STATE OF NEVADA

BRIAN SANDOVAL
Governor

RICHARD WHITLEY, MS
Director, DHHS

CODY L. PHINNEY, MPH
Administrator, DPBH

JOHN DIMURO, D.O., MBA
Chief Medical Officer

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC AND BEHAVIORAL HEALTH
BUREAU OF HEALTH CARE QUALITY AND COMPLIANCE
727 Fairview Dr., Suite E, Carson City, NV 89701
Telephone: 775-684-1030, Fax: 775-684-1073
dpbh.nv.gov

August 8, 2016

MEMORANDUM

To: Brian Saeman, Chair
State Board of Health

From: Cody Phinney, MPH, Secretary
State Board of Health

Re: Consideration and adoption of proposed regulation amendment(s) to NAC 449, "Medical Facilities and Other Related Entities", LCB File No. R059-16.

PURPOSE OF AMENDMENT

The main purpose of the amendment is to protect public safety and expand who can serve as the director of the obstetric center by:

- Requiring obstetric centers to obtain and maintain accreditation by a nationally recognized organization approved by the Division of Public and Behavioral Health (DPBH).
- Requiring the director to ensure staff and patients are adequately protected from fire or other disasters.
- Requiring that obstetric centers be constructed in accordance with the Guidelines for Design and Construction of Hospitals and Outpatient Facilities published by the Facility Guidelines Institute.
- Allowing an Advanced Practice Registered Nurse (APRN) certified as a nurse midwife to serve as the director of the center.
- Requiring the obstetric center to adopt nationally recognized infection control guidelines.
- Requiring an obstetric center to have a written agreement with at least one hospital capable of providing a higher level of obstetrical and neonatal care, but if a hospital refuses to enter into such an agreement or fails to respond to a written request for an agreement, the transfer agreement will not be required. However, the obstetric center will be required to notify each patient in writing that it does not have such an agreement.
- Requiring an obstetric center to be located within a 30 minute driving time of a licensed hospital that provides obstetrical care.

An errata to the proposed regulations which would require obstetric centers to implement employee tuberculosis screening standards, set for in NAC Chapter 441A and requiring the obstetric center to define "available" in policy as it relates to a physician being available during labor and delivery is also moving forward for consideration by the Board.

SUMMARY OF CHANGES TO NEVADA ADMINISTRATIVE CODE (NAC)

The Board of Health last revised regulations to NAC Chapter 449, "Medical Facilities and Other Related Entities" as it relates to obstetric centers was in August of 2004.

The proposed regulations currently moving forward accomplish the following:

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 certified 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.

POSSIBLE OUTCOME IF PROPOSED AMENDMENT IS NOT APPROVED

If the State Board of Health does not adopt or approve the proposed regulations, the increased safety measures in the proposed regulations would not go into force. For example, if an obstetric center were to open today it would not be required to be nationally accredited, to comply with the additional disaster protective measures, to adopt nationally recognized infection control guidelines or current tuberculosis screening standards set forth in NAC Chapter 441A, the Infectious Diseases and Toxic Agents chapter, which are the standards used by all other facility types in which tuberculosis screening is required or to be within a 30 minute drive time of a licensed hospital that provides a higher level of obstetrical care. In addition, the barriers currently in regulations would remain in place, discouraging the opening of obstetric centers by APRN's certified as a midwife. As currently there are no licensed obstetric centers in Nevada, it is likely this trend would continue limiting safe birthing alternatives for women.

APPLICABILITY OF PROPOSED AMENDMENT

These regulations will apply statewide to obstetric centers governed by NRS and NAC Chapter 449.

PUBLIC COMMENT RECEIVED

An outline of opportunities for public comment follows:

As currently there are no licensed obstetric centers in Nevada to send the proposed regulations and small business impact questionnaire to, to obtain input from industry:

1) The Nevada State Board of Nursing distributed the proposed regulations and small business impact questionnaire to all Advanced Practice Registered Nurses with an email on file with the Board;

2) An Advanced Practice Registered Nurse certified 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).

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

The proposed regulations and small business impact questionnaire was also posted on the Division's website and sent out through the Division's medical facilities listserv.

Input from the small business impact questionnaire included:
"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 in incalculable."

"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."

"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 CNM's in their regulations. A change in language would lessen the impact."

March 30, 2016: A public workshop was held on the proposed regulations at the Division of Public and Behavioral Health located at 727 Fairview Drive, Suite E, Carson City and video conferenced to the Division's office located at 4220 South Maryland Parkway, Suite 810 in Las Vegas.

Eleven individuals signed in at our Carson City location, six of those eleven individuals signed in as supporting the proposed regulations with recommendations/changes, two individuals did not indicate their stance on the sign in sheet, one was neutral, one noted there were concerns and one noted monitor.

One individual did not attend the meeting but provided written testimony which was read at the meeting in support of the proposed regulations with changes and a representative of 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."

Five individuals signed in at our Las Vegas location, four of those individuals signed in as opposed and one signed in as neutral.

A highlight of input provided during the public workshop is included below. Written comments with more detailed information provided to the Division of Public and Behavioral Health are included with this packet for your review.

Support for the proposed regulations expressed during the public workshop 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.

Concerns with the proposed regulations expressed during the public workshop 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 during the public workshop 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 certified 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.

Recommended changes received after the public workshop included 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.

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, requiring that an obstetric center notify each maternal patient in writing if it does not have a written transfer agreement with a hospital that provides a higher level of care or does not require a licensed physician to be on the premises while a patient is in labor or during birth.

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.

Other concerns expressed 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.
5) Do not require an experienced specialist on site if something goes wrong. No pediatrician or neonatal specialist required on site.

Review of the nationally recognized standards for birth centers (obstetric centers), Standards for Birth Centers of the American Association of Birth Centers (AABC), did reveal that agreements and/or policies and procedures are required as it relates to hospital care and transport services and requires the availability of consulting clinical specialists that are licensed to practice their profession and have the required skills and knowledge to provide care at a birthing center. It was not noted during the review that a written transfer agreement with a hospital is required, that emergency transport is required to be present during labor, that a physician is required to be onsite or that a birthing center should be within a required drive time of a hospital.

In addition, 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 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 certified 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.

Published studies, such as the one published in the Journal of Midwifery & Women's Health have concluded that midwife led birth centers are safe. A copy of the article has been included for your review.

