ADOPTED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R059-16

Effective December 21, 2016

EXPLANATION – Matter in ***italics*** is new; matter in brackets **[**~~omitted material~~**]** is material to be omitted.

AUTHORITY: §§1-21, NRS 449.0302.

A REGULATION relating to obstetric centers; revising requirements concerning the construction, operation and staff of an obstetric center; requiring the Division of Public and Behavioral Health of the Department of Health and Human Services to conduct an inspection of an obstetric center before issuing a license; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law requires the State Board of Health to: (1) adopt licensing standards for obstetric centers and any other regulations necessary or convenient to carry out the provisions of the statutes governing obstetric centers; and (2) require that the practices and policies of each obstetric center provide adequately for the protection of the health, safety and physical, moral and mental well-being of each person accommodated by the obstetric center. (NRS 449.0302) **Section 2** of this regulation requires the director of an obstetric center to prepare a plan prescribing the actions to be taken by members of the staff and patients of the obstetric center in the event of a fire or other disaster. **Sections 3 and 18** of this regulation revise requirements concerning the policies and procedures for the control of infection required to be adopted by an obstetric center. **Sections 2 and 3** also require an obstetric center to provide certain training to the members of its staff. **Sections 4 and 5** of this regulation revise the requirements to become a maternal patient at an obstetric center. **Section 6** of this regulation requires an obstetric center to maintain current accreditation by a nationally recognized organization. **Sections 7, 9 and 10** of this regulation amend requirements concerning the size and facilities of an obstetric center. **Section 7** also requires the Division of Public and Behavioral Health of the Department of Health and Human Services to conduct an inspection of an obstetric center before issuing a license to the obstetric center. **Sections 4, 11, 12 and 16** of this regulation revise the qualifications of persons who perform certain tasks or hold certain positions at an obstetric center. **Section 11** also more specifically defines the types of medical practitioners practicing at an obstetric center who are required to carry liability insurance.

Existing regulations require an obstetric center to provide nourishment for a maternal patient by providing: (1) a separate area for the storage of food which may be provided to the maternal patient by her family; or (2) food prepared by the obstetric center. (NAC 449.61142)

Section 8 of this regulation authorizes an obstetric center to also provide nourishment by providing food stored by the obstetric center. **Section 8** also requires an obstetric center to be equipped with an automated external defibrillator.

Existing regulations require an obstetric center to maintain and document each agreement to provide consultation services which the obstetric center enters into with certain physicians. (NAC 449.61152) **Section 12** revises the qualifications of a physician with whom the obstetric center enters into such an agreement. **Sections 13 and 15** of this regulation amend requirements concerning the maintenance of records by an obstetric center.

Existing regulations require an obstetric center to have a written agreement with at least one hospital or medical facility licensed to provide high-risk perinatal care to transfer patients to the hospital or medical facility if such care is necessary. (NAC 449.61174) **Section 21** of this regulation instead requires an obstetric center to have such an agreement with a licensed hospital that is capable of providing a higher level of obstetrical and neonatal care than the obstetric center or to have requested such an agreement. **Section 21** requires an obstetric center to notify each maternal patient in writing if it does not have such an agreement. Additionally, **section 21** requires an obstetric center to be located within 30 minutes of normal driving time from a licensed hospital that provides obstetrical care. Finally, **section 21** requires an obstetric center to develop and implement policies and procedures: (1) requiring a physician or his or her designee to be available during labor and delivery; and (2) for the emergency transfer of a patient to a licensed hospital.

Sections 14, 15, 17 and 19 of this regulation make nonsubstantive revisions to certain terminology.

Section 1. Chapter 449 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 and 3 of this regulation.

Sec. 2. ***The director of an obstetric center shall ensure that the obstetric center, members of its staff and patients are protected from fire and other disasters. The director of an obstetric center shall:***

1. Prepare a written plan prescribing the actions to be taken by members of the staff and patients in the event of a fire or other disaster. This plan must be approved by the governing body of the obstetric center and the local fire department within whose jurisdiction the obstetric center is located and must include:

(a) Procedures and routes for evacuation, which must be posted prominently in the obstetric center;

(b) Assignments of specific tasks and responsibilities to members of the staff;

(c) Instructions on how to use alarm stations and the location of alarm signals;

(d) Instructions on methods for containing a fire and the location of equipment for fighting fires; and

(e) Procedures for the notification of appropriate state and local governmental entities and appropriate persons, including the family members of patients and staff.

2. Ensure that each shift of members of the staff conducts a fire drill at least once each quarter and maintain a written, dated report and evaluation of each fire drill for at least 4 years after the date of the fire drill.

3. Ensure that each member of the staff of the obstetric center is trained immediately upon hire, and annually thereafter, to execute the written plan prepared pursuant to subsection 1 and maintain records of such training for at least 4 years after the training is conducted.

4. Ensure that each member of the staff fully rehearses the procedures prescribed in the written plan at least once each year for each type of disaster and maintain a written report and evaluation of each rehearsal for at least 4 years after the rehearsal.

