was provided (this is the total number of women who received care from the reporting midwife, including women who transferred into or out of the midwife's care):#	
2. The number of women receiving only midwifery care (this is the number of women who received care from the reporting midwife ONLY. Women who received lab tests or ultrasounds should be counted in this category. Women who consulted with or transferred care to a Physician or other Allied Healthcare Provider during pregnancy, should not be included in this category):	

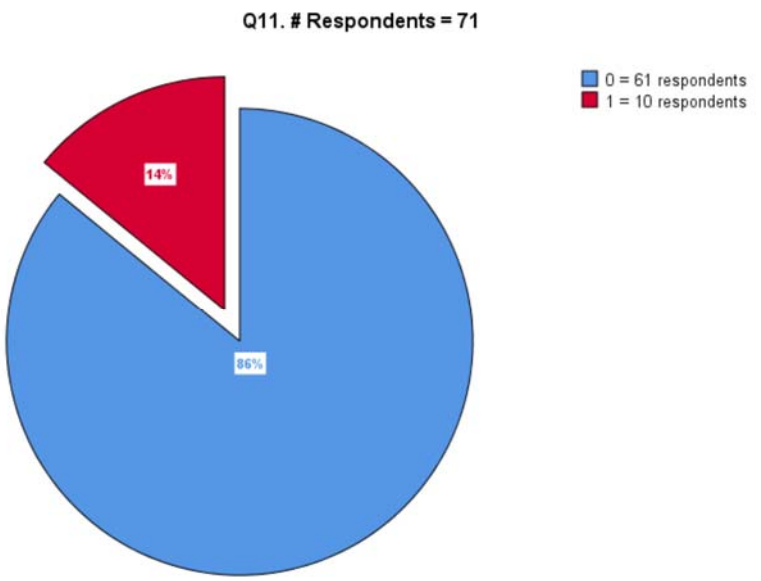
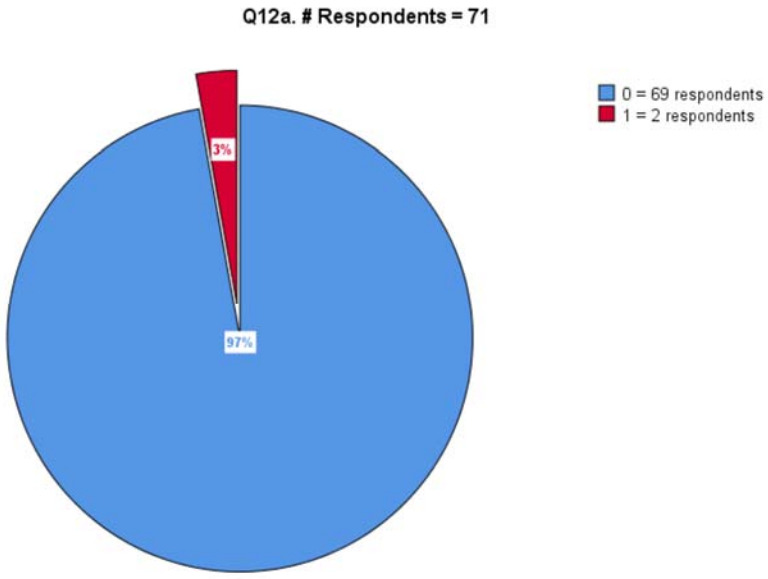
3. The number of deliveries performed (total number of planned homebirth deliveries managed by the reporting midwife):	
4a.–4c. The number of infants delivered by the reporting midwife, in the following Apgar score groupings (insert answers below): **<u>ONE Minute</u>** • 0–3 • 4–6 • 7–10	

4d.–4f. The number of infants delivered by the reporting midwife, in the following Apgar score groupings (insert answers below): **FIVE Minutes** • 0–3 • 4–6 • 7–10	
5a.–5c. If available, the number of infants delivered in the hospital after transfer, in the following Apgar score groupings (insert answers below): **ONE Minute** • 0–3 • 4–6 • 7–10	