Also included for your review is The American College of Obstetricians and Gynecologists document, "Obstetric Care Consensus, Levels of Maternal Care" which recognizes birth centers as a level of maternal care defined as, "Peripartum care of low-risk women with uncomplicated singleton term pregnancies with a vertex presentation who are expected to have an uncomplicated birth."

Although there were concerns expressed about the safety of birth centers, no published studies from a nationally recognized journal was provided to the Division showing that birth centers are not safe.

STAFF RECOMMENDATION

Staff recommends the State Board of Health adopt the proposed regulation amendments to NAC 449, "Medical Facilities and Other Related Entities", LCB File No. R059-16 with the errata as presented.

PRESENTER

Leticia Metherell, RN, Health Facilities Inspection Manager

LM

Enclosures

NOTICE OF PUBLIC WORKSHOP

NOTICE IS HEREBY GIVEN that the Division of Public and Behavioral Health will hold a public workshop to consider amendments to Nevada Administrative Code (NAC) Chapter 449.

The workshop will be conducted via videoconference beginning at 10:00 AM on Wednesday, March 30, 2016, at the following locations:

Division of Public and Behavioral Health Bureau of Health Care Quality and Compliance 727 Fairview Drive, Suite E Carson City, NV 89701	Division of Public and Behavioral Health Bureau of Health Care Quality and Compliance 4220 South Maryland Parkway, Suite 810, Building D Las Vegas, NV 89119

These workshops will be conducted in accordance with NRS 241.020, Nevada's Open Meeting Law.

AGENDA

1. Introduction of workshop process
2. Public comment on proposed amendments to Nevada Administrative Code Chapter 449
3. Public Comment

The proposed changes will revise Chapter 449 of the Nevada Administrative Code and are being proposed in accordance with NRS 449.0302.

The proposed regulations provide provisions for the following:

1) Requires that an obstetric center obtain and maintain current accreditation by a nationally recognized organization approved by the Division.
2) Requires the director to ensure staff and patients are adequately protected from fire or other disasters.
3) Requires that obstetric centers be constructed in accordance with the Guidelines for Design and Construction of Hospitals and Outpatient Facilities published by the Facility Guidelines Institute.
4) Allows an Advanced Practice Registered Nurse licensed as a nurse midwife in Nevada to serve as the director of the obstetric center.
5) Requires the obstetric center to adopt nationally recognized infection control guidelines.
6) Requires an obstetric center to have a written agreement with at least one hospital capable of providing a higher level of obstetrical and neonatal care or to make a good faith effort to enter into a written agreement.
7) Requires an obstetric center to be located within a 30 minute normal driving time of a licensed hospital that provides obstetrical care.

Members of the public may make oral comments at this meeting. Persons wishing to submit written testimony or documentary evidence may submit the material to Leticia Metherell, Health Facilities Inspection Manager at the following address:

Division of Public and Behavioral Health
727 Fairview Drive, Suite E
Carson City, NV 89701
775-684-1073 (FAX)

Members of the public who require special accommodations or assistance at the workshops are required to notify Betsy Greenspan, Administrative Assistant, in writing to the Division of Public and Behavioral Health, 727 Fairview Drive, Suite E, Carson City, Nevada, 89701, or by calling (775) 684-1032 at least five (5) working days prior to the date of the public workshop.

You may contact Leticia Metherell, Health Facilities Inspection Manager by calling 775-684-1045 for further information on the proposed regulations.

A copy of the notice and the proposed regulations are on file for inspection and/or may be copied at the following locations during normal business hours:

Division of Public and Behavioral Health
727 Fairview Drive, Suite E
Carson City, NV

Division of Public and Behavioral Health
4220 S. Maryland Parkway, Suite 810, Bldg D
Las Vegas, NV

Nevada State Library and Archives
100 Stewart Street
Carson City, NV

A copy of the regulations and small business impact statement can be found on-line by going to: http://dpbh.nv.gov/Reg/MedicalLabs/Notice_of_Public_Workshops_and_Proposed_Regulations/
A copy of this notice has been posted at the following locations:

1. Division of Public and Behavioral Health, 4150 Technology Way, First Floor Lobby, Carson City
2. Nevada State Library and Archives, 100 Stewart Street, Carson City
3. Legislative Building, 401 S. Carson Street, Carson City
4. Grant Sawyer Building, 555 E. Washington Avenue, Las Vegas
5. Washoe County District Health Department, 9TH and Wells, Reno
6. Division of Public and Behavioral Health's web page: http://dpbh.nv.gov/
7. Nevada Legislature's web page: https://www.leg.state.nv.us/App/Notice/A/

Copies may be obtained in person, by mail, or by calling (775) 684-1032.

Copies may also be obtained from any of the public libraries listed below:

Carson City Library
900 North Roop Street
Carson City, NV 89702

Churchill County Library
553 South Main Street
Fallon, NV 89406

Clark County District Library
833 Las Vegas Boulevard North
Las Vegas, NV 89101

Douglas County Library
1625 Library Lane
Minden, NV 89423

Elko County Library
720 Court Street
Elko, NV 89801

Esmeralda County Library
Corner of Crook and 4th Street
Goldfield, NV 89013-0484

Eureka Branch Library
210 South Monroe Street
Eureka, NV 89316-0283

Henderson District Public Library
280 South Water Street
Henderson, NV 89105

Humboldt County Library
85 East 5th Street
Winnemucca, NV 89445-3095

Lander County Library
625 South Broad Street
Battle Mountain, NV 89820-0141

Lincoln County Library
93 Maine Street
Pioche, NV 89043-0330

Lyon County Library
20 Nevin Way
Yerington, NV 89447-2399

Mineral County Library
110 1st Street
Hawthorne, NV 89415-1390

Pahrump Library District
701 East Street
Pahrump, NV 89041-0578

Pershing County Library
1125 Central Avenue
Lovelock, NV 89419-0781

Storey County Library
95 South R Street
Virginia City, NV 89440-0014

Tonopah Public Library
167 Central Street
Tonopah, NV 89049-0449

Washoe County Library
301 South Center Street
Reno, NV 89505-2151

White Pine County Library
950 Campton Street
Ely, NV 89301-1965

Per NRS 233B.064(2), upon adoption of any regulations, the agency, if requested to do so by an interested person, either prior to adoption or within 30 days thereafter, shall issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

NOTICE OF PUBLIC HEARING

Intent to Adopt Regulations
(LCB File No. R059-16)

NOTICE IS HEREBY GIVEN that the State Board of Health will hold a public hearing to consider amendments to Chapter 449 of Nevada Administrative Code (NAC), Medical Facilities and Other Related Entities. This public hearing is to be held in conjunction with the State Board of Health meeting on September 9, 2016.