Sec. 3. *1. An obstetric center shall develop and implement written policies and procedures to be followed by the employees of the obstetric center for the control of infection that are in accordance with nationally recognized guidelines. Acceptable guidelines include, without limitation, the most recent version of Guidelines for Perioperative Practice published by the Association of periOperative Registered Nurses, the most recent version of the*

***Guidelines for Environmental Infection Control in Health-Care Facilities** published by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services and the **2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings** published by the Centers for Disease Control and Prevention, or a combination of guidelines that address the control of infection at the obstetric center.*

2. The policies and procedures developed pursuant to subsection 1 must prescribe the procedures for:

(a) Hand hygiene;

(b) The disposal of all waste that constitutes a biohazard, including, without limitation, needles, syringes, medical waste, microbial waste and specimens;

(c) The proper use of syringes, needles, vials and lancets; and

(d) The proper sterilization and disinfection of all reusable equipment.

3. The director of an obstetric center shall make a copy of the policies and procedures developed by the obstetric center pursuant to subsection 1 available to each employee of the obstetric center.

4. Each employee of an obstetric center shall follow the manufacturer's guidelines for the use and maintenance of equipment, devices and supplies. The director of an obstetric center shall make the manufacturer's guidelines for equipment, devices or supplies available to each employee of the obstetric center who uses or maintains the equipment, devices or supplies.

5. An obstetric center shall:

(a) Train each employee of the obstetric center who has exposure to patients or specimens of patients or participates in the disinfection or sterilization of equipment at the obstetric

center on the policies and procedures for the control of infection developed pursuant to subsection 1; and

(b) Require a supervisor of each such employee to evaluate the employee on the employee's knowledge and skills concerning those policies and procedures within 10 working days after beginning his or her employment and at least once each year thereafter.

6. If an obstetric center that has developed policies and procedures for the control of infection pursuant to subsection 1 revises those policies and procedures, the obstetric center shall notify each employee of the obstetric center who has exposure to patients or specimens of patients or participates in the disinfection or sterilization of equipment at the obstetric center of the change and train each such employee concerning the revised policies and procedures within 10 working days after adopting the revised policies and procedures.

7. As used in this section, "employee" includes, without limitation, any person providing services at the obstetric center pursuant to a contract.

Sec. 4. NAC 449.6113 is hereby amended to read as follows:

449.6113 As used in NAC 449.6113 to 449.61178, inclusive, ***and sections 2 and 3 of this regulation,*** unless the context otherwise requires:

1. "Licensed advanced practice registered nurse" means an advanced practice registered nurse who is licensed pursuant to chapter 632 of NRS ~~[and who has specialized training in midwifery approved]~~ ***to practice in a role as a nurse midwife*** by the State Board of Nursing.

2. "Licensed physician" means a physician licensed pursuant to chapter 630 or 633 of NRS.

3. "Maternal patient" means a woman admitted to an obstetric center in accordance with NAC 449.61134 who has had a normal uncomplicated prenatal course, as determined by adequate prenatal care, and the prospect for a normal, uncomplicated birth, as defined by the

criteria established by the American College of Obstetricians and Gynecologists and by reasonable and generally accepted clinical standards for maternal and fetal health.

4. "Obstetric care" means the care which is provided, in accordance with NAC 449.6113 to 449.61178, inclusive, ***and sections 2 and 3 of this regulation*** immediately before, during and for not more than 24 hours after delivery to a maternal patient:

(a) Who has completed at least ~~[36]~~ ***37*** weeks of gestation and not more than 42 weeks of gestation; and

(b) Whose condition is reasonably expected to result in a normal and uncomplicated vaginal birth.

5. "Obstetric center" has the meaning ascribed to it in NRS 449.0155.

Sec. 5. NAC 449.61134 is hereby amended to read as follows:

449.61134 A woman may be a maternal patient at an obstetric center if:

1. She has completed at least ~~[36]~~ ***37*** weeks and not more than 42 weeks of gestation;

2. She has no major medical problems;

3. She has no previous history of major uterine wall surgery, cesarean section, or other obstetrical complications which are likely to recur;

4. She has parity of under six unless a justification for a variation is documented by the ~~[medical]~~ director for the obstetric center;

5. She is not less than 15 years or more than 40 years of age and is not a nullipara, unless the ~~[medical]~~ director has reviewed the age and parity of the maternal patient and approves the admission of the maternal patient on a case-by-case basis;

6. She has no ***clinically*** significant signs or symptoms of:

(a) Pregnancy-induced hypertension;

(b) Polyhydramnios or oligohydramnios;

(c) Abruptio placenta;

(d) Chorioamnionitis;

(e) Multiple gestation;

(f) Intrauterine growth retardation;

(g) ~~[If there is fetal distress,]~~ ***Meconium-stained*** amniotic fluid ~~[which is stained with meconium;]~~ ***associated with signs of fetal intolerance of labor;***

(h) Fetal ~~[distress;]~~ ***intolerance of labor;***

(i) ~~[Substance abuse;]~~ ***Active substance use disorder;***

(j) Placenta previa;

(k) Diabetes mellitus; or

(l) Anemia;

7. While in active labor, she demonstrates no ***clinically*** significant signs or symptoms of:

(a) Intrapartum hemorrhage;

(b) Active Herpes Simplex II of the genitals; or

(c) Malpresentation of the fetus including breech presentation;

8. She is in labor and progressing normally according to the established protocols of the obstetric center and the ~~[medical]~~ ***clinical*** staff of the obstetric center;

9. Her membranes were not ruptured more than 24 hours before her admission to the obstetric center;

10. She has no evidence of an infection;

11. Her pregnancy is appropriate for a setting where analgesia is limited; and

12. Her pregnancy is appropriate for a setting where anesthesia is limited to a local infiltration of the perineum or a pudendal block.