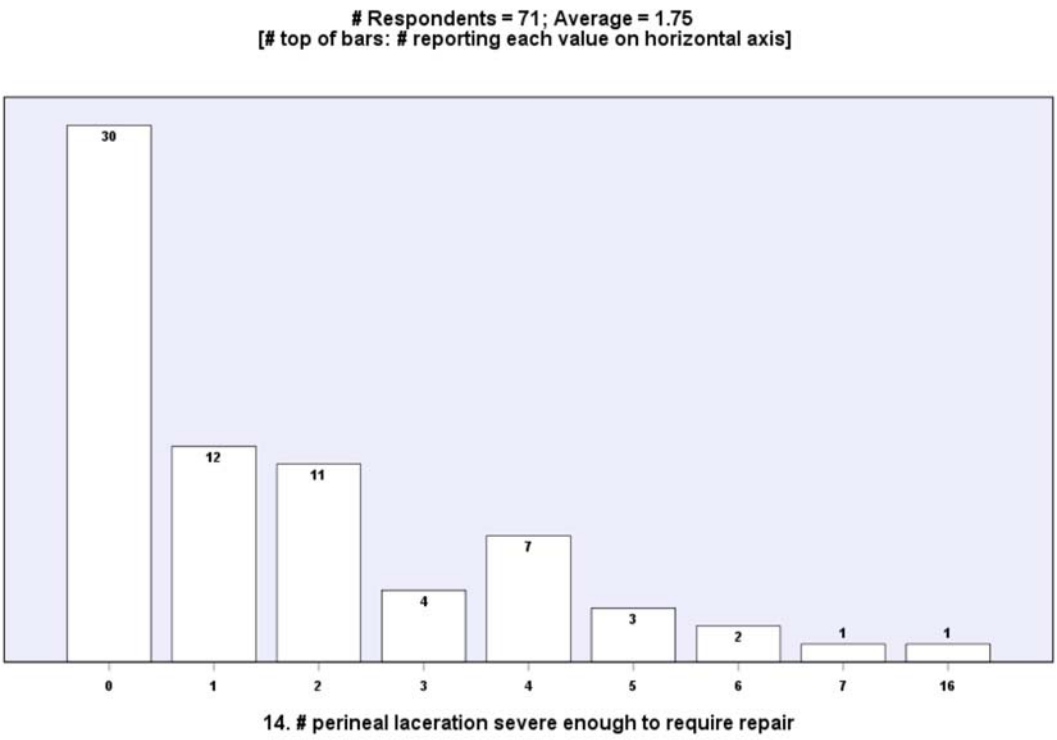
5d.–5f. If available, the number of infants delivered in the hospital after transfer, in the following Apgar score groupings (insert answers below): **FIVE Minutes** • 0–3 • 4–6 • 7–10	
6. The number of prenatal transfers (total number of women transferred out of midwifery into physician care prior to birth):	