The State Board of Health will be conducted via videoconference beginning at 9:00 a.m. on Friday, September 9, 2016 at the following locations:

Division of Public and Behavioral Health 4150 Technology Way Room #303 Carson City, NV 89706	Southern Nevada Health District 280 S. Decatur Blvd Las Vegas, NV 89107	Division of Aging and Disability Services Early Intervention Services 1020 Ruby Vista Drive, Suite 102 Elko, NV

The proposed changes to NAC 449 include the following:

- Requiring obstetric centers to obtain and maintain accreditation by a nationally recognized organization approved by the Division of Public and Behavioral Health (DPBH).
- Requiring the director to ensure staff and patients are adequately protected from fire or other disasters.
- Requiring that obstetric centers be constructed in accordance with the Guidelines for Design and Construction of Hospitals and Outpatient Facilities published by the Facility Guidelines Institute.
- Allowing an Advanced Practice Registered Nurse (APRN) certified as a nurse midwife to serve as the director of the center.
- Requiring the obstetric center to adopt nationally recognized infection control guidelines.
- Requiring an obstetric center to have a written agreement with at least one hospital capable of providing a higher level of obstetrical and neonatal care, but if a hospital refuses to enter into such an agreement or fails to respond to a written request for an agreement, the transfer agreement will not be required. However, the obstetric center will be required to notify each patient in writing that it does not have such an agreement.
- Requiring an obstetric center to be located within a 30 minute driving time of a licensed hospital that provides a higher level of obstetrical care.

- An errata to the proposed regulations which would require obstetric centers to implement employee tuberculosis screening standards, set for in NAC Chapter 441A and requiring the obstetric center to define "available" in policy as it relates to a physician being "available" during labor and delivery is also moving forward for consideration by the Board.

1. Anticipated effects on the business which NAC 449 regulates:
   A. *Adverse effects*: None. Currently there are no licensed obstetric centers in Nevada.
   B. *Beneficial:* Advanced Practice Registered Nurses (APRN) 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.
   C. *Immediate:* As soon as the proposed regulations become effective it would allow for APRN certified midwives to open obstetric centers.
   D. *Long-term:* There may be an increased number of obstetric centers in Nevada.

2. Anticipated effects on the public:
   A. *Adverse*: None.
   B. *Beneficial:* May expand the options low-risk women have to give birth in a licensed facility.
   C. *Immediate*: Would put additional safety measures in place that would be required to be followed if someone opened an obstetric center. It would also remove a barrier that has prevented APRN certified midwives from opening obstetric centers.
   D. *Long-term:* There may be an increased number of obstetric centers in Nevada providing low-risk women with a safe, licensed facility alternative to give birth.

3. The estimated cost to the Division of Public and Behavioral Health for enforcement of the proposed regulations is estimated to be an initial fee of $1,564 with an annual renewal fee of $782. These fees are currently set in regulations and would be used to cover the costs to enforce the proposed regulations.

The proposed regulations do not overlap or duplicate any other Nevada state regulations.

Members of the public may make oral comments at this meeting. Persons wishing to submit written testimony or documentary evidence in excess of two typed, 8-1/2" x 11" pages must submit the material to the Board's Secretary, Cody Phinney, to be received no later than August 24, 2016 at the following address:

Secretary, State Board of Health
Division of Public and Behavioral Health
4150 Technology Way, Suite 300
Carson City, NV 89706

Written comments, testimony, or documentary evidence in excess of two typed pages will not be accepted at the time of the hearing. The purpose of this requirement is to allow Board members adequate time to review the documents.

A copy of the notice and proposed regulations are on file for inspection and/or may be copied at the following locations during normal business hours:

Nevada Division of Public and Behavioral Health
727 Fairview Drive, Suite E
Carson City, NV 89701

Nevada State Library
100 Stewart Street
Carson City, NV 89701

Nevada Division of Public and Behavioral Health
4220 S. Maryland Parkway, Suite 810, Building D
Las Vegas, NV 89119

A copy of the regulations and small business impact statement can be found on-line by going to:
http://dpbh.nv.gov/Reg/MedicalLabs/Notice_of_Public_Workshops_and_Proposed_Regulations/

A copy of the public hearing notice can also be found at Nevada Legislature's web page:
https://www.leg.state.nv.us/App/Notice/A/

Copies may be obtained in person, by mail, or by calling the Division of Public and Behavioral Health at (775) 684-1030 in Carson City or (702) 486-6515 in Las Vegas.
Copies may also be obtained from any of the public libraries listed below:

Carson City Library
900 North Roop Street
Carson City, NV 89702

Churchill County Library
553 South Main Street
Fallon, NV 89406

Clark County District Library
1401 East Flamingo Road
Las Vegas, NV 89119

Douglas County Library
1625 Library Lane
Minden, NV 89423

Elko County Library
720 Court Street
Elko, NV 89801

Esmeralda County Library
Corner of Crook and 4th Street
Goldfield, NV 89013-0484

Eureka Branch Library
80 South Monroe Street
Eureka, NV 89316-0283

Henderson District Public Library
280 South Green Valley Parkway
Henderson, NV 89012

Humboldt County Library
85 East 5th Street
Winnemucca, NV 89445-3095

Lander County Library
625 South Broad Street
Battle Mountain, NV 89820-0141

Lincoln County Library
93 Maine Street
Pioche, NV 89043-0330

Lyon County Library
20 Nevin Way
Yerington, NV 89447-2399

Mineral County Library
110 1st Street
Hawthorne, NV 89415-1390

Pahrump Library District
701 East Street
Pahrump, NV 89041-0578

Pershing County Library
1125 Central Avenue
Lovelock, NV 89419-0781

Storey County Library
95 South R Street
Virginia City, NV 89440-0014

Tonopah Public Library
167 Central Street
Tonopah, NV 89049-0449

Washoe County Library
301 South Center Street
Reno, NV 89505-2151

White Pine County Library
950 Campton Street
Ely, NV 89301-1965

Per NRS 233B.064(2), upon adoption of any regulation, the agency, if requested to do so by an interested person, either prior to adoption or within 30 days thereafter, shall issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

Errata – LCB File No. R059-16

Blue italic = Proposed language found in LCB File No. R056-16
[~~Red strikethrough in brackets~~] = Proposed omitted material found in LCB File No. R059-16
Green italic = New language proposed in Errata
[Red brackets] = Proposed omitted material in Errata.