Sec. 6. NAC 449.61138 is hereby amended to read as follows:

449.61138 1. An application for a license or the renewal of a license may be denied if the facility, personnel or equipment fails to meet the requirements of NAC 449.002 to 449.99939, inclusive, ***and sections 2 and 3 of this regulation*** or if cause or circumstance exists that may, in the opinion of the Division, threaten or have the potential to threaten the safety or health of the public.

2. A license may be revoked or summarily suspended in accordance with NAC 449.002 to 449.99939, inclusive, ***and sections 2 and 3 of this regulation,*** and chapters 233B and 449 of NRS if the facility, personnel or equipment fails to meet the requirements of NAC 449.002 to 449.99939, inclusive, ***and sections 2 and 3 of this regulation,*** or if cause or circumstance exists that may, in the opinion of the Division, threaten or have the potential to threaten the safety or health of the public.

3. An obstetric center shall maintain current accreditation by a nationally recognized organization approved by the Division. Within 6 months after initial licensure, an obstetric center shall submit to the Division proof of such accreditation. If the accreditation of an obstetric center becomes invalid for any reason, including, without limitation, lapse or revocation, the obstetric center shall immediately terminate operations.

Sec. 7. NAC 449.6114 is hereby amended to read as follows:

449.6114 1. An obstetric center must be designed, constructed, equipped and maintained in a manner that protects the health and safety of the patients and personnel of the obstetric center and members of the general public.

2. ***The Board hereby adopts by reference the chapter containing the specific requirements for freestanding birth centers contained in the Guidelines for Design and Construction of Hospitals and Outpatient Facilities in the form most recently published by the Facility Guidelines Institute, unless the Board gives notice that a revision is not suitable for this State pursuant to subsection 3. A copy of this publication may be obtained from the Facility Guidelines Institute at the Internet address http://www.fgiguidelines.org/guidelines-main/ or by telephone at (800) 242-2626 for the price of $200.***

3. The Board will review each revision of the publication adopted by reference pursuant to subsection 2 to ensure its suitability for this State. If the Board determines that a revision is not suitable for this State, the Board will hold a public hearing to review its determination within 6 months after the date of the publication of the revision and give notice of that hearing. If, after the hearing, the Board does not revise its determination, the Board will give notice within 30 days after the hearing that the revision is not suitable for this State. If the Board does not give such notice, the revision becomes part of the publication adopted by reference pursuant to subsection 2.

4. An obstetric center shall comply with all applicable:

(a) Federal and state laws;

(b) Local ordinances, including, without limitation, zoning ordinances;

(c) Environmental, health and local building codes; ~~[and]~~

(d) Fire and safety codes, including, without limitation, those codes relating to ingress and egress of occupants, placement of smoke alarms, fire extinguishers or sprinkler systems, and fire escape routes ~~[,]~~ ***; and***

(e) Provisions of the publication adopted by reference in subsection 2,

➥ related to the ***design,*** construction and maintenance of the obstetric center. If there is a difference between state and local requirements, the more stringent requirements apply.

~~[3.]~~ ***5.*** Except as otherwise provided in subsection ~~[4.]~~ ***6,*** before any new construction of an obstetric center or any remodeling of an existing obstetric center is begun, the obstetric center must submit building plans for the new construction or remodeling to the entity designated to review such plans by the Division pursuant to the provisions of NAC 449.0115. The entity's review of those plans is advisory only and does not constitute approval for the licensing of the obstetric center. The Bureau shall not approve an obstetric center for licensure until all construction is completed and a survey is conducted at the site of the obstetric center.

~~[4.]~~ ***6.*** An obstetric center is not required to submit plans for remodeling to the entity designated to review such plans by the Division pursuant to the provisions of NAC 449.0115 if the remodeling is limited to refurbishing an area within the obstetric center, including, without limitation, painting the area, replacing the flooring in the area, repairing windows in the area, and replacing window or wall coverings in the area.

7. Before issuing a license to an obstetric center, the Division shall conduct an on-site inspection of the obstetric center.

Sec. 8. NAC 449.61142 is hereby amended to read as follows:

449.61142 1. An obstetric center shall provide:

(a) Services for labor, delivery, newborn and recovery care for not more than 24 hours after delivery.

(b) Areas for labor, delivery, newborn and recovery which are in a safe and clean environment in accordance with all applicable local, state and federal laws.

(c) Areas for:

(1) Maintenance and documentation of medical records of each maternal patient by physicians and nurses;

(2) Patient and family education;

(3) Treatment and examination of a maternal patient and newborn baby;

(4) Cleaning and storage of instruments and equipment which are located separately from the other areas of the obstetric center;

(5) Secure storage of drugs; and

(6) Family visitation.

(d) Simple nourishment for the maternal patient by providing:

(1) A separate area for appropriate storage of food which may be provided to the maternal patient by her family; or

(2) Food prepared ***or stored*** by the obstetric center. If food is prepared ***or stored*** by the obstetric center, the obstetric center must comply with all applicable local, state and federal laws relating to the preparation ***and storage*** of food by a medical facility.

2. An obstetric center must be equipped with those items needed to provide low-risk obstetrical care without general anesthesia and initial emergency procedures for life-threatening events to a maternal patient and newborn baby, including, but not limited to:

(a) Sterile supplies for delivering and caring for a newborn baby;

(b) Equipment for performing pelvic examinations;

(c) Sphygmomanometers and stethoscopes, in adult and infant sizes;

(d) Fetoscopes ~~[,]~~ ***and*** doppler ~~[and electronic]~~ fetal monitors;

(e) Supplies for measuring ~~[sugar]~~ ***glucose*** and protein in urine;

(f) Needles and syringes;

(g) Solutions and supplies for parenteral administration of fluids;

(h) Emergency drugs and equipment for the resuscitation of an adult and a newborn baby;

(i) Equipment for suctioning an airway, in appropriate sizes for adults and newborn babies;

(j) Protective gear for personnel of the obstetric center who may be exposed to body fluids of the maternal patient and the newborn baby;

(k) Equipment or other approved methods for warming solutions and blankets; ~~[and]~~

(l) Oxygen and apparatus for administering oxygen, in appropriate sizes for adults and newborn babies ~~[.]~~ ***; and***

(m) An automated external defibrillator.

Sec. 9. NAC 449.61144 is hereby amended to read as follows:

449.61144 An obstetric center must have adequate emergency electrical power:

1. By procuring batteries or an electricity-producing generator with sufficient fuel which is capable of providing power for 2 hours or more to ~~[:]~~ ***support:***

(a) ~~[All lights]~~ ***Emergency lighting*** in the obstetric center; and

(b) All ***clinical*** equipment in the obstetric center with the exception of the wall outlets located in a reception or waiting area.

2. By having the source of emergency power serviced on a regular basis and documenting that service in the records of maintenance of the obstetric center.

Sec. 10. NAC 449.61146 is hereby amended to read as follows:

449.61146 1. Each birth room in an obstetric center must:

(a) Be maintained in a condition which is adequate and appropriate to provide for the equipment, staff, supplies and any emergency procedures required during the period of labor,

delivery and recovery for the physical and emotional care of the maternal patient, any person accompanying the maternal patient for support and the newborn baby; ***and***

(b) ~~[Have at least 256 square feet with a minimum room dimension of 16 feet;~~

~~(c)]~~ Be located so as to provide unimpeded, rapid access to an exit of the building which will accommodate emergency transportation vehicles and equipment**.** ~~[; and~~

~~(d) Have facilities immediately available to the birth room for the washing of hands.~~

~~2. The obstetric center shall provide toilet and bathing facilities for use by a maternal patient, including:~~

~~(a) A toilet and lavatory maintained in or adjacent to the vicinity of the birth room; and~~

~~(b) A shower which is clean and in good repair.~~

~~3.]~~ ***2.*** Hallways and doors which provide entry into, exit from and access within the obstetric center and birth rooms must be of adequate width and configuration to accommodate the maneuvering of a stretcher from an ambulance, a wheelchair and other emergency equipment.

~~[4.]~~ ***3.*** The obstetric center must have an adequate supply of hot and cold running water under pressure for human consumption and other purposes relating to the care of the maternal patient and newborn baby.

~~[5.]~~ ***4.*** If office-based prenatal ~~[or other health]~~ care is provided at the obstetric center, the consultation and examining rooms for that care must be separate from the birth rooms.

Sec. 11. NAC 449.61148 is hereby amended to read as follows:

449.61148 1. Except as otherwise provided in NAC 449.6115, each obstetric center must have a governing body that is chaired by a principal in the organization which is operating the obstetric center or the licensee with legal authority for the operation of the obstetric center.

2. The governing body shall ensure that:

(a) Each maternal patient of the obstetric center receives care from:

(1) A licensed physician ***currently practicing in obstetrics*** or a licensed advanced practice registered nurse ~~[,]~~ ***currently practicing in obstetrics;*** and

(2) A registered nurse licensed pursuant to chapter 632 of NRS ~~[who has 2 years or more of experience in labor and delivery;]~~ ***whom the director of the obstetric center has deemed as clinically competent to provide pre- and postdelivery care;***

(b) At least one licensed physician or licensed advanced practice registered nurse, who is ***currently practicing in obstetrics and*** approved by the ~~[medical]~~ director of the obstetric center to provide care at the obstetric center, is present at the time of delivery;

(c) At least one registered nurse licensed pursuant to chapter 632 of NRS ~~[with 2 years of documented experience in labor and delivery in a general or obstetrical hospital, who is approved by]~~ ***whom*** the ~~[medical]~~ director ~~[to provide care at]~~ ***of*** the obstetric center ~~[, is on the premises during the time]~~ ***has deemed as clinically competent to provide*** pre- and postdelivery care is ***on the premises during the time such care is*** provided;

(d) An annual operating budget and a plan for capital expenditures for the obstetric center are established;

(e) The obstetric center is adequately staffed and equipped;

(f) There is documentation in the files of the obstetric center of the qualifications of each consultant under contract with and each member of the staff employed by the obstetric center;

(g) The obstetric center adopts, enforces and annually reviews written policies and procedures, which must be approved by the governing board, relating to the operation of and the provisions of care by the obstetric center;

(h) The obstetric center's protocols for treatment, assessments for risk status and criteria for the transfer of a maternal patient or a newborn baby are approved by ~~[a licensed physician who is:~~

~~(1) Currently certified by the American Board of Obstetrics and Gynecology, or an equivalent organization; and~~

~~(2) Currently practicing in the specialty of obstetric care, including routinely delivering newborn babies and caring for maternal patients;]~~ ***the director of the obstetric center;***

(i) A licensed physician who is currently certified by the American Board of Obstetrics and Gynecology is readily available as a consultant, in person or by telephone, during all hours of operation of the obstetric center; and

(j) The obstetric center files the appropriate records of births and deaths.

3. The governing body shall establish a policy for authentication that:

(a) Authorizes the use of rubber stamps, except on records documenting the medical care provided to a maternal patient and newborn baby, and prohibits the use of any stamp by any person other than the person whose signature the stamp represents;

(b) Approves a method for identifying the person making an entry in any record or chart; and

(c) Requires that the entry include the professional title of the person making the entry and the date and time that entry is made.

4. The governing body shall appoint a person to administer the obstetric center who is responsible for:

(a) The daily operation of the obstetric center;

(b) Reporting the pertinent activities concerning the obstetric center to the governing body at regular intervals;

(c) Appointing a person responsible for the obstetric center in the absence of the person appointed by the governing board; and

(d) Planning for the services provided by the obstetric center and the operation of the obstetric center.

5. The governing body shall ensure that the obstetric center maintains insurance for:

(a) Nonmedical liability in an amount of $50,000 or more; and

(b) Medical liability in an amount of $1,000,000 or more.

6. The governing body shall require each ~~[medical practitioner]~~ ***licensed physician or licensed advanced practice registered nurse*** who practices in the obstetric center to carry liability insurance in an amount of $1,000,000 or more.

Sec. 12. NAC 449.61152 is hereby amended to read as follows:

449.61152 1. An obstetric center shall designate a licensed physician who is currently certified by the American Board of Obstetrics and Gynecology, or an equivalent organization, and ***who is currently*** practicing obstetrics including the delivery of newborn babies and providing care to maternal clients, ***or a licensed advanced practice registered nurse who is currently practicing obstetrics including the delivery of newborn babies and providing care to maternal clients,*** to serve as the ~~[medical]~~ director of the obstetric center. The ~~[medical]~~ director is responsible for:

(a) The development and implementation of policies related to the care of a maternal patient;

(b) The coordination of ~~[medical]~~ ***clinical*** care at the obstetric center; and

(c) The development of, the maintenance of and the assurance of compliance with a written plan to provide ***,*** ~~[medical care]~~ in a licensed ~~[medical facility that can provide]~~ ***hospital,*** a higher level of care to each maternal patient and newborn baby under the care of the obstetric center

when the needs of the maternal patient or newborn baby exceed the capability of the obstetric center.

2. The ~~[medical]~~ director is responsible for the quality of ~~[medical]~~ care provided to each maternal patient and newborn baby under the care of the obstetric center and for the review of the ethical and professional practices of the ~~[medical]~~ ***clinical*** staff, including, but not limited to:

(a) The selection of members of the ~~[medical]~~ ***clinical*** staff;

(b) The delineation of the privileges accorded by the obstetric center to members of the ~~[medical]~~ ***clinical*** staff ~~[and members of allied health professions]~~ who provide services at the obstetric center;

(c) The reappraisal and appointment of each member of the staff; and

(d) The procedure to appeal the withdrawal or denial of any privilege of a member of the staff.

3. A roster of the privileges of each member of the ~~[medical]~~ ***clinical*** staff of the obstetric center must be kept in the files of the obstetric center specifying the privileges awarded to that member.

4. The obstetric center shall maintain and document each agreement to provide consultation services which the obstetric center enters into with a:

(a) Physician certified by the American Board of Obstetrics and Gynecology, or an equivalent organization; or

(b) Physician certified by the American Board of Pediatrics, or an equivalent organization,

➥ who has admitting privileges in his or her specialty at an appropriate licensed ~~[medical facility]~~ ***hospital*** that can provide a higher level of care to a maternal patient or newborn baby than the obstetric center can provide.

5. Each member of the ~~[medical]~~ ***clinical*** staff of the obstetric center must agree to abide by the rules of the obstetric center and NAC 449.6113 to 449.61178, inclusive ~~[.]~~ ***, and sections 2 and 3 of this regulation.***

Sec. 13. NAC 449.61154 is hereby amended to read as follows:

449.61154 1. An obstetric center shall maintain the records for each maternal patient admitted for care in the obstetric center in accordance with accepted professional practice.

2. Only authorized personnel may have access to medical records of the obstetric center. Information contained in a medical record of a maternal patient must not be released without the written consent of the maternal patient or guardian except:

(a) As required by law; or

(b) As otherwise provided by the agreement on admission.

3. A medical record must be in a format that may be readily and legibly reproduced when needed or requested.

4. A licensee who ceases operation shall notify the Division of the arrangements made for access to and the safe preservation of medical records in the custody of the licensee.

5. Medical records must not be removed from the obstetric center except upon the issuance of an order by a court of competent jurisdiction.

6. A complete copy of the medical record for each maternal patient transferred from the obstetric center must be sent with the maternal patient to the facility receiving that patient.

7. The medical record of a maternal patient discharged from the obstetric center must be completed within 20 days after the date that the maternal patient is discharged from the obstetric center.

8. Each medical record must be protected against loss, destruction and unauthorized use.

~~[9. The medical record of a maternal patient must be retained for 5 years or more after the date that the maternal patient is discharged from the obstetric center.]~~

Sec. 14. NAC 449.61156 is hereby amended to read as follows:

449.61156 The medical record of a ~~[maternal]~~ patient which is on file with the obstetric center must be completed, authenticated, accurate and current, and must include:

1. A complete identification of the ~~[maternal]~~ patient including information about the next of kin of the patient and the person or agency legally or financially responsible for the patient.

2. A statement concerning the admission and diagnosis of the ~~[maternal]~~ patient.

3. The medical history of the ~~[maternal]~~ patient.

4. Evidence of informed consent given for the care of the ~~[maternal]~~ patient.

5. Any clinical observation of the ~~[maternal]~~ patient, including, but not limited to, the notes of ~~[a physician, a nurse or any other professional person]~~ ***all clinical staff*** in attendance.

6. A report of all prescribed tests and examinations.

7. Confirmation of the original diagnosis, or the diagnosis at the time of discharge.

8. A summary of discharge prepared in accordance with the established policy of the obstetric center, and any provisions made for continuing care or follow-up of the ~~[maternal]~~ patient after discharge.

9. If the ~~[maternal]~~ patient has died while under the care of the obstetric center, documentation of the death which must be signed by ~~[the]~~ ***a*** physician ***.*** ~~[of record.]~~

Sec. 15. NAC 449.61158 is hereby amended to read as follows:

449.61158 ***1.*** An obstetric center shall establish a program for the review of the quality of care provided by the obstetric center. The program must include, without limitation:

~~[1.]~~ ***(a)*** Documentation in the medical records of ~~[the maternal]~~ ***each*** patient ~~[and newborn baby]~~ of the care provided as appropriate to the condition of the ~~[maternal]~~ patient ~~[or newborn baby,]~~ and the results or outcome of that care;

~~[2.]~~ ***(b)*** The time of admission and the time that the ~~[maternal]~~ patient was examined by a licensed physician or a licensed advanced practice registered nurse;

~~[3.]~~ ***(c)*** A statement which describes the condition of the ~~[maternal]~~ patient at the time that the patient is discharged from the obstetric center;

~~[4.]~~ ***(d)*** The instructions given to the ~~[maternal]~~ patient upon discharge and documentation of the ~~[maternal]~~ patient's understanding of those instructions;

~~[5.]~~ ***(e)*** For each ~~[maternal]~~ patient ~~[and newborn baby]~~ who is transferred to another hospital or medical facility, the reason for the transfer, the method of transfer, the time that the transfer was requested and the time that the ~~[maternal]~~ patient ~~[or newborn baby]~~ was discharged from the obstetric center;

~~[6.]~~ ***(f)*** Documentation of any incident of unusual occurrence or deviation from the usual standards of practice of patient care, any error in the administration of medications, any intrapartum infection of ~~[either maternal]~~ ***a*** patient ***,*** ~~[or newborn baby,]~~ and any morbidity or mortality; and

~~[7.]~~ ***(g)*** Documentation about the newborn babies delivered at the obstetric center, including, but not limited to:

~~[(a)]~~ ***(1)*** The number of deliveries;

~~[(b)]~~ ***(2)*** Any birth weight of less than 2500 grams;

~~[(c)]~~ ***(3)*** Any Apgar scores of newborn babies delivered at the obstetric center which are less than ~~[6]~~ ***7*** after 5 minutes;

~~[(d)]~~ ***(4)*** Any congenital defect of a newborn baby; and

~~[(e)]~~ ***(5)*** Any perinatal complication ***.*** ~~[of a maternal client or newborn baby.]~~

2. An obstetric center shall make available to the Division upon request any of the documentation required by subsection 1.

Sec. 16. NAC 449.6116 is hereby amended to read as follows:

449.6116 An obstetric center must:

1. Have on the premises at least one registered nurse licensed pursuant to chapter 632 of NRS with experience ~~[in perinatal care of a maternal patient and newborn baby]~~ ***providing pre- and postdelivery care*** when a maternal patient is on the premises receiving pre- and postdelivery care ***.*** ~~[;]~~

2. Have at least two attendants present at all times during each delivery, one of whom must be a licensed physician ***currently practicing obstetrics, including routinely delivering newborn babies and caring for maternal patients,*** or a licensed advanced practice registered nurse ~~[;]~~ ***currently practicing obstetrics, including routinely delivering newborn babies and caring for maternal patients. At least one of the attendants must be a member of the clinical staff of the obstetric center who is approved by the director of the obstetric center to serve as an attendant. An obstetric center shall notify each maternal patient in writing if the obstetric center does not require a licensed physician to be on the premises while a patient is in labor or during birth.***

3. Have the capacity of providing initial evaluation of risk status, appropriateness of admission and support of ~~[maternal]~~ patients in labor ***.*** ~~[;]~~

4. Maintain on-site equipment, drugs, oxygen and appropriately trained and educated personnel needed to provide obstetric care to a maternal patient and newborn baby ***.*** ~~[;]~~

5. Have appropriate clinical laboratory services available for use to provide safe obstetric care according to the needs of the maternal patient and ~~[medical]~~ ***clinical*** staff of the obstetric center ***.*** ~~[; and]~~

6. Have at least two persons who are ~~[trained and experienced in performing cardiopulmonary]~~ ***currently certified in basic life support and neonatal*** resuscitation ~~[in adults and newborn babies]~~ on the premises and immediately available during each delivery.

Sec. 17. NAC 449.61162 is hereby amended to read as follows:

449.61162 1. A maternal patient or newborn baby ~~[, as appropriate,]~~ may not be transferred from an obstetric center unless the transfer is appropriate based on the risk assessment of the maternal patient or newborn baby and the member of the ~~[medical]~~ ***clinical*** staff determines that:

(a) The maternal patient is at high risk for a complicated labor or delivery and does not meet the criteria for a low-risk, uncomplicated labor and delivery; or

(b) The medical needs of the maternal patient or newborn baby exceed the capability of the obstetric center to provide the necessary care.

2. A maternal patient or newborn baby ~~[, as appropriate,]~~ may not be discharged from the obstetric center unless the discharge is appropriate based on the risk assessment of the maternal patient or newborn baby and a member of the ~~[medical]~~ ***clinical*** staff determines that:

(a) If the maternal patient has not given birth, the maternal patient is not in active labor; or

(b) The maternal patient has had a normal low-risk, uncomplicated birth and that further medical problems or complications resulting from the birth are not anticipated.

3. The criteria for the transfer of a maternal patient or newborn baby must be written and included in the manual for the policy and procedure of the obstetric center.

4. If a maternal patient or newborn baby must be transferred, the maternal patient or newborn baby must be transferred to a ***licensed*** hospital ~~[or other medical facility]~~ which is capable of providing a higher level of obstetrical and neonatal care **.** ~~[and with which the obstetric center has a written agreement that acknowledges that the hospital or medical facility agrees to accept emergency maternal patients without regard to their ability to pay.]~~

Sec. 18. NAC 449.61166 is hereby amended to read as follows:

449.61166 ~~[1. The obstetric center shall establish such policies and procedures as are necessary for the control of infectious agents and disease. The policies and procedures must:~~

~~(a) Include a method of disposal, cleaning and treatment of equipment, linens, and supplies contaminated with blood or bodily fluids; and~~

~~(b) Be in conformance with universal precautions established by the Centers for Disease Control and Prevention and with all applicable local, state and federal laws.~~

~~2. The]~~ ***An*** obstetric center shall establish a program to monitor the health of each employee of the obstetric center. The program must include, but not be limited to:

~~[(a) Annual testing for tuberculosis;]~~

1. Maintaining a separate personnel file for each employee of the obstetric center that must include documentation that the employee has had the tests or obtained the certificates required by NAC 441A.375; and

~~[(b)]~~ ***2.*** Documentation as to whether the employee has had:

~~[(1)]~~ ***(a)*** Rubella and, if so, when the employee had rubella.

~~[(2)]~~ ***(b)*** A vaccination for rubella and, if so, when the employee had the vaccination.

~~[3. A copy of the precautions established by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services may be obtained for a cost of $46, plus shipping and handling, from:~~

~~The National Technical Information Service of the~~

~~Centers for Disease Control and Prevention~~

~~Research Department~~

~~5285 Port Royal Road~~

~~Springfield, Virginia 22161~~

~~Reference No. PB86133022~~

~~(703) 487-4870]~~

Sec. 19. NAC 449.61168 is hereby amended to read as follows:

449.61168 1. An obstetric center must maintain or have available adequate laboratory services to meet the needs of its maternal patients, newborn babies and ~~[medical]~~ ***clinical*** staff. The obstetric center shall ensure that all laboratory services provided to its maternal patients and newborn babies are provided by a medical laboratory licensed pursuant to chapter 652 of NRS.

2. Laboratory services must be available during all hours of operation of the obstetric center as necessary to meet the needs of the maternal patients, newborn babies and ~~[medical]~~ ***clinical*** staff.

3. If work is performed by an outside laboratory, the original report must be from a laboratory licensed pursuant to chapter 652 of NRS and contained in the medical record of the maternal patient. If services are provided by an outside laboratory, the conditions, procedures and availability of work performed must be in writing and available within the obstetric center.

4. Upon the receipt of a laboratory report, an obstetric center shall promptly:

(a) File a laboratory report in the appropriate medical record; and

(b) Notify the physician or advanced practice registered nurse who requested the report that the report has been received and filed in the medical record of the maternal patient.

5. A report of a tissue specimen must be signed by a pathologist. The ~~[medical]~~ ***clinical*** staff of the obstetric center and a pathologist must determine whether a tissue specimen requires a macroscopic examination, or a macroscopic and microscopic examination.

6. If a maternal patient needs blood or blood products, the maternal patient must be transferred to a licensed hospital which has the capability of providing ~~[perinatal]~~ ***the appropriate level of*** services.

Sec. 20. NAC 449.6117 is hereby amended to read as follows:

449.6117 1. An obstetric center shall ensure that drugs and controlled substances are possessed, distributed and administered by members of the ~~[medical]~~ ***clinical*** staff in the obstetric center in conformance with all applicable federal, state and local laws.

2. All drugs and controlled substances distributed at an obstetric center must be possessed and distributed by a licensed physician or a licensed advanced practice registered nurse in accordance with his or her registration from the State Board of Pharmacy and the Drug Enforcement Administration of the Department of Justice. The licensed physician or licensed advanced practice registered nurse shall establish and maintain a list of drugs and controlled substances which are available for use by the licensed physician or licensed advanced practice registered nurse for maternal patients and newborn babies in the obstetric center.

3. An obstetric center shall establish a policy to ensure quality control and dispensing of drugs and controlled substances. The obstetric center must have a specific area for storing the

drugs and controlled substances which include, without limitation, locked storage for drugs, double-locked storage for controlled substances and locked refrigerated storage. A facility for washing hands must be provided near the area in which the drugs and controlled substances are to be distributed.

4. A drug or controlled substance may not be administered at an obstetric center without an order from a licensed physician or a licensed advanced practice registered nurse. An order for the administration of a drug or controlled substance must be entered into the medical record of the maternal patient and be signed by the physician or advanced practice registered nurse who made the order. The order must include the name of the drug, dosage, time or frequency of administration, and if other than oral, the route of administration.

5. The obstetric center shall provide a separate refrigerator for the storage of drugs and controlled substances. The temperature in the refrigerator must be maintained between 36 degrees Fahrenheit, or 2 degrees Centigrade, and 46 degrees Fahrenheit, or 8 degrees Centigrade. The temperature of the room in which the drugs and controlled substances that are not refrigerated are stored must not exceed 86 degrees Fahrenheit, or 30 degrees Centigrade.

Sec. 21. NAC 449.61174 is hereby amended to read as follows:

449.61174 1. ~~[An]~~ ***Except as otherwise provided in subsection 2, an*** obstetric center must have a written agreement with at least:

(a) One ***licensed*** hospital ~~[or medical facility licensed to provide high-risk perinatal]~~ ***that is capable of providing a higher level of obstetrical and neonatal*** care ~~[;]~~ ***than the obstetric center;*** and

(b) One transportation service which can provide a vehicle with equipment appropriate to the needs of a maternal patient or newborn baby during a transfer for the obstetric center,

➥ that assures the expedient transfer of a maternal patient or newborn baby in accordance to established written protocols of the obstetric center when a maternal patient or newborn baby requires care beyond the capability of the obstetric center or a maternal patient is deemed to have a condition or the potential for such a condition that would result in an abnormal or complicated delivery.

2. ***An obstetric center that does not have a written agreement with a licensed hospital pursuant to subsection 1 shall send a certified letter requesting such an agreement to at least one licensed hospital that provides a higher level of obstetrical and neonatal care than the obstetric center. If the hospital refuses to enter into such an agreement or does not respond to the certified letter within 30 days after the letter is mailed, the obstetric center is not required to have such an agreement. If an obstetric center does not have such an agreement, the obstetric center shall notify each maternal patient in writing that it does not have such an agreement.***

3. An obstetric center must be located within 30 minutes of normal driving time from a licensed hospital that provides obstetrical care.

4. An obstetric center shall develop and implement policies and procedures:

(a) That require a physician with whom the obstetric center has entered into an agreement pursuant to subsection 4 of NAC 449.61152 or a designee of the physician to be available during labor and delivery. The policies and procedures must describe the manner in which the physician or his or her designee will be available.

(b) For the emergency transfer of a patient to a licensed hospital.

5. The ~~[medical]~~ director of the obstetric center shall:

(a) Determine the criteria and conditions under which a maternal patient or newborn baby should be considered for transfer. The criteria and conditions must be included in the written policy and procedures for the obstetric center.

(b) Annually review those criteria and conditions.

~~[3.]~~ ***6.*** An obstetric center ~~[must]~~ ***shall*** establish written procedures to determine the level of care and the mode of transportation required to ensure that the maternal patient and newborn baby receive expeditious and safe care appropriate to the needs of the maternal patient or newborn baby during the transfer.

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.