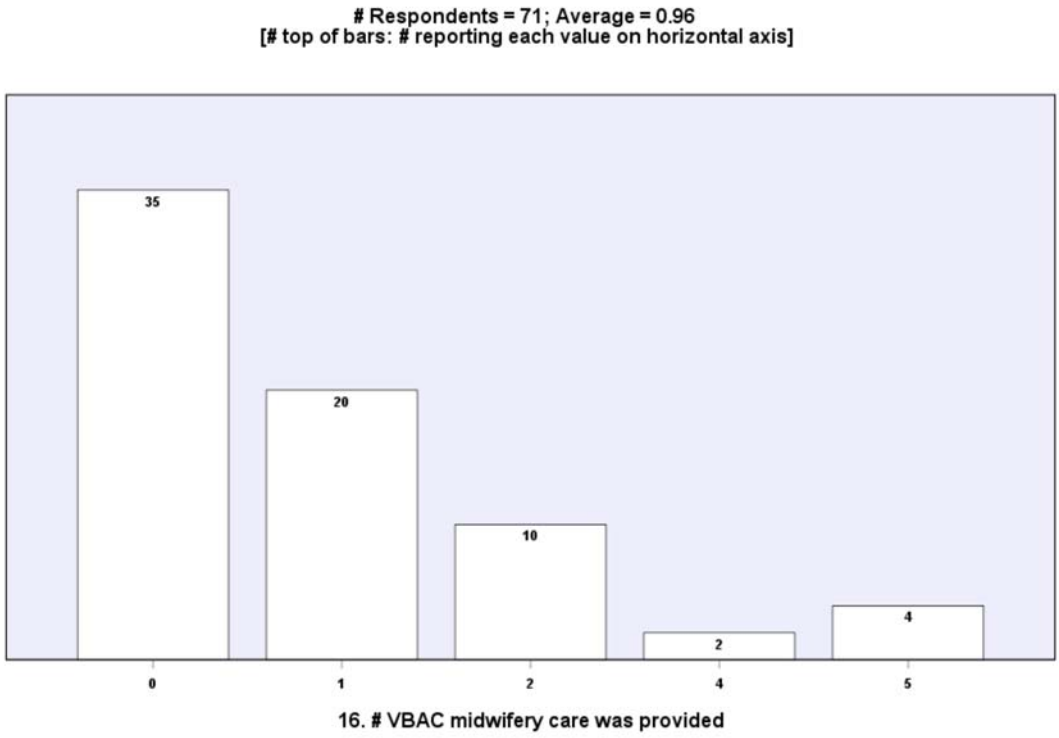
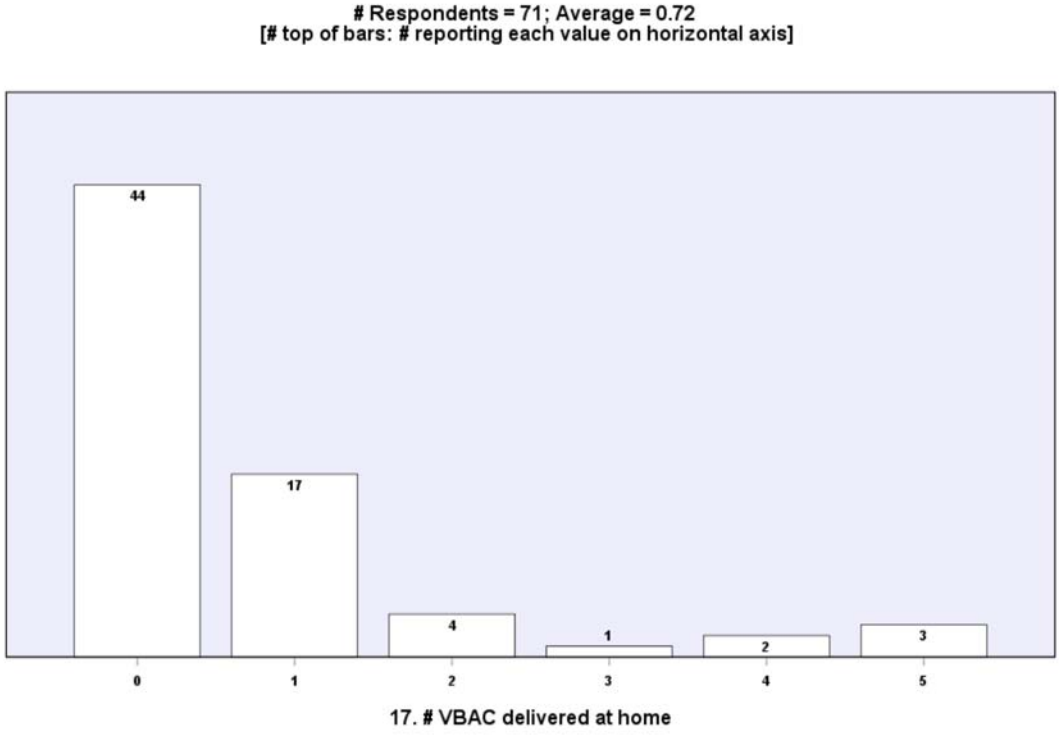
7. The number of transfers during labor and/or delivery (total number of women who transferred from a planned homebirth into physician care after the onset of labor has been identified):	
8. The number of transferred *mothers* immediately following birth within the first 24 hours (total number of women transferred into physician care within the first 24 hours after a planned homebirth):	