Section 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~~] [certified as a nurse midwife] *is licensed 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.

Rationale: This is a technical change to reflect that a nurse midwife is not certified as a nurse midwife by the State Board of Nursing but is instead licensed to practice in a role as a nurse midwife by the State Board of Nursing.

Section 18
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)]~~ ***1.*** [Annual testing for tuberculosis;] *Maintaining a separate personnel file for each employee of the center that must include, without limitation, 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~~]

Rationale: To bring obstetric centers to the tuberculosis screening standards found in NAC Chapter 441A, the Infectious Diseases and Toxic Agents chapter, to help ensure the safety of patients.

Section 21
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 must 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 of a licensed hospital that provides obstetrical care.
4. An obstetric center must have policies and procedures:

1. (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; and
(b) For the emergency transfer of a patient to a licensed hospital.
2. The policy must define "available" as used in subsection (4) (1) (a) of Section 21.
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 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.

Rationale: To make it clear in an obstetric center's policy what the word "available" means. Once defined in policy the center would be held to this policy standard.

PROPOSED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R059-16

May 23, 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 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 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 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 the maternal patient by providing: (1) a separate area for 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 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 of a hospital that provides obstetrical care. Finally, **section 21** requires an obstetric center to have policies and procedures concerning the emergency transfer of a patient to a hospital.

Sections 14, 15, 17 and 19 of this regulation make non-substantive 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 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 of 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 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.

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 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 must 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]~~ ***certified 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;~~

~~(e)~~] 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 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 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)]~~ ***1.*** Annual testing for tuberculosis; 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 must 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 of a licensed hospital that provides obstetrical care.

4. An obstetric center must have 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; and

(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 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.

SMALL BUSINESS IMPACT STATEMENT 2016
PROPOSED AMENDMENTS TO NAC CHAPTER 449

The Division of Public and Behavioral Health (DPBH) has determined that the proposed amendments would not have a direct financial effect on obstetric centers because currently there are no licensed obstetric centers in Nevada. The proposed amendments would have an indirect financial benefit by removing a barrier for Advanced Practice Registered Nurses licensed as nurse midwifes in Nevada from opening an obstetric center, therefore allowing them to expand their businesses. It creates a negative financial impact by requiring accreditation with its associated costs. The proposed regulations are not expected to negatively impact the formation, operation or expansion of a small business in Nevada.

A small business is defined in Nevada Revised Statutes NRS 233B as a "business conducted for profit which employs fewer than 150 full-time or part-time employees."

This small business impact statement is made pursuant to NRS 233B.0608 (3) and complies with the requirements of NRS 233B.0609. As required by NRS 233B.0608 (3), this statement identifies the methods used by the agency in determining the impact of the proposed regulations on a small business and provides the reasons for the conclusions of the agency followed by certification by the person responsible for the agency.

Background

The main things the proposed regulations include:
1) Requires that an obstetric center obtain and maintain current accreditation by a nationally recognized organization approved by the Division.
2) Requires the director to ensure staff and patients are adequately protected from fire or other disasters.
3) Requires that obstetric centers be constructed in accordance with the Guidelines for Design and Construction of Hospitals and Outpatient Facilities published by the Facility Guidelines Institute.
4) Allows an Advanced Practice Registered Nurse licensed as a nurse midwife in Nevada to serve as the director of the obstetric center.
5) Requires the obstetric center to adopt nationally recognized infection control guidelines.
6) Requires an obstetric center to have a written agreement with at least one hospital capable of providing a higher level of obstetrical and neonatal care or to make a good faith effort to enter into a written agreement with at least one hospital.
7) Requires an obstetric center to be located within a 30 minute normal driving time of a licensed hospital that provides obstetrical care.

1) **A description of the manner in which comment was solicited from affected small businesses, a summary of their response and an explanation of the manner in which other interested persons may obtain a copy of the summary.**

Pursuant to NRS 233B.0608 (2) (a), the Division of Public and Behavioral Health has made a concerted effort to determine whether the proposed regulations are likely to impose an economic burden upon a small business. Currently there are no licensed obstetric centers in Nevada to send the proposed regulations and small business impact questionnaire to, so to obtain input the proposed regulations were sent to:

1) The Nevada State Board of Nursing who distributed the proposed regulations and small business impact questionnaire to all Advanced Practice Registered Nurses with an email on file with the Board.
2) The Nevada Hospital Association.
4) An Advanced Practice Registered Nurse licensed as a nurse midwife in Nevada who then distributed them to:

- The American Association of Birth Centers (AABC)
- The Commission for the Accreditation of Birth Centers (CABC)
- The American College of Nurse-Midwives (ACNM)

The proposed regulations and small business impact questionnaire were also posted on the Division's website and sent out through the Division's medical facilities listserv.

The questions on the questionnaire were:

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

Summary of 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".	**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	**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

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.	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.		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.

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

Division of Public and Behavioral Health
727 Fairview Drive, Suite E
Carson City, NV 89701
Betsy Greenspan: Phone: 775-684-1032; Email: bgreenspan@health.nv.gov

2) Describe the manner in which the analysis was conducted.

An analysis of the input collected from stakeholders was conducted by a health facilities inspection manager. The analysis involved analyzing feedback obtained from the small business impact questionnaire as well as information gathered from communicating with different stakeholders. Current regulations governing obstetric centers were also reviewed as part of the analysis. This information was then used to complete this small business impact statement including the conclusion on the impact of the proposed regulation on a small business found in number 8.

The estimated economic effect of the proposed regulation on the small business which it is to regulate including, without limitation both adverse and beneficial effects and both direct and indirect effects.

Direct 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 the barrier that keeps them from applying to open a center.

Indirect Beneficial Effects: Allows certain midwife businesses to expand their businesses to include the services provided by an obstetric center.

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

Indirect 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.

3) Provide a description of the methods that the agency considered to reduce the impact of the proposed regulation on small businesses and a statement regarding whether the agency actually used any of those methods.

