DIVISION OF PUBLIC & BEHAVIORAL HEALTH
BUREAU OF HEALTH CARE QUALITY AND COMPLIANCE

LCB File No. R059-16

Informational Statement per NRS 233B.066

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

The two main reasons for the need to adopt the proposed regulations are to:
1) Protect public safety by requiring national accreditation and the adoption of nationally recognized infection control guidelines.
2) Remove barriers from opening an obstetric center for Advanced Practice Registered Nurses licensed as nurse midwifes. Currently there are no licensed obstetric centers in Nevada. It is believed this change would encourage the opening of obstetric centers in Nevada giving women options for safe and effective, licensed alternatives to give birth.

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 by the Notice of Public Hearing posted at Division of Public and Behavioral Health locations, State Library and Archives, and county libraries. The Notice of Public Hearing provides several methods for an individual to obtain a copy of the proposed regulations, changes to the proposed regulations (errata) and small business impact statement. As currently there are no licensed obstetric centers in Nevada to send the Notice of Public Hearing to, to obtain input from industry:

1) An Advanced Practice Registered Nurse licensed as a nurse midwife in Nevada distributed the information to:

- The American Association of Birth Centers (AABC);
- The Commission for the Accreditation of Birth Centers (CABC); and
- The American College of Nurse-Midwives (ACNM) (Nevada Affiliate).

2) The information was provided to the Nevada Hospital Association.

A request was also made to the Nevada State Board of Nursing requesting they distribute the Notice of Public Hearing to all Advanced Practice Registered Nurses with an email on file with the Board.

The public hearing notice, proposed regulations, and small business impact statement were also posted on the Division's website and sent out through the Division's medical facilities listserv.

The following is a summary of the testimony provided during the State Board of Health's Public Hearing on September 9, 2016:

A Board member asked if we had considered requiring Advanced Cardiovascular Life Support (ACLS) and Pediatric Advanced Life Support (PALS). It was explained that this was considered. Obstetric Centers would not be providing care at the level of advanced cardiac life support. Instead, an obstetric center would provide basic life support until emergency transport arrived. In addition, the proposed regulations require certification in neonatal resuscitation instead of PALS because certification in neonatal resuscitation is very specific to the newborn, whereas PALS is more generalized and includes the general pediatric population. This is in line with national standards, such as those of the American Association of Birth Centers (AABC) Standards for Birth Centers, which require adult cardiopulmonary resuscitation and neonatal resuscitation.

A Board member requested clarification as to whether the physician or licensed advanced practice registered nurse (licensed as a nurse midwife) had to be in the maternal patient's room during delivery. It was clarified that the regulations do not specify that the individual has to be in the room but instead must be present at the time of delivery.

A Board member asked how we came up with the transfer agreement process in the proposed regulations. First, it was felt that an obstetric center should make a good faith effort to enter into a written transfer agreement with at least one licensed hospital that is capable of providing a higher level of obstetrical and neonatal care, as ideally a written transfer agreement would be in place. The proposed regulations accomplish this by requiring the center to send a certified letter to at least one hospital requesting such an agreement. If the hospital refuses or does not respond to the request, a written transfer agreement would not be required. A written statement from the Chair of the American College of Obstetricians and Gynecologists (ACOG), Nevada's Section, was read: "We would prefer that a written agreement be made between a birth center and a receiving hospital, as per the ACOG/SMFM Obstetric Care Consensus on Maternal Levels of Care. However, the American Association for Birth Centers recommends written agreements and/or policies and procedures for interaction with other facilities. Since the Commission for the Accreditation of Birth Centers does not require written agreements, we will simply prefer that there be a written agreement, but we do not feel this must be mandatory."

An example of what happened to an ambulatory surgical center as it relates to written transfer agreements was also provided. A hospital in a rural area refused to enter into a transfer agreement with a surgery center located in the same rural area. The surgery center was therefore, out of compliance with the requirement to have a written transfer agreement despite the fact that they made the effort to obtain one with the local hospital but it was out of their control. In the end, just to meet this regulatory requirement they were able to enter into a written transfer agreement with a hospital in another rural community some distance away. In the end, if a true emergency occurred in which a person required immediate assistance they would have been transferred to the local hospital without the agreement. A Board member asked if a hospital would be required to take a patient if a transfer was required. The response was yes, a hospital would be required to take a patient.

It was also noted that other States, such as Florida, with licensed, operating birthing centers do not require a written transfer agreement.

Not testified during the hearing, but of note, a statement provided by the Commission for the Accreditation of Birth Centers (CABC), noted: "CABC commends the proposed language regarding transfer agreements with tertiary care and providers. We agree that a written transfer agreement is ideal, though we have found that the unwillingness of many hospitals or providers to enter into such an agreement has a negative consequence of limiting safe choices for women. The majority of accredited birth centers use written policies and procedures to guide transfers, and the CABC indicators include several criteria to be met for practice and review of transfers and referrals."

A Board member wanted clarification regarding the availability of the physician during labor and delivery. It was explained that the physician must be available by phone or onsite. An errata to the regulations would require that a center's policy must define what "available" means as used in this context, to make it very clear how the center would meet the requirement for a physician to be available. It was testified that a call schedule could be used to meet this requirement.

One person testified during the public comment section of the hearing. She recommended that the required space for a birth room be reduced to 100 square feet.

Not testified to during the hearing but of note, the proposed regulations reduce the birth room space from having at least 256 square feet with a minimum room dimension of 16 feet, in current regulations, to the room size outlined in the Guidelines for Design and Construction of Hospitals and Outpatient Facilities with the specific requirements for freestanding birth centers currently at 200 square feet with a minimum clear dimension of 12 feet, as outlined in the current guidelines.

A public workshop was held on March 30, 2016. Below follows a summary of testimony and comments received as a result of the public workshop process.

Support for the proposed regulations expressed as part of the public workshop process included:

1) A study of birth centers showed that less than two percent of women needed emergency transport and most emergencies were not life-threatening. Less than one percent of infants required emergency transport.
2) Birth centers have a low caesarean section rate and that birth centers offer a safe place for low-risk women to have babies and reduce harm caused by treatment intensity in childbirth.
3) Obstetric centers are a great opportunity for women to have a low intervention birth setting option.
4) The American Association of Birth Centers (AABC) was not present but provided written comments including, "These regulations may benefit from further changes in the future, but at this time AABC writes in support of the proposed changes to the Nevada freestanding birth center regulations as written."

Concerns with the proposed regulations expressed as a part of the public workshop process included:

1) No emergency transport is present during labor.
2) A thirty minute drive from a hospital is too long.
3) Should require a written transfer agreement to a hospital.

4) There is no value of obstetric centers in urban environments when hospitals are available to provide critical care with specially trained physicians.
5) Do not require an experienced specialist on site if something goes wrong. No pediatrician or neonatal specialist required on site.

One individual in support of birthing centers commented that a rural hospital that delivers infants has no specialists such as neonatologists. In addition, she stated quick transport care is not available with transport times being one and a half hours to one city and three hours to another for higher level care. She also stated there is no obstetrician, surgeon or anesthesiologist on site at the hospital during the evening.

Recommended changes to the proposed regulations expressed as a result of the public workshop process included:
1) Clarifying that both APRN's and physicians who practice in obstetric centers be required to carry liability insurance in an amount of $1,000,000 or more.
2) Changing the gestation timeframe from at least 36 weeks of gestation to at least 37 weeks of gestation.
3) Changing the language to include certified professional midwives (CPMs) in addition to the APRNs licensed as a nurse midwife in the proposed regulations.
4) Allowing women the option to have a vaginal birth after a cesarean section in obstetric centers.
5) Requiring the patient sign an informed consent acknowledging that the free standing obstetrical center does not have a physician on the premises while she is in labor or a written transfer agreement with a higher level of care, if the obstetric center does not require a physician to be onsite or does not have a written transfer agreement.

A summary for the Hearing for Amendment of Nevada Administrative Code (NAC) 449, LCB File No. R059-16 can be obtained by contacting:

Division of Public and Behavioral Health
727 Fairview Drive, Suite E, Carson City, NV 89701
Phone: 775-684-1030

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

Fifty seven people signed in at the Board of Health hearing held on September 9, 2016. Leticia Metherell, Health Facilities Inspection Manager for the Division of Public and Behavioral Health presented the proposal to amend Nevada Administrative Code (NAC) 449, "Medical Facilities and Other Related Entities." One person testified during the public comment section of the public hearing recommending the birthing room size requirement be decreased.

Name: Melinda Hoskins Phone: 775-720-4625

Written comments were provided during the public workshop and public hearing processes and are provided along with the informational statement. Information for individuals providing written comments are noted in the table below.

Name	Phone	Email	Organization
Kate Bauer	215-234-8068	aabc@birthcenters.org	American Association of Birth Centers
Dr. Robert Pretzlaff			Dignity Health – St. Rose Dominican
Katie Ryan	702-616-4847	katie.ryan@dignityhealth.org	Dignity Health – St. Rose Dominican
Marissa Brown	775-827-0184	marissa@nvha.net	Nevada Hospital Association
Jamie L Haeuser	877-241-0262		The Commission for the Accreditation of Birth Centers, Inc.
Ashton Osborne	877-241-0262		The Commission for the Accreditation of Birth Centers, Inc.
Tiffany Hoffman		sacredbirthspace@gmail.com	Nevada Midwifery Licensure Collective
Dr. Keith R. Brill		drkbrill@whasn.com	American College of Obstetricians and Gynecologists (ACOG), Nevada Section

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.

As currently there are no licensed obstetric centers in Nevada, the public workshop notice which included information on how to obtain a copy of the proposed regulations and small business impact statement was provided to the Nevada State Board of Nursing to distribute the information to all Advanced Practice Registered Nurses with an email on file with the Board, an Advanced Practice Registered Nurse licensed as a nurse midwife in Nevada distributed the information to The American Association of Birth Centers (AABC), The Commission for the Accreditation of Birth Centers (CABC), and The American College of Nurse-Midwives (ACNM), and the information was also sent to the Nevada Hospital Association.

The workshop notice, small business impact statement, and draft regulations were posted on the Division of Public and Behavioral Health's website and distributed through the Division's medical facilities listserv.

Summary of Response

Summary Of Comments Received (3 small business impact questionnaires were received)			
Will a specific regulation have an adverse economic effect upon your business?	**Will the regulation (s) have any beneficial effect upon your business?**	**Do you anticipate any indirect adverse effects upon your business?**	**Do you anticipate any indirect beneficial effects upon your business?**
No = 2 Yes = 1	No = 2 Yes = 1	Yes = 2 No Answer: 1	No = 1 Yes = 2
Comments: Current regulations have precluded my opening a free-standing "obstetric center" in Northern Nevada as they basically embed vicarious liability into the responsibilities of the "Medical Director". Physicians are unwilling to currently consider working with Certified Nurse-Midwives in the operation of an "obstetric center". The amount the limited regulation changes could cost my business is incalculable.	**Comments:** Adoption of the proposed regulation should allow me to move forward with the opening of a free-standing "obstetric center", otherwise known as a free-standing birth center. So the adoption of the proposed regulations will allow me to expand my business, increase the number of employees I have reason to hire, and provide additional choices to women in the community regarding where and with whom they receive prenatal care and give birth.	**Comments:**	**Comments:** Business expansion. With additional options for birthing families in the area, more awareness of normal birth will facilitate more desire for families to look for perinatal education and support as provided by the (name of business). Birth Center regulations are sorely needed. The language limiting the types of midwives allowed to deliver in birth centers will negatively affect the number of clients I am able to sign as well as where I will be able to serve them. This would also eliminate the option of opening a birth center in the future. Other states include CPM's with CNMs in their regulations. A change in language would lessen the impact.

The small business impact summary statement for LCB File No. R059-16 can be obtained by contacting:

Division of Public and Behavioral Health
727 Fairview Drive, Suite E, Carson City, NV 89701
Phone: 775-684-1030

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.

The proposed regulations were modified based on some of the input provided by industry including clarifying that both physicians and APRN's are to carry liability insurance, changing the gestation timeframe from at least 36 weeks of gestation to at least 37 weeks of gestation, and requiring that an obstetric center notify each maternal patient in writing if it does not have a written transfer agreement with a hospital or does not require a licensed physician to be on the premises while a patient is in labor or during birth.

State laws governing obstetric centers (also known as birth centers) in other states were reviewed when developing the proposed obstetric center regulations. Some states require that a birth center be within a certain drive time to a hospital and some do not. Nevada's current regulations do not require an obstetric center to be within a certain drive time of a hospital. As safety concerns were expressed, the proposed regulations add a requirement to current regulations that would require a birth center to be within a 30 minute drive time from a birth center to a hospital that provides a higher level of obstetrical care. The 30 minute drive time was based on requirements used by two other states that have active birth centers in their states therefore it is a standard that has been used and tested. Based on this information the recommendation to reduce the drive time was not made.

National standards, as well as some other states, do not require a written transfer agreement but do require policies and procedures be put in place relating to transfers. The proposed regulations do take an extra step in requiring that an obstetric center contact a hospital to enter into a written agreement but if the hospital refuses or fails to respond then the obstetric center would be required to follow their transfer policy and procedure. Requiring a written transfer agreement with a hospital may result in an obstetric center not being in compliance with state regulations or not being allowed to open due to something out of their control. Transfer policies and procedures are required to ensure safe transfers of patients and maternal patients must be notified in writing that there is no written transfer agreement in place. Based on this the recommendation to require a written transfer agreement was not made.

Based on national standards and review of other state regulations the requirement to have a physician present during labor or birth was not made. National standards such as AABC do not require that a physician be present and some states with active birth centers in their state do not require a physician to be present. The American College of Obstetricians and Gynecologists document, "Obstetric Care Consensus, Levels of Maternal Care", lists the types of health care

providers required to attend a birth and includes certified nurse midwives and other midwives, family physicians and ob-gyns. The proposed regulations require that a physician or advanced practice registered nurse licensed as a nurse midwife be present. These nurses have specialized training in the delivery of babies to low risk women including dealing with an emergency until transport arrives. Advanced practice registered nurses are independent practitioners and the Nevada Board of Nursing confirmed the proposed regulations were within the scope of practice of these nurses. Based on this information the recommendation to require that a physician specialist by required to be on site.

The proposed regulations were not modified to include Certified Professional Midwives (CPM) because CPM's are not licensed in Nevada. It was felt that the director of an obstetric center must hold a Nevada license in the profession allowed to serve as a director to ensure that a Nevada regulatory board has oversight of these practitioners and the care that they provide.

An errata was also proposed and approved by the Board of Health clarifying the definition of a Licensed Advanced Practice Registered Nurse, as used in the proposed regulations, requiring that employees of the obstetric center be screened for tuberculosis in accordance with NAC 441A.375, the Infectious Diseases and Toxic Agents chapter, and requires the obstetric center to define "available" in the center's policies and procedures, as it relates to the availability of the physician or his or her designee during labor and delivery.

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.

   Immediate Beneficial Effects: Advanced Practice Registered Nurses licensed as nurse midwives in Nevada would be able to serve as the director of an obstetric center therefore removing a barrier that keeps them from applying to open a center.

   Long Term Beneficial Effects: Allows certain midwife businesses to expand their businesses to include the services provided by an obstetric center, therefore this may result in the long term effect of having effective and safe, licensed alternatives for women to give birth.

   Immediate Adverse Effects: None. Currently there are no licensed obstetric centers in Nevada.

   Long Term Adverse Effects: The benefits of the proposed regulations would not extend to all midwives but would only extend to Advanced Practice Registered Nurses licensed as nurse midwives in Nevada. Requiring accreditation would result in an additional cost in addition to licensing fees.

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

Obstetric centers have fees currently established in Nevada Administrative Code (NAC) 449.013 to cover the cost to the agency for enforcement of the proposed regulations. It is estimated it

would cost the agency the fee amounts to enforce the proposed regulations, which currently are set at $1,564 for an initial inspection and 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.

There are no other state or federal regulations that overlap or duplicate what is in the proposed regulations.

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 impose a new fee or increase any existing fee.