Steve Sisolak Governor

Richard Whitley, MS *Director*



DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF PUBLIC AND BEHAVIORAL HEALTH Helping people. It's who we are and what we do



Lisa Sherych *Administrator*

Ihsan Azzam, Ph.D., M.D. Chief Medical Officer

DIVISION OF PUBLIC & BEHAVIORAL HEALTH BUREAU OF HEALTH CARE QUALITY AND COMPLIANCE LCB FILE NO. R062-21

Informational Statement per NRS 233B.066

1. A clear and concise explanation of the need for the adopted regulation;

The proposed changes to NAC Chapter 449 are being moved forward as a result of Assembly Bill 287 of the 81st (2021) legislative session which voids the obstetric center regulations codified as NAC 449.6113 to 449.61178 and requires the Board of Health to adopt separate regulations governing the licensing and operation of freestanding birthing centers that align with the standards established by the American Association of Birth Centers, the accrediting body of the Commission for the Accreditation of Birth Centers, or another nationally recognized organization for accrediting freestanding birthing centers. In addition, the regulations adopted by the Board of Health must allow for the provision of supervised training to providers of health care, as appropriate, at a freestanding birthing center.

Of note, after consultation with the Board of Pharmacy and a Legislative Counsel Bureau (LCB) attorney, it was determined that non-licensed midwives, such as individuals that are only certified professional midwives, are not authorized to administer medications; therefore, the proposed regulations do not align with the standards adopted by reference, Indicators of Compliance with Standards for Birth Centers, published by the Commission for the Accreditation of Birth Centers in Section 12 of the proposed regulations, which allows certified midwives (CM) or Certified Professional Midwives (CPM) with Midwifery Education Accreditation Council (MEAC) accredited education or a Bridge Certificate to administer certain medications as outlined in the standards. Because of this and in order to ensure public safety, the proposed regulations require at least one of the two required attendants present at each delivery of a newborn at a freestanding birthing center, to be a clinical provider who is authorized under federal and state law to possess and administer dangerous drugs.

2. A description of how public comment was solicited, a summary of public response, and an explanation how other interested persons may obtain a copy of the summary;

Public comment was solicited via a public workshop and a public hearing. Below you will find a summary of the public response and an explanation on how other interested persons may obtain a copy of the summary.

Public Workshop – October 15, 2021

A public workshop was held on October 15, 2021, via a virtual meeting with a call-in option. The following is a summary of the testimony provided during the public workshop:

- We are here to help so I'm just intending to learn all I can. We have done some research with our APRN midwives. We don't have objections. We're just happy to be part of the process.
- We are currently the first and only state licensed freestanding state license and nationally accredited freestanding birth center in Nevada. I've been employed with Serenity Birth Center for the past 3 years. I'm in favor of the proposal amendments to Nevada NAC 449. The new proposed regulations will have a huge cost savings for our practice and our center and for future birth centers in the state of Nevada. One of our biggest challenges from local, city, and state regulations was being compared to an ambulatory surgical center. Our land is actually zoned for a hospital and with this comparison came overbearing costs and a lot of them could be avoided for the services we provide. At the birth center, a simple example would be that our life safety equipment used in the center is all battery operated whereas in a surgical center, most safety equipment requires a wall mounted voltage outlet. We also use portable oxygen. We don't have gases within our walls like an ambulatory surgery center would have. The new regulations are aligned with existing freestanding birth center guidelines. Our center's Commission for the Accreditation of Birth Centers accreditation became effective September 22, 2021, which is currently a requirement of NAC 449.6113 and assures the highest level of evidence-based care and safety for patients.
- Serenity Birth Center is the first state licensed and nationally accredited facility in NV. My vision for birth centers and more options for women in NV spans back over two decades. A Northern NV Certified Nurse Midwife and I were an integral part of changing legislation to allow birth centers to exist in Nevada. Serenity Birth Center is a healthcare facility for childbirth where care is provided in the midwifery and wellness model. Birth Centers are an integrative part of the health care system and are guided by principles of prevention, sensitivity, safety, appropriate medical intervention and costeffectiveness. While the practice of midwifery and the support of physiologic birth and newborn transition may occur in other settings, this is the exclusive model of care in a birth center. The birth center respects and facilitates a woman's right to informed choices about her health care and baby's health care based on her values and beliefs. The woman's family, as she defines it, is welcome to participate in the pregnancy, birth, postpartum period and well-woman care. Licensed and accredited birth centers are approved as a safe place of birth for healthy, low-risk women and neonates by the American College of Obstetricians and Gynecologists (ACOG). Additionally, the midwifery model of care improves outcomes for maternal and infant health. Preterm birth rates and cesarian sections are reduced. Infant birth weights are increased. Satisfaction by mothers and families are increased while costs are reduced for families. I support these proposed changes as they will reduce costs at my current

center in regard to staff salaries, unnecessary equipment, medical supplies, and building regulations. The proposed amendment will improve daily operations at my Center to continue providing evidence-based care which in turn helps me meet my multi-decade long goal of there being more birthing options for women and families in Nevada.

- I am excited to support the move to promote a proliferation of freestanding birth centers in Nevada. This is a tremendous move in the direction of promoting equity and access to birthing access and birthing options for all pregnant people in Nevada and I appreciate the work that you have done to pull this together and the support of the folks who worked to make these regulations therefore making beginning, operating, and having a birthing center in Nevada as successful as possible.
- I'm in support of the proposed amendment. I'm the director of nursing at Serenity Birth Center. My main role over the last 22 and a half years has been reviewing local, city, state and national birth center laws and regulations and from there, I have worked to implement policies and procedures to ensure compliance. At the physical birth center and for our staff our priority is evidence- based care and safety for the family seeking care with us and the proposed amendments align with national guidelines for scope of care including safety, OSHA, HIPAA, clear staff education, facility equipment and supplies, health record research and quality improvement programs. There are many proposed changes that will have cost savings as a result of this proposed change and improved safety and effectiveness that are in line with freestanding birth centers nationwide. Our center is one of 84 nationally accredited centers in the United States. Only 17% of presenting birth centers are accredited and Nevada should be proud to hold us accountable to these standards. We are excited and in support of these proposed amendments.
- From a public health perspective these regulations serve to really promote public health for pregnant persons and for the community as a whole by providing safe ways for people to have options in the birthing process.

Written Testimony – November 19, 2021

Written testimony was received from a senior counsel representing the Accreditation Association for Ambulatory Health Care, Inc., dated November 19, 2021, which noted: We recently became aware of the proposed amendments to Chapter 449 of NAC1 and Medicaid Services Manual (MSM) Chapter 2002 to require freestanding birthing center (FSBC) accreditation. We noted that the authorizing statute, NRS 449.0302(12) provided opportunity for review of additional accreditation organizations not specifically listed in the law; however, it does not appear that the same language was included in the regulatory proposal. As such, AAAHC respectfully requests that the Division eliminate the barrier to entry into the Nevada FSBC accreditation market by providing the opportunity for additional organizations to become approved FSBC accreditors. Attached please find our recommendations for updating the language to allow for future competition in the Nevada FSBC accreditation market.

Subsection 12 of Section 16.5 of AB 287 of the 81st (2021) legislative session reads as follows:

12. The Board shall adopt separate regulations governing the licensing and operation of freestanding birthing centers. Such regulations must: (a) Align with the standards established by the American Association of Birth Centers, or its successor organization, the accrediting body of the Commission for the Accreditation of Birth

Centers, or its successor organization, or another nationally recognized organization for accrediting freestanding birthing centers; and (b) Allow the provision of supervised training to providers of health care, as appropriate, at a freestanding birthing center.

Although in most cases we would open up accreditation regulatory requirements to any nationally recognized organization for accrediting freestanding birthing centers, in this case the bill language is clear that the proposed regulations must align with one of the standards listed in subsection 12 of Section 16.5 of the bill and does not require that it be opened up to all accrediting organizations.

In this particular case the use of one accrediting organization's standards to align the proposed regulations is in line with the statutory requirement. It is an evidence-based nationally recognized accrediting standard specifically listed in the bill in which the only licensed freestanding birthing center is accredited by; therefore, removing financial and compliance burdens on freestanding birthing centers that may be created if the proposed regulations attempted to align with multiple accrediting standards. In addition, once the proposed regulations aligned with accrediting standards becomes effective, it would not be possible to realign them to any new accrediting standards without going through the regulatory process. In conclusion, based on how the bill is written, staff have determined that the most effective, efficient, and least burdensome manner for implementation of this component of the proposed regulations, is to align them with one evidence-based nationally recognized birthing center standard.

Public Hearing – June 3, 2022

The public hearing was held before the Board of Health on June 3, 2022. An overview of the proposed regulations was presented to the Board of Health, including testimony noting that:

• Section 12 adopts by reference certain standards published by the Commission for the Accreditation of Birth Centers; and requires a freestanding birthing center to comply with and maintain a copy of those standards. When evaluating the proposed regulations, it is important to also take into consideration, the Indicators of Compliance with Standards for Birth Centers published by the Commission for the Accreditation of Birth Centers, for which the proposed regulations require a center to comply, as these cover many provisions not specifically listed out in the proposed regulations.

Two board members noted that they had read the Commission for the Accreditation of Birth Centers, Indicators of Compliance with Standards for Birth Centers "Indicators".

One Board member noted that she originally had concerns but after reading the "Indicators" she no longer had concerns and was supportive of the selected standard.

Another board member expressed concerns about hospital transfers. It was noted that the "Indicators" require a pre-arranged plan for ready access to pediatrics/neonatology in the event of a transfer, as well as a pre-arranged plan for ready access to obstetrical services. It was noted that this standard would be checked for compliance during a survey.

Section 2C.9.c Obstetric Consultation Services on page 80 notes:

"Evidence of: The birth center's ability to provide access to obstetrical and acute care services for the mother and fetus, including:

"A pre-arranged plan for ready access to obstetrical and acute care services for the mother and fetus in the event of a transfer, including transfer of health records and care."; and

Section 2C. 9.d – Pediatric Consultative Services on page 81 notes:

"A pre-arranged plan for ready access to pediatric/neonatology and acute care services for the mother and fetus in the event of a transfer, including transfer of health records and care.".

One person testified in support of the proposed regulations noting the importance of taking into account the financial impacts of operating a birthing center.

No one testified in opposition of the proposed regulations.

Any other persons interested in obtaining a copy of the summary may e-mail, call, or mail in a request to:

Leticia Metherell Division of Public and Behavioral Health 727 Fairview Drive, Suite E Carson City, NV 89701 Phone: 775-684-1045

Email: lmetherell@health.nv.gov

- 3. A statement indicating the number of persons who attended each hearing, testified at each hearing, and submitted written statements regarding the proposed regulation. This statement should include for each person identified pursuant to this section that testified and/or provided written statements at each hearing regarding the proposed regulation, the following information, if provided to the agency conducting the hearing:
 - (a) Name
 - (b) Telephone Number
 - (c) Business Address
 - (d) Business telephone number
 - (e) Electronic mail address; and
 - (f) Name of entity or organization represented

Public Workshop – October 15, 2021

The public workshop was attended by 9 individuals, not including Division of Public and Behavioral Health Staff.

Testimony was provided by five individuals, and one of these individuals, in addition to providing their own testimony, provided testimony on behalf of another individual, for a total of 6 individuals providing testimony. All individuals in which testimony was heard at the public workshop are noted below.

Fred Olmstead, Nevada Board of Nursing 5011 Meadowood Mall Way, #300, Reno, NV 89502,

Phone:775-687-7700

Email: folmstead@nsbn.state.nv.us

Cheryl Rude, Serenity Birth Center 332 South Jones Blvd, Las Vegas, NV 89107

Phone: 702-269-6018,

Email: cheryl@lvbirthcenter.com

Genevieve Burkett, Serenity Birth Center 332 South Jones Blvd, Las Vegas, NV 89107,

Phone: 702-269-6018

Email: genevieve@lvbirthcenter.com

Linda Anderson, Nevada Public Health Foundation (NPHF)

NPHF Office location: 3476 Executive Pointe Way, Suite 10, Carson City, NV 89706,

Phone: 775-884-0392 Email: lindaa@nphf.org

Tara Raines, Children's Advocacy Alliance Cheryl Rude provided testimony on behalf of April Clyde (Serenity Birth Center)

Written Testimony - November 19, 2021

Three of the individuals that provided or whose testimony was provided at the public workshop also submitted written statements in support for the 10/15/21 workshop.

In addition, another individual, noted below, submitted written statements regarding the proposed regulations.

Ann Carrera, JD, Sr. Counsel Accreditation Association for Ambulatory Health Care, Inc. 5250 Old Orchard RD, Ste 200 Skokie, Illinois, 60077

Phone: 847-853-6060 Email: www.aaahc.org

Public Hearing – June 3, 2022

The Nevada Board of Health public hearing was held on June 3, 2022. There were 59 distinct virtual attendees signed into the hearing. Of note, this included individuals that may have been attending the hearing for other Board of Health agenda items and were not there specifically for the hearing on the proposed regulations. In addition, some of those signed in were members of the Nevada Department of Health and Human Services staff, only provided a phone number, first name only, first initial followed by last name, or "iPhone". All those noted on the Carson City in person sign in sheet were either Nevada Department of Health and Human Services staff or members of the Board of Health. Only one person, a representative of the Southern Nevada Health District, was noted on the Las Vegas in person sign in sheet.

Please refer to the attached three documents, 6.3.2022 Board of Health Rollcall DPBH.pdf, 6.3.2022 Board of Health Rollcall SNHD.pdf and the BOHvirtualparticipants060322 spreadsheet, for the lists of those that attended the public hearing, including the information provided by the attendees to our agency.

4. A description of how comment was solicited (i.e., notices) from affected businesses, a summary of their response, and an explanation how other interested persons may obtain a copy of the summary.

A Small Business Impact Questionnaire and a copy of the proposed regulations were emailed to the one licensed freestanding birthing center and the 5 other individuals who have expressed interest in freestanding birthing centers on August 18, 2021.

The questions were:

- 1) How many employees are currently employed by your business?
- 2) Will a specific regulation have an adverse economic effect upon your business?
- 3) Will the regulation(s) have any beneficial effect upon your business?
- 4) Do you anticipate any indirect adverse effects upon your business?
- 5) Do you anticipate any indirect beneficial effects upon your business?

Summary of Responses

Out of the small-business impact questionnaires sent to the one freestanding birthing center licensed at the time the questionnaire was distributed, one response from the licensed freestanding birthing center was recorded as received.

Will a specific regulation have an	Will the	Do you anticipate any	Do you anticipate
adverse economic effect upon your business?	regulation(s) have any beneficial effect	indirect adverse effects upon your business?	any indirect beneficial effects
	upon your business?		upon your business?
Yes - 1	Yes - 1	Yes - 1	Yes - 1
No - 0	No - 0	No – 0	No – 0
Comments – With the proposed changes to birth attendants, our birth center can save an average of \$5,200/month and \$63,000/year on salaries. This is calculated at 30 births/month at \$350 per birth for a total of \$10,500. Estimating a conservative coverage for birth	plumbing being grandfathered in for already established birth centers could save the cost of adding sink, shower,	Each renewal year of malpractice puts a potential indirect adverse	and because of that, we will be able to
attendant at 50% coverage by student midwife/midwife in training.		supplies can be costly.	

birth center all of these new regulations will be a huge cost savings.	

Any other persons interested in obtaining a copy of the summary may e-mail, call, or mail in a request to:

Leticia Metherell Division of Public and Behavioral Health 727 Fairview Drive, Suite E Carson City, NV 89701 Phone: 775-684-1045

Email: lmetherell@health.nv.gov

5. If, after consideration of public comment, the regulation was adopted without changing any part of the proposed regulation, a summary of the reasons for adopting the regulation without change. The statement should also explain the reasons for making any changes to the regulation as proposed.

Written testimony was received from a senior counsel representing the Accreditation Association for Ambulatory Health Care, Inc., dated November 19, 2021, which noted: We recently became aware of the proposed amendments to Chapter 449 of NAC1 and Medicaid Services Manual (MSM) Chapter 2002 to require freestanding birthing center (FSBC) accreditation. We noted that the authorizing statute, NRS 449.0302(12) provided opportunity for review of additional accreditation organizations not specifically listed in the law; however, it does not appear that the same language was included in the regulatory proposal. As such, AAAHC respectfully requests that the Division eliminate the barrier to entry into the Nevada FSBC accreditation market by providing the opportunity for additional organizations to become approved FSBC accreditors. Attached please find our recommendations for updating the language to allow for future competition in the Nevada FSBC accreditation market.

Subsection 12 of Section 16.5 of AB 287 of the 81st (2021) legislative session reads as follows:

12. The Board shall adopt separate regulations governing the licensing and operation of freestanding birthing centers. Such regulations must: (a) Align with the standards established by the American Association of Birth Centers, or its successor organization, the accrediting body of the Commission for the Accreditation of Birth Centers, or its successor organization, or another nationally recognized organization for accrediting freestanding birthing centers; and (b) Allow the provision of supervised training to providers of health care, as appropriate, at a freestanding birthing center.

Although in most cases we would open up accreditation regulatory requirements to any nationally recognized organization for accrediting freestanding birthing centers, in this case the bill language is clear that the proposed regulations must align with one of the standards listed in subsection 12 of Section 16.5 of the bill and does not require that it be opened up to all accrediting organizations.

In this particular case the use of one accrediting organization's standards to align the proposed regulations is in line with the statutory requirement. It is an evidence-based nationally recognized accrediting standard specifically

listed in the bill in which the only licensed freestanding birthing center is accredited by; therefore, removing financial and compliance burdens on freestanding birthing centers that may be created if the proposed regulations attempted to align with multiple accrediting standards. In addition, once the proposed regulations aligned with accrediting standards becomes effective, it would not be possible to realign them to any new accrediting standards without going through the regulatory process. In conclusion, based on how the bill is written, staff have determined that the most effective, efficient, and least burdensome manner for implementation of this component of the proposed regulations, is to align them with one evidence-based nationally recognized birthing center standard; therefore, the proposed regulations were not revised to reflect this recommended change.

After consultation with the Board of Pharmacy and Legislative Counsel Bureau (LCB) attorneys, it was determined that non-licensed midwives, such as individuals that are only certified professional midwives, are not authorized to administer medications; therefore, the proposed regulations were revised to require:

- 1) At least one of the two required attendants present at each delivery of a newborn at a freestanding birthing center, to be a clinical provider who is authorized under federal and state law to possess and administer dangerous drugs; and
- 2) At least one member of the staff required to be present on the premises of the center in accordance with the proposed regulations, be a staff member that is authorized under federal and state law to administer drugs.

In addition, the proposed regulations set the parameters for when a non-licensed birth assistant or other staff member who is competent to provide care but is not authorized under federal and state law to administer drugs, be the only staff member present in the center.

The list of drugs that could be administered at a freestanding birthing center was also removed as staff authorized under federal and state law to administer drugs, would be allowed to do so, within their scope of practice and in accordance with applicable laws.

- 6. The estimated economic effect of the regulation on the business which it is to regulate and on the public. These must be stated separately, and in each case must include:
 - (a) Both adverse and beneficial effects; and
 - (b) Both immediate and long-term effects.

Beneficial effects: The small business questionnaire revealed the following beneficial effect: With the proposed changes to birth attendants, our birth center can save an average of \$5,200/month and \$63,000/year on salaries. This is calculated at 30 births/month at \$350 per birth for a total of \$10,500. Estimating a conservative coverage for birth attendant at 50% coverage by student midwife/midwife in training. It is unknown if the cost savings would be passed on to the consumer (members of the public). Cost savings may result in the potential for delaying increase in costs passed down to the consumer.

Adverse effects: Feedback from industry noted that not allowing birth assistants to provide services in a freestanding birthing center creates an adverse financial effect; therefore, the allowance of the use of birth assistants was added to the proposed regulations, eliminating this adverse effect. It is anticipated that there will be no adverse financial impacts to the public.

In addition, adverse financial impact on a small business opening a brand-new freestanding birthing center includes costs for building space, staffing costs, equipment and supplies, and other costs related to opening a

new freestanding birthing center. The costs may vary depending on multiple factors, including but not limited to, location, size of the center, the number of staff employed, the staff mix, and other factors; therefore, the cost cannot be determined. The small business questionnaire also revealed the following indirect adverse effect:

Each renewal year of malpractice puts a potential indirect adverse effect on the business due to national premium increases. The continued rising prices of medical supplies can be costly.

Current statutes not authorizing certified, non-licensed, midwives to administer medications is a barrier to these midwives being able to open and operate a freestanding birthing center without depending on a licensed certified nurse midwife or physician. The adopted regulations are written in a manner that would allow these individuals to operate a freestanding birthing center independently, upon passage of statutes that would authorize them to administer medications.

Immediate effects: Upon the adopted regulations becoming effective, the one licensed freestanding birthing center will be able to implement the cost saving measures in the adopted regulations, including but not limited to, the use of birth assistants instead of more expensive staff to perform the job duties of a birthing assistant. The immediate financial impact to the public is unknown, but it is anticipated that there would be no immediate negative financial impact to the public.

Long-term effects: If legislation is passed allowing certified, non-licensed, midwives to administer medications in freestanding birthing centers, it is anticipated the adopted regulations would result in an increased number of licensed freestanding birthing centers. The long-term financial impact to the public is unknown, but it is anticipated that a cost savings to freestanding birthing centers, would delay any potential adverse financial impacts or minimize them, if any.

7. The estimated cost to the agency for enforcement of the proposed regulation.

The estimated cost to enforce the proposed regulations is equal to the initial licensing fee of \$1,564 with an annual renewal fee of \$782.

8. A description of any regulations of other state or government agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the regulation overlaps or duplicates a federal regulation, name the regulating federal agency.

The proposed regulations do not overlap or duplicate any regulations of other state or government agencies.

9. If the regulation includes provisions which are more stringent than a federal regulation which regulates the same activity, a summary of such provisions; and

There are no known federal regulations that regulate the same activity.

10. If the regulation establishes a new fee or increases an existing fee, a statement indicating the total annual amount the agency expects to collect and the manner in which the money will be used.

The proposed regulations do not provide a new fee or increase an existing fee. The fee to license obstetric centers was already established in regulations and will be the same fee used to license freestanding birthing centers. The licensing fee will be used to license and regulate freestanding birthing centers. The annual amount

collected will be \$782 until such time that additional freestanding birthing centers become licensed, which is unknown at this time.
In addition, if a freestanding birthing center chooses to modify their license pursuant to NAC 449.0168, a \$250 fee will be assessed. As it is unknown whether a freestanding birthing center would submit a request to modify its license or how often a modification may be requested, the annual amount cannot be determined.
4150 Technology Way, Suite 300 ● Carson City, Nevada 89706