The Division of Public and Behavioral Health used several methods to reduce the impact of the proposed regulations on small businesses including discussions with stakeholders, distribution of small business impact questionnaires to stakeholders to provide input on how the proposed obstetric center regulations may impact their businesses, review of existing regulations and analysis of the information gathered in order to consider modifications in the proposed regulations to reduce the impact. The feedback to expand the proposed regulations to include Certified Professional Midwifes (CPM) as the director of an obstetric center was considered. The proposed regulations were not modified to include CPM's 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.

Feedback was received that the cost of accreditation would be an indirect adverse effect. After further discussion with the stakeholder that provided this feedback, she stated that accreditation should be required despite the additional cost because it ensures licensed facilities have to follow evidence based standards for quality of care that may be updated before regulations are updated and also because of insurance requirements.

The proposed regulations completely removed the need for a written transfer agreement with a hospital. There was also no provision for the obstetric center to make an effort to obtain a written agreement. Based on this feedback, modifications were made to the proposed regulations requiring that an obstetric center make a good faith effort to enter into a written agreement with at least one hospital providing obstetric services. After making the good faith effort, if the obstetric center was not able to obtain a written transfer agreement then transfer policies and procedures would need to be in place.

A public workshop will be scheduled allowing for further input by stakeholders and the public regarding the proposed regulations and how they will impact industry. Comments received during the public workshop will also be taken into consideration for possible further revisions to the regulations to reduce the economic impact on facilities.

4) 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.

6) If the proposed regulation provides a new fee or increases an existing fee, the total annual amount DPBH 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.

7) **An explanation of why any duplicative or more stringent provisions than federal, state or local standards regulating the same activity are necessary.**

There are no other federal, state or local standards regulating obstetric centers.

8) **Provide a summary of the reasons for the conclusions of the agency regarding the impact of a regulation on small businesses.**

The reason for the Division's conclusion on the impact of the proposed regulation on small businesses is based on the feedback received by stakeholders. The conclusion is that the proposed regulations would have a positive financial impact for some but at the same time would generate an additional cost to operate an obstetric center by requiring that obstetric centers be accredited. This was discussed with one stakeholder who stated she believed in accreditation and felt that accreditation should be required despite the cost.

Certification by Person Responsible for the Agency

I, Cody Phinney, Administrator of the Division of Public and Behavioral Health certify to the best of my knowledge or belief, a concerted effort was made to determine the impact of the proposed regulation on small businesses and the information contained in this statement was prepared properly and is accurate.

Signature Cody Phinney Date: 2/20/16

Dignity Health.
St. Rose Dominican

3001 St. Rose Pkwy.
Henderson, NV 89052
direct 702.616.5000
fax 702.616.5511
strosehospitals.org

March 30, 2016

Cody L. Phinney, MPH
Nevada Division of Public and Behavioral Health
Bureau of Health Care Quality and Compliance
727 Fairview Drive, Suite E
Carson City, NV 89701

Re: Freestanding Obstetric Centers; Nevada Administrative Code Chapter 449

Dear Administrator Phinney:

On behalf of our three hospitals in Nevada, Dignity Health-St. Rose Dominican appreciates the opportunity to submit comments on the proposed freestanding obstetric center recommendations. As the nation's fifth-largest health system, Dignity Health is committed to our mission of providing compassionate, high-quality care to all and strongly supports a system of health care that includes timely access to services. Dignity Health believes that these proposed regulations do not take into account the health and safety of some of the most fragile of patients – the baby.

The State's proposal has created many concerns about the type of treatment both the baby and the mother would receive in a critical situation. Dignity Health-St. Rose Dominican would like to bring to your attention these specific items:

1) No Pediatrician or Neonatal Specialist Required – As we all know, not every baby is born healthy. We appreciate that the State requires these obstetric centers to screen their patients for a number of medical conditions and substance abuse, but these screenings do not guarantee that the baby will be born without a major medical problem. When something goes wrong, that baby needs immediate specialty care and it's concerning that these obstetric centers are not required to have an experienced specialist that can quickly take action to keep the baby alive. Intubation of a newborn is extremely difficult and requires a higher level of experience than most clinicians in this setting would have. These centers can be required to contain all of the equipment in the world, but they truly need a specialist that can provide the proper care in the proper timeframe.

   In Sec. 8.2.a.2, the proposed regulations state that the registered nurse has to be deemed "clinically competent" by the director and the more formal documented experience was removed (Sec. 8.2.c). What does "clinically competent" mean? This is not defined in section 1.

In Sec. 9.4.b, the proposed regulations state that a higher level of care needs to be "readily available by telephone and for emergency services." Having someone available via telephone is not helpful in a life-threatening situation and this language is not specific enough. These centers need someone on campus to deal with these situations.

2) Transfer Agreement – Sec. 18 outlines the need for the obstetric center to enter into a transfer agreement with a hospital that is "capable of providing a higher level of obstetrical and neonatal care … or has attempted, in good faith to enter into an agreement with at least one hospital..." What does "in good faith" mean?

   In Sec. 19.1, the proposed regulations mandate that the obstetric center "be located within a 30 minute normal driving time of a licensed hospital that provides obstetrical care." 30 minutes is far too long when dealing with the life-threatening condition of a newborn. We would suggest that the timeframe be changed to no longer than 5 minutes.

Dignity Health-St. Rose Dominican appreciates the opportunity to respond to the freestanding obstetric center recommendations and hopes our input is helpful as your office proceeds further. If you have any questions, please feel free to contact Katie Ryan, Director of Communications and Public Policy at (702) 616-4847 or at katie.ryan@dignityhealth.org.

Sincerely,

Dr. Robert Pretzlaff
Chief Medical Officer
Dignity Health-St. Rose Dominican

Katie Ryan
Director, Communications and Public Policy
Dignity Health-St. Rose Dominican

Dignity Health.
St. Rose Dominican

3001 St. Rose Pkwy.
Henderson, NV 89052
direct 702.616.5000
fax 702.616.5511
strosehospitals.org

August 9, 2016

Cody L. Phinney, MPH,
Secretary, State Board of Health
Division of Public and Behavioral Health
4150 Technology Way, Suite 300
Carson City, NV 89706

Re: LCB File No. R059-16, and September 9, 2016 Hearing before the Nevada Board of Health proposing Freestanding Obstetric Centers; Nevada Administrative Code Chapter 449

Dear Administrator Phinney:

On behalf of our three hospitals in Nevada, Dignity Health-St. Rose Dominican appreciates the opportunity to submit comments on the proposed freestanding obstetric center recommendations. As the nation's fifth-largest health system, Dignity Health is committed to our mission of providing compassionate, high-quality care to all and strongly supports a system of health care that includes timely access to services. Dignity Health believes that these proposed regulations do not take into account the health and safety of some of the most fragile of patients – the baby.