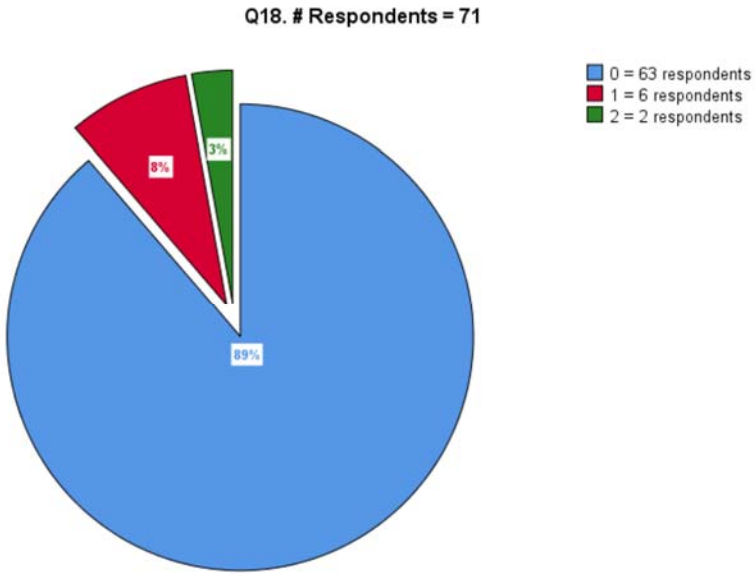
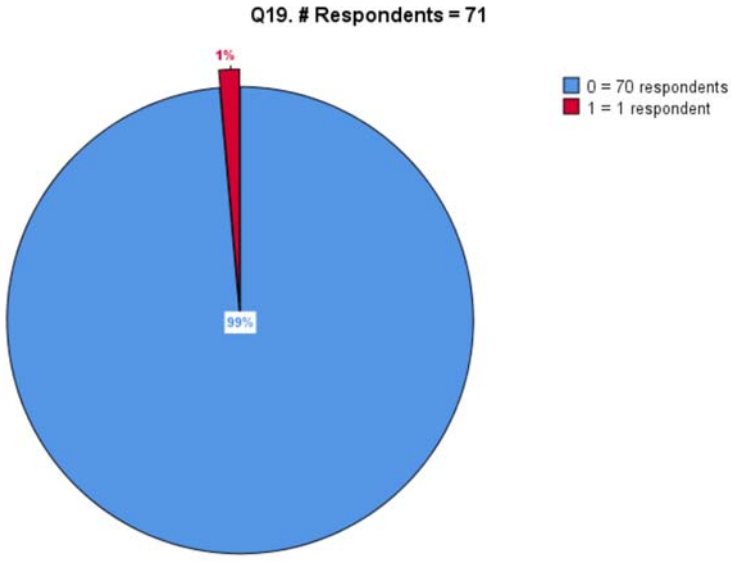
9. The number of transferred *infants* immediately following birth within the first 24 hours (total number of infants transferred into physician care within the first 24 hours after a planned homebirth):	
10. The number of infants referred for medical care after 24 hours of age and before 8 days of age (not including referrals for pediatric checkups):	

11. The number of infants referred for medical care on or after 8 days of age and before 6 weeks of age (not including referrals for pediatric checkups):	
12. The number of perinatal deaths while under the reporting midwife's care. 12(a) The number of **prenatal** fetal deaths occurring prior to the onset of labor:	

12(b) The number of **intrapartum** fetal deaths occurring after the onset of labor but before birth:	• **All Respondents Reported "0" (Zero); TOTAL # Respondents = 71**
12(c) The number of **postpartum** infant deaths occurring after birth and prior to the 28th day of life:	
13. The number of perinatal deaths after transfer of care to a medical professional. 13(a) The number of **prenatal** fetal deaths prior to the onset of labor:	

13(b) The number of **intrapartum** fetal deaths occurring after the onset of labor but before birth:	• **All Respondents Reported "0" (Zero); TOTAL # Respondents = 71**
13(c) The number of **postpartum** infant deaths occurring after birth and prior to the 28th day of life:	• **All Respondents Reported "0" (Zero); TOTAL # Respondents = 71**
14. The number of women who experienced a perineal laceration severe enough to require repair, whether or not the laceration was repaired:	
15. The number of maternal deaths:	• **All Respondents Reported "0" (Zero); TOTAL # Respondents = 71**

16. The number of VBAC women to whom midwifery care was provided:	
17. The number of VBAC women who delivered at home:	

18. The number of VBAC women transferred during labor and/or delivery:	
19. The number of VBAC women who birthed vaginally in hospital:	

20. The number of VBAC women planning a homebirth where a uterine rupture occurred: