



COLORADO

**Department of
Regulatory Agencies**

Colorado Office of Policy, Research &
Regulatory Reform

2022 Sunrise Review

Certified Midwives



October 14, 2022



COLORADO

**Department of
Regulatory Agencies**

Executive Director's Office

October 14, 2022

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 General Assembly established the sunrise review process in 1985 as a way to determine whether regulation of a certain profession or occupation is necessary before enacting laws for such regulation and to determine the least restrictive regulatory alternative consistent with the public interest. Pursuant to section 24-34-104.1, 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 its evaluation of the sunrise application for the regulation of Certified Midwives and is pleased to submit this written report.

The report discusses the question of whether there is a need for regulation in order to protect the public from potential harm, whether regulation would serve to mitigate the potential harm and whether the public can be adequately protected by other means in a more cost-effective manner.

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

Sincerely,

Patty Salazar
Executive Director



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Background

Sunrise Process

Colorado law, section 24-34-104.1, Colorado Revised Statutes (C.R.S.), requires that individuals or groups proposing legislation to regulate any occupation or profession first submit information to the Department of Regulatory Agencies (DORA) for the purposes of a sunrise review. The intent of the law is to impose regulation on occupations and professions only when it is necessary to protect the public health, safety or welfare. DORA's Colorado Office of Policy, Research and Regulatory Reform (COPRRR) must prepare a report evaluating the justification for regulation based upon the criteria contained in the sunrise statute:¹

- (I) Whether the unregulated practice of the occupation or profession clearly harms or endangers the health, safety, or welfare of the public, and whether the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument;
- (II) Whether the public needs, and can reasonably be expected to benefit from, an assurance of initial and continuing professional or occupational competence;
- (III) Whether the public can be adequately protected by other means in a more cost-effective manner; and
- (IV) Whether the imposition of any disqualifications on applicants for licensure, certification, relicensure, or recertification based on criminal history serves public safety or commercial or consumer protection interests.

Any professional or occupational group or organization, any individual, or any other interested party may submit an application for the regulation of an unregulated occupation or profession. Applications must be accompanied by supporting signatures and must include a description of the proposed regulation and justification for such regulation.

Methodology

During the sunrise review, COPRRR staff performed a literature search, contacted and interviewed the sunrise applicant, contacted regulators in Colorado, reviewed laws in other states and interviewed stakeholders. To determine the number and types of complaints filed against Certified Midwives, COPRRR staff also contacted regulatory agencies in other states.

¹ § 24-34-104.1(4)(b), C.R.S.

Profile of the Profession

Midwives provide health care to pregnant women during pregnancy, labor, delivery and the postpartum period. Midwifery care may also include care of the newborn.²

Midwifery may be practiced by nurse-midwives or non-nurse midwives. In the United States, midwives are further categorized by their training and credentials.

- **Certified Midwives** are non-nurse midwives who have completed an accredited graduate-level program in midwifery, have passed a national examination and are certified by the American Midwifery Certification Board (AMCB).
- **Certified Nurse-Midwives**³ are registered nurses who have completed an accredited graduate-level program in midwifery, have passed a national examination and are certified by the AMCB.
- **Certified Professional Midwives**⁴ are non-nurse midwives who have completed an accredited educational program in midwifery,⁵ have passed a national examination and are certified by the North American Registry of Midwives. Certified Professional Midwives may also have their skills and knowledge verified by a qualified preceptor if they have not completed an accredited educational program.
- **Lay midwives** are non-nurse midwives who have completed an apprenticeship or informal training in midwifery.

Certified Nurse-Midwives and Certified Midwives are trained to attend births in both hospital and non-hospital settings while Certified Professional Midwives and lay midwives are trained to attend births outside of hospital settings.

Non-nurse midwives are often referred to as Direct-Entry Midwives since they enter educational programs in midwifery directly, without first completing an educational program in nursing. While Certified Midwives are technically Direct-Entry Midwives, they do attend the same graduate-level programs in midwifery as Certified Nurse-Midwives, take the same national examination as Certified Nurse-Midwives and, in some states, share the same scope of practice as Certified Nurse-Midwives. Also, Certified Midwives are often regulated alongside Certified Nurse-Midwives under a state board of nursing.

While other types of midwives are discussed in this section for background purposes, Certified Midwives are the subject of this report.

² Encyclopedia Britannica. *Midwifery*. Retrieved March 29, 2022, from www.britannica.com/science/midwifery

³ In order to practice in Colorado, a Certified Nurse-Midwife must be licensed by the State Board of Nursing as an Advanced Practice Registered Nurse.

⁴ In order to practice in Colorado, a Certified Professional Midwife must register as a Direct-Entry Midwife with the Director of the Division of Professions and Occupations in the Department of Regulatory Agencies.

⁵ The Midwifery Education Accreditation Council accredits a variety of midwifery programs, including non-degree granting programs, associate degree programs, bachelor's degree programs and master's degree programs.

In 1994, the American College of Nurse-Midwives created the Certified Midwife credential to expand access to midwifery care by providing an additional pathway to enter the profession.⁶

The scope of practice in which Certified Midwives are trained and must demonstrate clinical competence encompasses providing health-care services to women, which includes supporting women during a pregnancy, labor and delivery. They may also perform gynecological examinations, provide family planning services, treat sexually transmitted infections and counsel patients on healthy lifestyles and prevention.⁷ Additionally, Certified Midwives may provide primary care services and independently prescribe medication.⁸

While Certified Midwives may work in offices, clinics, birth centers and in the home, they may also attend births in hospital settings.