After the workshop, we still believe the State's proposal has created many concerns about the type of treatment both the baby and the mother will receive in a critical situation. Dignity Health-St. Rose Dominican still believes these specific items need to be addressed:

1) No Pediatrician or Neonatal Specialist Required – As we all know, not every baby is born healthy. We appreciate that the State requires these obstetric centers to screen their patients for a number of medical conditions and substance abuse, but these screenings do not guarantee that the baby will be born without a major medical problem. When something goes wrong, that baby needs immediate specialty care and it's concerning that these obstetric centers are not required to have an experienced specialist that can quickly take action to keep the baby alive. Intubation of a newborn is extremely difficult and requires a higher level of experience than most clinicians in this setting would have. These centers can be required to contain all of the equipment in the world, but they truly need a specialist that can provide the proper care in the proper timeframe.

   In Sec. 11.2.c, the proposed regulations state that the registered nurse has to be deemed "clinically competent" by the director and the more formal documented experience was

removed. We appreciate the clarification in the new version, dated May 23, 2016, that the RN must be clinically competent in pre- and post-care, but we still believe that there should be a standard in place to define "clinically competent."

2) Transfer Agreement – Sec. 21 and Errata thereto outline the need for the obstetric center to enter into a transfer agreement with "one licensed hospital that is capable of providing a higher level of obstetrical and neonatal care than the obstetric center," and, "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." We still believe that each of these obstetric centers should be mandated to have a transfer agreement with a licensed hospital.

   In Sec. 21.3, the proposed regulations, with Errata, mandate that the obstetric center "be located within a 30 minute normal driving time of a licensed hospital that provides obstetrical care." 30 minutes is far too long when dealing with the life-threatening condition of a newborn. We would suggest that the timeframe be changed to no longer than five (5) minutes in urban settings, acknowledging that in rural areas this brings up concerns of provider capacity.

Dignity Health-St. Rose Dominican appreciates the opportunity to comment on these proposed regulations. If you have any questions, please feel free to contact Katie Ryan, Director of Communications and Public Policy at (702) 616-4847 or at katie.ryan@dignityhealth.org.

Sincerely,

Dr. Robert Pretzlaff
Chief Medical Officer
Dignity Health-St. Rose Dominican

Katie Ryan
Director, Communications and Public Policy
Dignity Health-St. Rose Dominican

NHA
Nevada Hospital Association

5190 Neil Road, Ste. 400
Reno, NV 89502
775-827-0184 • 775-827-0190

TESTIMONY BEFORE THE
NEVADA DIVISION OF PUBLIC AND BEHAVIORAL HEALTH
PUBLIC WORKSHOP ON FREE STANDING OB CENTERS

Presented by:
Marissa Brown, Director of Workforce and Clinical Services
Nevada Hospital Association

Good morning. I am Marissa Brown, Director of Workforce and Clinical Services with the Nevada Hospital Association (NHA) representing all of Nevada's acute care hospitals along with psychiatric, rehabilitation and other specialty hospitals in Nevada. I appreciate the opportunity to express NHA's input on the revised proposed amendments to free standing obstetrical centers in NRS 449.

Although we recognize that some adjustments were made to the proposed amendments regarding the transfer agreement, the following are additional concerns expressed by some NHA members:

- The proposed regulations do not mandate the presence of a pediatrician or neonatal specialist. Although the proposed regulations require obstetric centers to screen their patients for medical conditions and substance abuse, this does not guarantee a healthy outcome. If something goes wrong, the baby needs immediate specialty care. It is concerning that free standing obstetric centers in Nevada are not required to have an experienced specialist on site to intervene and provide proper care within the proper timeframe.
- Considering the complexity of a newborn and how quickly something can go wrong, regulations should require the presence of emergency transport, such as an ALS ambulance, when the free standing obstetrical center has laboring patients.
- Section 8, Subsection 2(a) states that the registered nurse has to be deemed "clinically competent." This is not defined.
- Section 9, Subsection 4(b) states that a higher level of care needs to be "readily available by telephone and for emergency services". This language is not specific, and

NHA
Nevada Hospital Association

5190 Neil Road, Ste. 400
Reno, NV 89502
775-827-0184 • 775-827-0190

there needs to be someone available on site to deal with unexpected life threatening situations needing emergent attention.

- Section 18 outlines the need for the obstetric center to enter into a transfer agreement with a hospital that is "capable of providing a higher level of obstetrical and neonatal care, as appropriate, or has attempted in good faith to enter into an agreement with at least one hospital located pursuant to Section 19. If the obstetric center, after making an attempt in good faith to enter into an agreement pursuant to this section is not able to enter into a written agreement then the obstetric center, must have policies and procedures in place outlining the emergency transport of a patient to a hospital which must include the requirement that a transfer plan be developed for each patient;" What does "in good faith" mean? Health care facilities that provide a lower level of care are required in statute to have a written transfer agreement in place. Does this statute provide an exception to this rule specific to free standing obstetrical centers or will it change statute for all other types of facilities?
- In Section 19, the proposed regulations mandate the obstetric center "be located within a 30 minute normal driving time of a licensed hospital that provides obstetrical care." Thirty minutes is too long when dealing with the life-threatening condition of a newborn.

Thank you for your time and for allowing me to provide comments today on behalf of Nevada Hospital Association members. I will be happy to answer any questions.

NHA
Nevada Hospital Association

5190 Neil Road, Ste. 400
Reno, NV 89502
775-827-0184 • 775-827-0190

ADDITIONAL COMMENTS TO TESTIMONY FROM THE NEVADA HOSPITAL ASSOCIATION PROVIDED TO NEVADA DIVISION OF PUBLIC AND BEHAVIORAL HEALTH PUBLIC WORKSHOP ON FREE STANDING OB CENTERS

Presented by:
Marissa Brown, Director of Workforce and Clinical Services
Nevada Hospital Association

As an addendum to comments provided by the Nevada Hospital Association at the Public Workshop on free standing obstetrical centers on March 30, 2016, regarding the revised proposed amendments to free standing obstetrical centers in NRS 449, we are proposing the following:

- Because this license is issued by the "State of Nevada", it should be made clear that no discrimination in who is served is permissible under the Nevada and U.S. Constitution; therefore, the proposed regulations should require free standing obstetrical centers to accept all residents of Nevada, including those persons who are Medicaid eligible.
- Public safety being a paramount responsibility of any facility licensed by this Division, every patient should be made aware of the limitations of free standing obstetrical centers to meet their needs. Therefore, the proposed regulations should require the patient to sign informed consent acknowledging that in the event of an emergency, the free standing obstetrical center does not have a physician on premises while they are in labor, or a written transfer agreement with a higher level of care.

Thank you for your time and for allowing me to provide additional comments on behalf of Nevada Hospital Association members.

American College of Obstetricians and Gynecologists (ACOG)
Nevada Section

March 30, 2016

TO: Division of Public and Behavioral Health

FROM: Keith R. Brill, MD, FACOG, FACS Chair, Nevada Section of ACOG

RE: Proposed Regulation Changes of The State Board of Health regarding Obstetric Centers

The Nevada Section of ACOG does support the proposed regulations along with some proposed amendments. I have provided data that supports the regulation changes. To summarize:

1. We agree with the need for accreditation by a national organization that follows the American Association of Birth Centers (AABC) Standards for Birth Centers.

2. We agree with the change to have the clinical director be an APRN or a physician trained in obstetrical care. APRNs are licensed independent practitioners in the state of Nevada, and section 2301 of the Affordable Care Act requires states that recognize freestanding birth centers to provide coverage and separate payments for freestanding birth center facility services and services rendered by certain professionals providing services in a freestanding birth center, to the extent the State licenses or otherwise recognizes such providers under state law.

3. Regarding Sec. 8.6, we ask for clarification regarding whether an APRN is considered to be a "medical practitioner." We request that the language be changed to:

   "The governing body shall require each licensed Advanced practice registered nurse and licensed physician who practices in the obstetric center to carry liability insurance in an amount of $1,000,000 or more."

4. The definition of a term pregnancy is generally accepted as the completion of at least 37 weeks and not more than 42 weeks of gestation. As such, we recommend that Sec 2.1 be changed to:

   "She has completed at least 37 weeks and not more than 42 weeks of gestation;"

5. 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 (see below). However, the American Association for Birth Centers recommends written agreements and/or policies and procedures for interaction with other facilities (see below). Since the Commission for the Accreditation of Birth Centers (CABC) does not require written agreements, we will simply prefer that there be a written agreement, but we do not feel this must be mandatory.

American College of Obstetricians and Gynecologists (ACOG) Nevada Section

Supporting literature (bold emphasis added by me):

From the **Joint Statement of Practice Relations Between Obstetrician-Gynecologists and Certified Nurse-Midwives/Certified Midwives, which is a document that was jointly developed by the American College of Nurse-Midwives (ACNM) and the American College of Obstetricians and Gynecologists (ACOG):**

"ACOG and the ACNM recognize the importance of options and preferences of women in their health care. Ob-gyns and CNMs/CMs work in a variety of settings including private practice, community health facilities, clinics, hospitals, and accredited birth centers.

Accredited birth centers—a birthing center within a hospital complex, or a freestanding birthing center that meets the standards of **the Accreditation Association for Ambulatory Health Care, the Joint Commission, or the American Association of Birth Centers, or is accredited by the Commission for the Accreditation of Birth Centers (CABC).**"

From ACOG/SMFM (Society for Maternal-Fetal Medicine) Obstetric Care Consensus on Maternal Levels of Care published in the American Journal of Obstetrics and Gynecology in 2014:

"Birth centers provide peripartum care to low-risk women with uncomplicated singleton **term pregnancies** with a vertex presentation who are expected to have an uncomplicated birth. Cesarean delivery or operative vaginal delivery are not offered at birth centers.

In a freestanding birth center....medical consultation should be available at all times. These facilities should be to initiate emergency procedures (including cardiopulmonary and newborn resuscitation and stabilization) at all times, to meet unexpected needs of the woman and newborn within the center, and to facilitate transport to an acute care setting when necessary. To ensure optimal care of all women, a birth center should have a clear understanding of its capability to provide maternal and neonatal care and the threshold at which it should transfer women to a facility with a higher level of care. **A birth center should have an established agreement with a receiving hospital and have policies and procedures in place for timely transport.** These transfer plans should include risk identification; determination of conditions necessitating consultation; referral and transfer; and a reliable, accurate, and comprehensive communication system between participating facilities and transport teams. All facilities should have quality improvement programs that include efforts to maximize patient safety."

The **AABC Standards for Birth Centers** (copyright 2008) states:

"10. There are agreements and/or policies and procedures for interaction with other agencies,

American College of Obstetricians and Gynecologists (ACOG)
Nevada Section

institutions and individuals for services to clients including but not limited to:

A. Obstetric/newborn acute care in licensed hospitals

B. Transport services

C. Obstetric consultation services

D. Pediatric consultation services

E. Laboratory and diagnostic services

F. Childbirth education/parent education support services

G. Home health care services

11. All contracts, agreements, policies and procedures are reviewed annually and updated as needed."

Thank you,

Keith R. Brill, MD, FACOG, FACS

drkbrill@whasn.com

American Association of Birth Centers

America's Birth Center Resource

3123 Gottschall Road - Perkiomenville, PA 18074 - Tel: 215-234-8068 - Fax: 215-234-8829 - aabc@birthcenters.org - www.birthcenters.org

February 5, 2016

Leticia Metherell, RN, CPM
Health Facilities Inspection Manager
Bureau of Health Care Quality and Compliance
727 Fairview Drive, Suite E
Carson City, NV 89701

Dear Ms. Metherell,

I am writing to you on behalf of the American Association of Birth Centers (AABC), the national organization for birth centers and the foremost resource on freestanding birth centers (FSBCs), to express support of the proposed regulations for Obstetric Care Centers NAC449.6113. These revised regulations will lay the foundation for improved access to high quality, client and family-centered, cost saving birth center care.

The American Association of Birth Centers (AABC) is a multidisciplinary membership organization comprised of birth centers, individuals and organizations that support the birth center model including certified nurse-midwives (CNMs), certified professional midwives (CPMs), physicians, nurses, women and their families. Founded in 1983, AABC is dedicated to developing quality holistic services for childbearing families that promote self-reliance and confidence in birth and parenting.