Certified Midwives must complete an educational program accredited by the Accreditation Commission for Midwifery Education (ACME).⁹

Currently, about 38 midwifery programs in the United States are accredited by ACME.¹⁰ Only two of these programs admit or offer degrees for non-nurse midwives, and both of these programs are located on the East Coast.¹¹ While the College of Nursing at the University of Colorado offers a midwifery program that prepares students to become Certified Nurse-Midwives, it does not offer a program for Certified Midwives.¹²

The prerequisites to entering an educational program to become a Certified Midwife include a bachelor's degree in any subject and specific health and science courses.¹³

The discussion below describes the program at State University of New York, Downstate (SUNY Downstate) as an example of a program that prepares Certified Midwives. The two available educational programs for Certified Midwives are accredited by ACME and are, therefore, held to the same educational standards.

⁶ American College of Nurse-Midwives. *Certified Midwife Credential*. Retrieved March 29, 2022, from www.midwife.org/certified-midwife-credential

⁷ Bureau of Labor Statistics. *Occupational Outlook Handbook: Nurse Anesthetists, Nurse Midwives and Nurse Practitioners*. Retrieved March 29, 2022, from www.bls.gov/ooh/healthcare/nurse-anesthetists-nurse-midwives-and-nurse-practitioners.htm#tab-2

⁸ American College of Nurse-Midwives. *Definition of Midwifery and Scope of Practice of Certified Nurse-Midwives and Certified Midwives*. Retrieved March 29, 2022, from www.midwife.org/acnm/files/acnmlibrarydata/uploadfilename/000000000266/Definition%20Midwifery%20Scope%20of%20Practice_2021.pdf

⁹ American College of Nurse-Midwives. *Definition of Midwifery and Scope of Practice of Certified Nurse-Midwives and Certified Midwives*. Retrieved March 29, 2022, from www.midwife.org/acnm/files/acnmlibrarydata/uploadfilename/000000000266/Definition%20Midwifery%20Scope%20of%20Practice_2021.pdf

¹⁰ American College of Nurse-Midwives. *Become a Midwife*. Retrieved March 29, 2022, from www.midwife.org/Become-a-Midwife

¹¹ American College of Nurse-Midwives. *Education Programs for Certified Midwives*. Retrieved May 3, 2022, from www.midwife.org/education-programs-for-certified-midwives

¹² University of Colorado, Anschutz Medical Campus, College of Nursing. *Nurse-Midwifery*. Retrieved March 29, 2022, from nursing.cuanschutz.edu/academics/graduate-specialties/advanced-ms-dnp-specialties/nurse-midwifery

¹³ American College of Nurse-Midwives. *Become a Midwife*. Retrieved March 29, 2022, from www.midwife.org/Become-a-Midwife

SUNY Downstate requires non-nurse applicants to complete the following college-level, prerequisite courses:¹⁴

- Biology or genetics,
- General chemistry,
- Microbiology,
- Anatomy and physiology,
- Developmental psychology,
- General psychology,
- General sociology or cultural anthropology,
- Pathophysiology,
- Nutrition, and
- Statistics.

At SUNY Downstate, which is located in Brooklyn, the midwifery program's curriculum for non-nurse students is only slightly different than the curriculum for students who are registered nurses. Non-nurse students are required to take a three-credit course that teaches basic health skills, such as sterile techniques, catheterization and medication administration.

Otherwise, all students, nurse and non-nurse, attend a three-year, master's-level program. The program provides students with a mix of classroom and clinical education, covering topics, such as:¹⁵

- Antepartum care;
- Intrapartum care;
- Medical and obstetric complications of pregnancy;
- Neonatology;
- Postpartum care;
- Gynecologic, reproductive and sexual health;
- Advanced physical assessment of women;
- Pelvic assessment of women;
- Advanced pathophysiology of acute and chronic conditions in women and their primary care;
- Clinical practicum in primary care;
- Advanced Pharmacology;
- Obstetric Pharmacotherapeutics; and
- Preparation for midwifery practice.

¹⁴ SUNY Downstate, School of Health Professions. *Curriculum*. Retrieved on July 18, 2022, www.downstate.edu/education-training/school-of-health-professions/programs/midwifery/curriculum/index.html

¹⁵ SUNY Downstate, School of Health Professions. *Curriculum*. Retrieved on July 18, 2022, www.downstate.edu/education-training/school-of-health-professions/programs/midwifery/curriculum/index.html

Students at SUNY Downstate work alongside faculty in a variety of settings such as, clinics, private practices, birth centers and hospitals, to gain clinical experience in:¹⁶

- Primary care,
- Gynecologic care,
- Reproductive and sexual health family planning,
- Antepartum care,
- Intrapartum care, and
- Postpartum care.

After completing an ACME-accredited midwifery program, a graduate is eligible to take the certification examination administered by the AMCB.¹⁷

The AMCB Certification Examination is a computer-based examination that is intended to assess whether test takers have the clinical knowledge necessary for the safe practice of midwifery at the entry level.¹⁸ The examination includes questions related to patient care that a Certified Midwife may encounter in a clinical setting.¹⁹ Examinees are provided four hours to complete 175 multiple-choice questions. During the examination, examinees have the ability to review and change previously answered questions.²⁰

Table 1 illustrates the subjects covered in the examination and the percentage of the examination related to each subject.

Table 1
AMCB Certification Examination Content²¹

Subjects	Percentage of Examination
Antepartum Care	21%
Intrapartum Care	21%
Postpartum Care	18%
Newborn Care	10%
Well Woman/Gynecological Care	19%
Women’s Health/Primary Care	11%

¹⁶ SUNY Downstate, School of Health Professions. *Curriculum*. Retrieved on July 18, 2022, www.downstate.edu/education-training/school-of-health-professions/programs/midwifery/curriculum/index.html

¹⁷ American Midwifery Certification Board. *Certification Examination*. Retrieved March 30, 2022, from www.amcbmidwife.org/amcb-certification

¹⁸ American Midwifery Certification Board. *Certification Examination*. Retrieved March 30, 2022, from www.amcbmidwife.org/amcb-certification

¹⁹ AMCB Certification Exam Candidate Handbook Nurse-Midwifery and Midwifery, American Midwifery Certification Board (2022), p. 16.

²⁰ American Midwifery Certification Board. *Certification Examination*. Retrieved March 30, 2022, from www.amcbmidwife.org/amcb-certification

²¹ AMCB Certification Exam Candidate Handbook Nurse-Midwifery and Midwifery, American Midwifery Certification Board (2022), p. 17.

The AMCB Certification Examination is offered at PSI testing centers throughout the country. In Colorado, it is offered at nine locations:²²

- Centennial,
- Colorado Springs,
- Denver,
- Durango,
- Englewood,
- Fort Collins,
- Grand Junction,
- Pueblo, and
- Wheat Ridge.

The fee to take the examination is \$500, and the fee to re-take the examination is \$350.

Graduates are provided two years to pass the examination and may only take the examination four times.²³

Every five years, Certified Midwives must complete specific continuing education requirements in order to renew their certification.²⁴

Certified Midwives are currently regulated in the District of Columbia and nine states: Delaware, Hawaii, Maine, Maryland, New Jersey, New York, Oklahoma, Rhode Island and Virginia.²⁵

In the United States, only 126 Certified Midwives have active certification with the AMCB. In Colorado, Certified Midwives are qualified to register as Direct-Entry Midwives; however, by doing so, Certified Midwives would have to limit their practice to a much narrower scope than their educational programs prepare them for and in which they must demonstrate clinical competence. For instance, Direct-Entry Midwives are limited to attending out-of-hospital births. Certified Midwives, on the other hand, are trained to attend births in both hospital and out-of-hospital settings. Further, the Colorado Office of Policy, Research and Regulatory Reform could find no evidence that any Certified Midwives are registered as Direct-Entry Midwives in Colorado.

²² PSI. *Test Center List*. Retrieved by conducting a search on March 30, 2022, from online.goamp.com/CandidateHome/CandidateInformation.aspx

²³ American Midwifery Certification Board. *Step-by-Step Application Process*. Retrieved March 30, 2022, from www.amcbmidwife.org/amcb-certification/application-process

²⁴ American College of Nurse-Midwives. *Definition of Midwifery and Scope of Practice of Certified Nurse-Midwives and Certified Midwives*. Retrieved March 29, 2022, from www.midwife.org/acnm/files/acnmlibrarydata/uploadfilename/000000000266/Definition%20Midwifery%20Scope%20of%20Practice_2021.pdf

²⁵ American College of Nurse-Midwives. *Certified Midwife Credential*. Retrieved March 29, 2022, from www.midwife.org/certified-midwife-credential

Data regarding potential earnings and job growth specific to Certified Midwives are not available. However, Certified Midwives are taught midwifery to the same educational standards as Certified Nurse-Midwives and may work in the same settings, so their earnings and job growth are likely comparable. In 2020, the median annual wage for Certified Nurse-Midwives was \$111,130.²⁶ From 2020 to 2030, the employment of Certified Nurse-Midwives is expected to grow 11 percent.²⁷

²⁶ U.S. Bureau of Labor Statistics. *Occupational Outlook Handbook: Nurse Anesthetists, Nurse Midwives and Nurse Practitioners*. Retrieved March 29, 2022, from www.bls.gov/ooh/healthcare/nurse-anesthetists-nurse-midwives-and-nurse-practitioners.htm#tab-5

²⁷ U.S. Bureau of Labor Statistics. *Occupational Outlook Handbook: Nurse Anesthetists, Nurse Midwives and Nurse Practitioners*. Retrieved March 29, 2022, from www.bls.gov/ooh/healthcare/nurse-anesthetists-nurse-midwives-and-nurse-practitioners.htm#tab-6

Proposal for Regulation

The Colorado Affiliate of the American College of Nurse-Midwives (Applicant) submitted a sunrise application to the Colorado Office of Policy, Research and Regulatory Reform in the Department of Regulatory Agencies for review consistent with section 24-34-104.1, Colorado Revised Statutes (C.R.S.). The application identifies licensure of Certified Midwives as the appropriate level of regulation. The application further proposes that certification with the American Midwifery Certification Board (AMCB) be required as a condition of licensure.

According to the Applicant, licensing Certified Midwives would increase access to midwifery care in vulnerable and underserved populations since it would create an additional route for entry into graduate-level midwifery educational programs, and this could, in turn, help ameliorate increasing rates of maternal mortality, maternal morbidity and racial disparities in birth outcomes.

Also, since students seeking to work as a Certified Midwife would not need to complete an educational program in nursing prior to entering a graduate-level midwifery program, creating a licensure program for Certified Midwives could free up space in nursing schools.

The Applicant maintains that a shortage of maternity care workers is expected to grow, especially in rural areas. According to the applicant, 37 percent of Colorado counties do not have a hospital offering maternity care services, a birth center or any maternity care providers, and increasing access to midwifery services is a strategy for improving care in underserved areas.

Additionally, the Applicant states that data in other states demonstrates that licensing Certified Midwives increases the racial and ethnic diversity of midwives.

In order to become a Certified Midwife, a candidate must:

- Complete a graduate program in midwifery accredited by the Accreditation Commission for Midwifery Education, and
- Pass a national certification examination administered by the AMCB.

The AMCB requires Certified Midwives to renew their certification every five years. In order to renew, Certified Midwives must complete certain requirements to demonstrate continuing competence, which includes 20 hours of continuing education. If these requirements are not met, Certified Midwives may renew their certification by retaking the AMCB Examination.²⁸ As the Applicant proposes certification be required, continuing education would, therefore, be mandated as a condition of licensure. Consequently, the Applicant submitted the Mandatory Continuing Education application pursuant to section 24-34-901, C.R.S.

²⁸ American Midwifery Certification Board. *Purposes/Objectives*. Retrieved October 11, 2022, from <https://www.amcbmidwife.org/certificate-maintenance-program/purpose-objectives>

The applicant further proposes that Certified Midwives be regulated by the State Board of Nursing and have the same disqualifications for licensure based on criminal history as licensed nurses.

Summary of Current Regulation

Federal Laws and Regulations

At this time, no federal laws require Certified Midwives to be registered, certified or licensed in order to practice midwifery.

The Colorado Regulatory Environment

The definition of the practice of medicine specifically includes the practice of midwifery. However, the Medical Practice Act, under section 12-240-107(1)(f), Colorado Revised Statutes (C.R.S.), specifically exempts from the requirement to be licensed by the Colorado Medical Board:

- Certified Nurse-Midwives licensed as nurses under the Nurse and Nurse Aide Practice Act, and
- Registered Direct-Entry Midwives.

The State Board of Nursing regulates nurses. Under the Nurse and Nurse Aide Practice Act, a Certified Nurse-Midwife must be an Advanced Practice Registered Nurse with certification from the American Midwifery Certification Board (AMCB).

The Director of the Division of Professions and Occupations regulates Direct-Entry Midwives. To register as a Direct-Entry Midwife, an applicant must:

- Be a Certified Professional Midwife; or
- Complete a midwifery program accredited by the Midwifery Education and Accreditation Council (MEAC) and pass the North American Registry of Midwives (NARM) examination; or
- Complete a midwifery program that is substantially similar to a midwifery program accredited by MEAC and pass the NARM examination.

Neither the Medical Practice Act nor the Nurse and Nurse Aide Practice Act authorize Certified Midwives.

While a Certified Midwife would qualify to register as a Direct-Entry Midwife in Colorado, as previously stated, the scope of practice of Direct-Entry Midwives in Colorado is narrower than Certified Midwives educational programs prepare them for and in which they must demonstrate clinical competence.

Regulation in Other States

According to the Applicant, nine states and the District of Columbia currently regulate Certified Midwives. The Colorado Office of Policy, Research and Regulatory Reform (COPRRR) contacted all 10 jurisdictions to gather information about the complaint and disciplinary activity in those jurisdictions.

In order to be licensed as a Certified Midwife in each of these states, an applicant must either have certification with the AMCB or:

- Graduate from an ACME-accredited educational program, and
- Pass the AMCB Certification Examination.

Table 2 illustrates the licensing, complaint and disciplinary activity in calendar years 2020 and 2021.

**Table 2
Licensing, Complaint & Disciplinary Activity**

State	Licenses	Complaints	Discipline
Delaware	0	0	0
District of Columbia	Unknown	Unknown	Unknown
Hawaii	Unknown*	Unknown*	Unknown*
Maine	1	0	0
Maryland	Unknown	Unknown	Unknown
New Jersey	14	Unknown	Unknown
New York	Unknown**	Unknown**	Unknown**
Oklahoma	0	0	0
Rhode Island	1	0	0
Virginia	0	0	0

*Hawaii does not differentiate between Certified Midwives and Certified Professional Midwives; they are both considered “licensed midwives” Certified Nurse-Midwives are licensed separately under the Hawaii Board of Nursing.

**New York does not differentiate between Certified Midwives or Certified Nurse-Midwives; they are both considered “licensed midwives.” Certified Professional Midwives are not authorized to practice in New York.

It was difficult to gather licensing, complaint and disciplinary data related to Certified Midwives because, in some states, the name of the license does not indicate the type of midwife.

Additionally, several states only recently passed laws authorizing Certified Midwives to practice midwifery, and they have not yet initiated licensing. In Virginia, for example, the authority for Certified Midwives to practice was granted in 2021, but no rules have been adopted at this time. Both Maryland and the District of Columbia also enacted legislation to authorize Certified Midwives to practice in 2021, but COPRRR staff could not find any evidence of the establishment of a Certified Midwives licensure program or rules in either jurisdiction.

In Oklahoma, legislation was passed in 2020 and the rules were adopted in the following year. However, at this time, no Certified Midwives have sought licensure in that state.

Additionally, the District of Columbia, Maryland and New Jersey did not respond to COPRRR's requests for information.

While state-by-state data is difficult to come by, as of February 2022, 126 Certified Midwives were actively certified with the AMCB in the United States. Since the two graduate programs for Certified Midwives are located in the Northeast, it is likely that most of the licensed, practicing Certified Midwives are concentrated in that region. As Certified Midwives gain the authority to practice in additional states, however, this will likely change.

Analysis and Recommendations

Public Harm

The first sunrise criterion asks:

Whether the unregulated practice of the occupation or profession clearly harms or endangers the health, safety, or welfare of the public, and whether the potential for harm is easily recognizable and not remote or dependent on tenuous argument.

In order to determine whether the regulation of Certified Midwives is necessary, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) staff requested that the Colorado Affiliate of the American College of Nurse-Midwives (Applicant) and other stakeholders provide specific examples of harm.

According to the Applicant, the potential for harm related to midwifery includes physical harm to the patient, which may result in injury or death.

No cases of harm related to practice of Certified Midwives were uncovered during the sunrise review. However, the Applicant was able to provide cases of harm related to practice of Certified Nurse-Midwives. Since Certified Nurse-Midwives undergo the same graduate-level education and must pass the same national examination to demonstrate competence as Certified Midwives, it is reasonable to conclude that the harm related to the practice of Certified Nurse-Midwives is substantially similar to that of Certified Midwives.

Considering this, COPRRR has accepted cases of harm related to Certified Nurse-Midwives as surrogate cases for Certified Midwives. The Applicant provided 10 cases of alleged harm related to the practice of Certified Nurse-Midwives, and the Division of Professions and Occupations (Division) provided 16 cases of alleged harm related to the practice of Certified Nurse-Midwives.

COPRRR also considered cases of harm related to practice by Direct-Entry Midwives since the practice of midwifery by these types of practitioners does, at times, overlap and such cases may shed light on the potential for harm related to the practice of midwifery generally. Therefore, the Division provided six cases of alleged harm related to the practice of Direct-Entry Midwives.

In order to uncover additional cases of harm, COPRRR reached out to the 9 states and the District of Columbia where Certified Midwives are regulated. In many of these states, however, the authority to regulate Certified Midwives was only recently adopted, so no Certified Midwives had been licensed yet. Other states do not differentiate between licensed midwives based on their qualifications, so, in these states, COPRRR was unable to determine the number or type of disciplinary actions taken against licensed midwives who were trained as Certified Midwives.

While no cases of harm related to the practice of Certified Midwives were provided by the Applicant or uncovered by COPRRR staff, 32 cases of harm related to the practice of midwifery and gynecology were provided. Out of these cases, COPRRR staff found at least 12 cases that demonstrated clear evidence of harm, including five fatalities. Ten of these cases related to substandard practice. Examples of these cases are provided below, with COPRRR's analysis.

Public Harm: Substandard Practice

Example of Substandard Practice

In 2012, a Certified Nurse-Midwife who provided gynecologic care at a clinic in Colorado was reported to the State Board of Nursing for problems with her practice, including:

- Prescribing two to four times the appropriate dose of misoprostol for an intrauterine device (IUD) placement, resulting in severe cramping in the patient;
- Failing to order appropriate tests and thoroughly document an examination and differential diagnosis of a patient who had abdominal pain, a history of uterine cysts and no menses for 16 months after delivering a baby; and
- Informing a patient her uterus was normal and failing to advise her of a benign fibroid.

The State Board of Nursing subsequently placed the Certified Nurse-Midwife on probation and required her practice to be monitored by another Certified Nurse-Midwife.

Analysis

At least two patients in this case were harmed when the Certified Nurse-Midwife failed to provide care according to the commonly accepted standard of practice.

- *Misoprostol is no longer recommended for an IUD placement because it does not help, and it makes the patient uncomfortable. In this case, the wrong dosage was prescribed, which unnecessarily increased the patient's discomfort.*
- *It is the standard of practice for Certified Nurse-Midwives to document every possible diagnosis and why certain diagnoses were ruled out. In this case, the actual problem and harm to the patient is unknown.*
- *By failing to inform a patient that she has fibroids in her uterus, the Certified Nurse-Midwife withheld information that the patient needed in order to share in the decision-making process related to her care.*

Example of Substandard Practice

In 2012, a Certified Nurse-Midwife in Colorado cared for a woman who arrived at a hospital by ambulance. The patient had been contracting since the previous night and her amniotic sac had ruptured. The Certified Nurse-Midwife examined the patient and

two hours later sent her home. The patient delivered at home within a few hours and began hemorrhaging.

The Certified Nurse-Midwife admitted to using poor clinical judgement when assessing the patient, failing to document assessment data in the patient's chart and failing to develop a therapeutic relationship with the patient.

The Certified Nurse-Midwife was terminated from the hospital based on this case and two similar cases in which she had received warnings about her practice. The State Board of Nursing subsequently placed the Certified Nurse-Midwife on probation and required her practice to be monitored by another Certified Nurse-Midwife.

Analysis

The patient was harmed when she was sent home from the hospital and had to deliver a preterm baby at home without a birth attendant. Hemorrhaging is common in childbirth and uncontrolled hemorrhaging can lead to maternal death.

Example of Substandard Practice

In 2011, a woman in Michigan was at term in her second pregnancy. In her first pregnancy, she had a successful vaginal delivery at a hospital. Seeking more personal care than she had previously experienced delivering in a hospital, she chose to deliver her second baby at a birth center under the care of a Certified Nurse-Midwife.

The baby was noted to be in breech position two months before her due date, and this position was confirmed by ultrasound one month later. Although a breech birth is considered to be high risk, she was allowed to labor at an out-of-hospital birth center.

Labor proceeded normally until the second stage, which is typically one to two hours in a second pregnancy. After pushing for nearly six hours, the baby was born up to the chest, but the head was stuck.

According to a news report, it was seven minutes before the head was delivered. The baby was born "blue and lifeless." Paramedics were called after four minutes of attempted resuscitation, and the baby was transported to a hospital and spent 13 days in the Neonatal Intensive Care Unit (NICU) before dying from "severe brain damage and organ failure."²⁹

Analysis

Clearly, the baby and the family were harmed in this case. Knowing that the baby was breech, the mother should have been transferred to a hospital. By failing to transfer care to an appropriate facility, the baby suffered organ

²⁹ Louise Knott Ahern, "Couple awarded \$5 million after botched midwife delivery," *USA Today*, May 27, 2014.

failure and brain damage and later died after spending nearly two weeks in a NICU, a situation that was preventable and likely devastating to the family. The Michigan Board of Nursing found the Certified Nurse-Midwife's conduct to be negligent, and the Certified Nurse-Midwife subsequently surrendered her license.

Public Harm: Fraud and Falsifying Records

In addition to 10 cases related to substandard practice, COPRRR staff also identified one case of harm related to fraud and falsifying records. This case with COPRRR's analysis is outlined below.

Example of Fraud and Falsifying Records

In 2016, the State Board of Nursing issued a letter of admonition to a Colorado-licensed Certified Nurse-Midwife who had previously been disciplined as a Registered Nurse in Guam. The reasons for Guam's disciplinary action and termination by his employer were:

- Practicing outside of the scope of practice of a registered nurse,
- Falsifying records,
- Engaging in fraudulent activities related to his place of business, and
- Impersonating a medical provider.

According to records from Guam, during this time, the Registered Nurse, who had not yet qualified as a Certified Nurse-Midwife, cared for two women during labor, delivery and the postpartum period. There is no record that the obstetrician on call was notified; and there was no physician oversight during the time the care was provided. He subsequently logged into the facility's electronic system where he filled out and signed the patient records using an obstetrician's login and name.

Analysis

It is unknown whether any patients were physically harmed by the actions of the Certified Nurse-Midwife when he was employed as a Registered Nurse in Guam. However, fraud and falsifying records in health-care settings is harmful to patients, employers and the public.

Public Harm: Controlled Substances

One of the cases in which COPRRR found clear evidence of harm concerned a Certified Nurse-Midwife who prescribed controlled substances outside the course of legitimate practice.

Example of Prescribing Controlled Substances to a Family Member and Outside the Course of Legitimate Practice

In 2013, a Certified Nurse-Midwife wrote a prescription for a controlled substance for a family member. The prescription was also written outside the course of legitimate practice. The State Board of Nursing subsequently issued a letter of admonition.

Analysis

Prescribing controlled substances outside the course of legitimate practice causes significant harm to the public since controlled substances are highly addictive and prone to abuse. It is also unethical for practitioners to treat family members. In such a case, a practitioner's personal feelings may cloud their clinical judgement. This is especially dangerous if someone in the family or the prescriber is abusing or diverting drugs.

Potential for Harm: Substandard Practice

Out of the 20 cases in which actual harm was not substantiated, 12 cases demonstrated a clear potential for harm. Of these cases, 10 related to substandard practice.

Example of Substandard Practice

In 2019, a Colorado-licensed Certified Nurse-Midwife failed to document vital entries in a patient's records and failed to notify the patient of her urine test and the medications needed to treat an infection. Based on this, the State Board of Nursing issued a letter of admonition.

Analysis

In this case, the patient outcome is unknown. It is also unknown if the patient was pregnant. However, an untreated bladder infection can be serious and could result in a kidney infection and sepsis, which can be fatal.

Example of Substandard Practice

In 2017, a Direct-Entry Midwife in Colorado cared for a client who had a medical history that established her as high-risk for a home birth. The midwife had cared for the patient during a previous pregnancy and delivery in which the patient was transported to emergency services due to a delayed placental delivery and some hemorrhaging.

During the second pregnancy, the midwife failed to timely initiate transport of the patient even though the blood loss exceeded allowable amounts, the bleeding was uncontrolled, and the mother's vital signs were unstable.

Analysis

In this case, the patient outcome is unknown. However, delayed placental delivery and severe, uncontrollable hemorrhaging can be serious and could result in maternal death.

Example of Substandard Practice

In 2017, a pregnant woman who was at term with her first baby was attended by a Certified Nurse-Midwife at a birth center in North Carolina. The baby was delivered and needed resuscitation. Forty-seven minutes later, the baby was pronounced dead. According to a lawsuit related to this case, the Certified Nurse-Midwife allegedly failed to:³⁰

- Consult with physicians according to their protocols with a prenatal weight gain of more than 60 pounds;
- Adequately monitor vital signs and fetal heart rate monitoring according to protocol;
- Consult after laboring for more than four hours according to protocol; and
- Use appropriate resuscitation measures and call for paramedics to transfer the baby to the hospital.

Analysis

While the allegations in this case are unsubstantiated, they are serious and the infant died following delivery. If the allegations against the Certified Nurse-Midwife are found to be true, the North Carolina Board of Nursing could take disciplinary action against the Certified Nurse-Midwife's license. However, COPRRR could not find evidence of a disciplinary action related to this case.

Potential for Harm: Drug and Alcohol Abuse

Additionally, one case in which patient harm was unsubstantiated concerned a Certified Nurse-Midwife who had a history of drug and alcohol abuse. While patient harm is unknown, this case clearly demonstrates the potential for patient harm.

Case of Drug and Alcohol Abuse

In 2007, the State Board of Nursing required a Certified Nurse-Midwife to enter into an agreement for a conditional license, in which she was required to participate in a peer assistance program for abuse of alcohol. The Certified Nurse-Midwife had previously been publicly disciplined by the Wyoming Board of Nursing when she was found to have been incapacitated and under the influence of alcohol during her nursing shift. In 2007, the Wyoming Board of Nursing publicly reprimanded her and further modified her conditional license by adding additional restrictions, such as drug screening for both alcohol and opiates and monthly monitoring of the nurse's prescriptions through the

³⁰ Cullen Browder, "Durham couple suing Cary birthing center over newborn's death," *WRAL.com*, December 18, 2019.

state's Prescription Drug Monitoring Program. The Wyoming Board of Nursing's action was based on the nurse's testimony that she had relapsed and had a history of abusing controlled substances, and the finding that she had failed to disclose disciplinary actions in other states.

Analysis

It is unknown whether the nurse harmed any patients during the time she was abusing drugs and alcohol. However, the potential for harm to patients related to excessive use and abuse of drugs and alcohol is high since substance abuse impairs a practitioner's judgement and their ability to perform midwifery duties safely. Certified Nurse-Midwives also have access to controlled substances and can easily divert drugs. Drug diversion in hospital settings is especially problematic because drugs may be diverted from patients who require pain relief.

In total, COPRRR uncovered 24 cases in which harm was either established or there was a clear potential for harm. These cases span a 15-year period from 2004 to 2019, and 16 of these cases took place in Colorado.

COPRRR found that harm in midwifery is mostly related to substandard practice. However, evidence of harm in midwifery was also found in cases related to:

- Fraud and falsification of records,
- Drug and alcohol abuse, and
- Prescribing controlled substances outside the course of legitimate practice.

Harm related to substandard practice often occurred when the midwife either delayed the transfer of care to emergency services when necessary or failed to refer to, or consult with, another health-care provider when the patient's care exceeded the skills and knowledge of the midwife. These types of cases occurred in all settings in which a midwife may practice, including patient homes, birth centers and hospitals.

Need for Regulation

The second sunrise criterion asks:

Whether the public needs and can reasonably be expected to benefit from an assurance of initial and continuing professional or occupational competence.

The practice of midwifery is already regulated in Colorado. While it is currently possible for Certified Midwives to obtain registration as Direct-Entry Midwives in Colorado, any Certified Midwives who did would be limited to working to a much narrower scope of practice than their training prepares them for and in which they must demonstrate clinical competence. Specifically, Direct-Entry Midwives are not allowed to practice in

hospital-based settings, and they also have very limited prescriptive authority. For Certified Midwives to practice to the level for which they are trained and in which they must demonstrate clinical competence, legislation must be passed that authorizes them to do so.

At this time, COPRRR could find no evidence that any Certified Midwives are currently practicing in Colorado.

The vast majority of the cases submitted to and evaluated by COPRRR relate to substandard practice. COPRRR found clear evidence of patient harm caused by substandard practice in 10 cases, including five fatalities.

Midwives are independent practitioners with a limited scope of practice. When conditions exist that are beyond their education, skill and knowledge, they are generally expected to refer, or transfer care of the client, to an appropriate health-care provider. Failure to refer or transfer care can result in complications in pregnancy, labor and delivery, including the death of the fetus or newborn. In rare cases, the mother's life may also be in danger. While no cases were submitted in which a maternal death occurred, the potential for harm does exist.

While many women are able to go through a pregnancy, labor and delivery safely with no complications, many things can and do happen during this time that require assessment and care by a skilled practitioner, and the evidence provided demonstrates that the public would benefit from an initial demonstration of competence related to the practice of midwifery.

If the regulatory program for Certified Midwives proposed by the Applicant is created, all Certified Midwives would be required to complete mandatory continuing education (MCE) every five years in addition to other requirements in order to demonstrate continued competence. Consequently, the Applicant submitted an MCE application as required in section 24-34-901, Colorado Revised Statutes (C.R.S.). However, the application submitted by the Applicant failed to demonstrate a need for ongoing MCE.

Alternatives to Regulation

The third sunrise criterion asks:

Whether the public can be adequately protected by other means in a more cost-effective manner.

While midwifery is practiced without regulation in some states, because the risk of harm is significant, the public policy in Colorado has long supported the regulation of midwifery.

In fact, the Medical Practice Act includes the practice of midwifery in the definition of the practice of medicine, so in order to practice midwifery in Colorado, practitioners must be licensed by the Medical Board. The Medical Practice Act recognizes only two exemptions to this requirement:

- Certified Nurse-Midwives, and
- Direct-Entry Midwives.

Certified Nurse-Midwives are regulated under the Nurse and Nurse Aide Practice Act and, in order to practice, they must be licensed by the State Board of Nursing. Direct-Entry Midwives are regulated under the Direct-Entry Midwives Practice Act and, in order to practice, they must be registered by the Director of the Division of Professions and Occupations.

As midwifery is considered the practice of medicine and anyone who practices midwifery must either be licensed under the Medical Practice Act, the Nurse and Nurse Aide Practice Act or the Direct-Entry Midwives Practice Act, if Certified Midwives are authorized to practice, they should also be regulated.

Collateral Consequences

The fourth sunrise criterion asks:

Whether the imposition of any disqualifications on applicants for licensure, certification, relicensure, or recertification based on criminal history serves public safety or commercial or consumer protection interests.

Most of the cases of harm found in the sunrise review relate to substandard practice. Only three cases concern other types of harm:

- Fraud and falsification of patient records,
- Drug and alcohol abuse, and
- Prescribing controlled substances to a family member and prescribing controlled substances outside the course of legitimate practice.

As both Certified Midwives and Certified Nurse-Midwives practice midwifery and are trained to the same educational standards and must demonstrate the same clinical competence, it would be reasonable to expect that these practitioners would share the same grounds for discipline.

The grounds for discipline that are established for Certified Nurse-Midwives in the Nurse and Nurse Aide Practice Act applies to all licensed nurses in Colorado and include, among other things:³¹

- Being convicted of a felony or any crime that would be considered a violation of the Nurse and Nurse-Aide Practice Act;
- Falsifying or negligently making incorrect entries or failing to make essential entries in patient records;
- Excessively or habitually using or abusing or engaging in excessive or habitual use or abuse of alcohol, a habit-forming drug, a controlled substance, or any other similar drugs;
- Prescribing, distributing or administering any controlled substance to themselves or to a family member;
- Prescribing, distributing or administering any controlled substance outside the course of legitimate practice; and
- Diverting controlled substances or similar drugs from the person's place of employment.

As the above list demonstrates, in addition to the grounds for discipline based on criminal convictions, Certified Nurse-Midwives have separate grounds for discipline for falsifying patient records, drug and alcohol abuse, prescribing controlled substances to family members and prescribing a controlled substances outside the course of legitimate practice. Since the three cases identified would fall under separate grounds for discipline, COPRRR did not uncover any cases that directly support the need for disqualifications related to criminal convictions.

That said, Certified Nurse-Midwives do have prescriptive authority, which includes prescribing controlled substances. Since Certified Midwives share the same training and must demonstrate the same clinical competence, it is reasonable to assume that they would also have this authority if they were regulated.

Misuse, abuse and diversion of controlled substances is especially harmful to patients and to the public in general, so it would be expected that regulators would be allowed to consider criminal history related to drugs when evaluating an applicant for licensure. While an individual may not be using or abusing drugs themselves and may not have diverted drugs from their employer, they could have a history of criminal activity related to drugs that would raise questions about whether the practitioner should be trusted with controlled substances or drugs that have similar effects.

Likewise, Certified Midwives have significant access to sensitive personal and financial information related to their patients, so it would be expected that regulators who are evaluating an applicant for licensure would be provided the authority to consider a criminal history of theft, fraud, financial abuse and other similar crimes against property.

³¹ §§ 12-255-120(1)(b)(h)(i)(p)(s) and (gg), C.R.S.

Finally, Certified Midwives are health-care providers whose entry-level competence includes both midwifery and gynecological care. Considering the sensitive nature of this health-care field, it would also be expected that regulators would have the authority to consider criminal history involving crimes against a person, such as violent or sexually related offenses, when evaluating an applicant for licensure.

While COPRRR found no evidence related to such cases, midwifery is already regulated in Colorado under the Medical Practice Act, the Nurse and Nurse Aid Practice Act and the Direct-Entry Midwives Practice Act. Considering this, if the General Assembly decides to establish a new category of midwife, it would be reasonable to expect that the disqualifications that apply to other similar practitioners, especially Certified Nurse-Midwives, would also apply to Certified Midwives.

Conclusion

COPRRR was unable to find any cases of harm related to the practice of midwifery by Certified Midwives. As there are only 126 Certified Midwives practicing in the United States, the inability to find evidence of harm is more likely related to the small size of the profession rather than the actual risk of harm, or lack thereof.

While COPRRR did not find any cases of harm related to practice by Certified Midwives, COPRRR did consider 32 cases of harm related to the practice of midwifery, including 26 cases involving Certified Nurse-Midwives and six cases involving Direct-Entry Midwives.

Certified Midwives receive the same midwifery training and take the same national examination to prove entry-level competence as Certified Nurse-Midwives. Therefore, the harm related to midwifery as it is practiced by Certified Nurse-Midwives is likely to be substantially similar to the harm related to midwifery as it is practiced by Certified Midwives.

COPRRR looked for but could not find any cases comparing the patient outcomes of Certified Midwives with the patient outcomes of Certified Nurse-Midwives. However, an educator who is involved in the education of both Certified Midwives and Certified Nurse-Midwives reported that, in classrooms and clinical settings, the non-nurse students in the midwifery program perform as well as the nurse students.

COPRRR also reviewed a handful of cases of harm related to Direct-Entry Midwives. While their training standards and entry-level competence is different from that of Certified Midwives, their practice does at times overlap, and these cases can shed light on the potential for harm related to midwifery in general.

After a thorough review of the cases of harm, it is reasonable to conclude that, if the General Assembly elects to create a new category of midwife, regulation of Certified Midwives is justified.

Moreover, the public policy of Colorado has long supported the regulation of the practice of midwifery. In fact, the practice of midwifery is already regulated under three laws in Colorado:

- The Medical Practice Act,
- The Nurse and Nurse Aide Practice Act, and
- The Direct-Entry Midwives Practice Act.

While the practice of midwifery is already regulated in Colorado, under the current law, Certified Midwives are only allowed to register as Direct-Entry Midwives, so they are limited to working to a narrower scope of practice than their training prepares them for and in which they must demonstrate clinical competence.

Specifically, in addition to supporting women during a pregnancy, labor and delivery, Certified Midwives are also trained to:³²

- Perform gynecological examinations,
- Provide family planning services, and
- Treat sexually transmitted infections.

Certified Midwives are also trained to independently prescribe medication.

Finally, Certified Midwives are trained to work in both hospital settings and non-hospital settings, but under the Direct-Entry Midwives Practice Act, they are only allowed to work in non-hospital settings.

During the sunrise review, COPRRR interviewed stakeholders, and one story that was shared demonstrates the problem that this situation creates.

A Certified Midwife who had been licensed and worked for several years in another state without any problems moved to California where her qualifications were not recognized. In order to continue to work in her chosen profession, she decided to apply to nursing school, complete a bachelor's degree in nursing, complete another graduate-level educational program in midwifery and pass another examination required to demonstrate entry-level competence. With the exception of the bachelor's degree in nursing, she had already taken these steps in the state where she was previously licensed. However, because she did not hold a nursing degree, she could not get licensed as a nurse, which was required in order to practice as a Certified Nurse-Midwife. The cost and time that this required would not have been necessary if the state had recognized the qualifications that this practitioner already held.

³² Bureau of Labor Statistics. *Occupational Outlook Handbook: Nurse Anesthetists, Nurse Midwives and Nurse Practitioners*. Retrieved March 29, 2022, from www.bls.gov/ooh/healthcare/nurse-anesthetists-nurse-midwives-and-nurse-practitioners.htm#tab-2

In addition to the unnecessary expenses and time that this placed on the individual practitioner, it also has serious consequences for the public. First, it decreases access to nursing care since one of the spots in nursing school was filled by someone who was already qualified to practice midwifery in another state. Second, it decreases access to midwifery services since other qualified practitioners may not be willing to complete all these steps when they could easily practice in other states where their qualifications are already recognized.

Considering this, the barrier to entering the profession for a Certified Midwife in Colorado is not the creation of a regulatory program, as it is with the vast majority of professions, but the lack of one.

If the General Assembly chooses to recognize this category of midwife, Certified Midwives should be regulated alongside Certified Nurse-Midwives, with whom they share the same training in midwifery, must demonstrate the same clinical competence and share the same standards of practice.

Placing Certified Midwives under the State Board of Nursing, which already regulates Certified Nurse-Midwives, would enable them to work to their full potential, and it may also attract more qualified midwives to practice in Colorado. This could benefit the state by increasing midwifery services to Coloradans.

Additionally, by recognizing the qualifications of Certified Midwives, the General Assembly would create an opportunity for educational programs for Certified Nurse-Midwives to extend their programs to non-nurse students. This could benefit Coloradans because more spots in nursing school would be available, which would increase access to nursing services in the state.

If the General Assembly decides to recognize this category of midwife, it would be reasonable for Certified Midwives to share the same regulatory system, such as the requirements for prescriptive authority and the grounds for discipline, as Certified Nurse-Midwives. The one exception to this is that Certified Midwives should not be required to be licensed as Registered Nurses in order to practice.

For these reasons, the General Assembly should regulate Certified Midwives under the Nurse and Nurse Aide Practice Act.

Recommendation - Regulate Certified Midwives under the Nurse and Nurse Aide Practice Act.