AABC believes that regulations for FSBCs should be evidence based national industry standards that have been proven safe and effective. AABC established the National Standards for Birth Centers to provide a tool for measuring the quality of services provided to childbearing families in birth centers. The Standards are owned by the AABC. They are reviewed periodically to assure that they remain consistent with evolving evidence-based maternity care. The Commission for the Accreditation of Birth Centers (CABC) has developed specific indicators for assessment and compliance with the Standards.

AABC supports CABC accreditation as one basis for state licensure. Other states have successfully demonstrated that when birth centers achieve and maintain licensure through this accreditation, they are high quality facilities for low risk

birth. CABC accreditation provides concrete indications that a birth center meets high evidence-based standards, widely recognized benchmarks, and current best practices for maternity care, neonatal care, business operations, and safety. This, in turn, provides important and warranted assurance to clients (both women and their families), states, insurers, consulting providers, and hospitals.

Regulations for FSBCs should be facility specific to the birth center. All maternity care providers in birth centers should be held to the same regulations for birth center practice, regardless of their educational preparation. It is best for scope of practice issues for providers to be addressed under those practitioners' individual licensing boards and not in birth center regulations.

Regulations should require practice guidelines and policies that include plans to transfer to an acute care hospital with maternity and newborn services. Guidelines for transfers should include plans for emergent and non-emergent situations for both mothers and newborns, before, during labor, and postpartum. These guidelines should also include indications for transfer, and plans for communication with receiving hospital both during and after transfer has been achieved. Hospitals should be expected to cooperate in planning transfer arrangements, and not to place barriers in the way of safe transitions of care when they are needed.

Regulations for the physical layout of birth centers should be based on business occupancy requirements and should not require enhancements that increase cost but do not improve safety. Because care provided in freestanding birth centers is limited to low risk obstetrics and newborn care, business occupancy construction standards are the acceptable level. There is no need for facility construction to be at the level of hospitals to safely meet the needs of the low risk women and infants served in birth centers.

The American Association of Birth Centers is committed to ensuring safe, high-quality, family-centered options for birthplaces and providers. The success of these such options depends on public trust and viable birth-center models.

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.

Sincerely,

Kate E Bauer
Executive Director

The updating of Nevada birth center regulations is welcomed and supported by the Nevada Midwifery Licensure Collective. Extending the current rule to allow midwives, in addition to physicians, to attend births that take place in a birth center is one of the most important changes. However, the current proposed regulation changes continue to unnecessarily limit a woman's ability to choose their qualified maternity care attendant. We are proposing language changes to include certified professional midwives (CPMs) into the language.

In the 2015 ACOG report entitled 'Levels of Maternal Care', CNMs, CMs, and CPMs who are legally recognized to practice within the jurisdiction of the birth center are all recognized as qualified primary care providers. CPMs are not currently licensed or regulated in the state of Nevada, but licensure is likely not far off. Whether CPMs initiate the legislation ourselves or outside parties initiate it, it is on the horizon. Nevada is currently the only state west of the Rockies that does not have CPM licensure, whether mandatory or voluntary. Nationwide, the majority of freestanding birth centers currently in operation are owned and run by CPMs. The currently proposed changes of allowing only APRNs in addition to physicians to attend births in birth centers will place an undue burden on CPMs currently practicing according to judicial decision in the state of Nevada, when licensure is created.

The additional changes reflect language that follows current evidence and the definition in regulations in other states in selection of low risk maternal clients. Excessive client restriction criteria impair the ability of a freestanding birth center (obstetric center) to keep their doors open and provide services to the women of our community without improving outcomes.

Proposed Regulations
Additions
(Current Proposed changes: *New language in italics)*
*(***Alternate Language for Proposed Changes:** new language in **bold type**)
(Green text- explanation of alternate language)
Deletions
(Current proposed deletions: [in brackets, red typeface, crossed out])
(Alternate proposed deletions: [~~in brackets, black crossed-out~~])
Green text- explanation of proposed deletions)
Sec. 1 NAC Section 449.6113 is also amended to read as follows:

ADD new subsection 4, as follows:
4. **"Certified Professional Midwife" means a midwife who is not necessarily a nurse, who has been certified by the North American Registry of Midwives, and who practices legally in Nevada either by statute or by judicial decision."**

Renumber 4 as 5:
~~4.~~ 5. "**Maternity** care" means care which is provided in accordance with NAC 449.6113 to 449.61178, inclusive, immediately before, during, and for not more than 24 hours after delivery to ~~[a maternal patient:]~~ **a low risk maternal client as defined in section 2.**

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

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

Renumber 5 as 6:
~~5.~~ 6. "Obstetric center" has the meaning ascribed to it in NRS 449.0155, and may also be referred to as a "freestanding birth center" or "FSBC".

Sec. 2 NAC 449.61134 is also amended to read as follows:

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

4. DELETE entire subsection 4 There is no evidentiary basis for restricting birth center birth because of multiparity, which in this subsection has been arbitrarily cut off at 6.

5. CHANGE ~~5~~ to 4
~~[and is not a nullipara]~~ Nulliparous women should not be treated differently than multiparous women in risk categorization. It does not place her in a "high risk" category. Having all nulliparous women approved by the center director would be prohibitive in an open staff model.

6. (g) REINSTATE **"if there is fetal distress,"** ~~[amniotic fluid which is stained with meconium]~~ Meconium in and of itself does not insinuate fetal distress, and as such further evaluation regarding the appropriateness of transfer should be decided by each maternity care professional on an individual basis.

COMBINE Subsections 9 and 10 as follows:
"9. **Her membranes were not ruptured more than 24 hours before her admission to the obstetric centers;** ~~—~~ **or she has no evidence of an infection.**

Sec. 2 Optional rewording of Section 2 in entirety. **"Low-risk maternal client" means an individual who: (a) Is at term gestation (between 36 and 42 weeks), in general good health with uncomplicated prenatal course and participating in ongoing prenatal care, and prospects for a normal uncomplicated birth as defined by reasonable and generally accepted criteria of maternal and fetal health; (b) Has no obstetrical complications likely to recur; (c) Has no significant signs or symptoms of anemia, active herpes genitalia, placenta previa, known noncephalic presentation during active labor, pregnancy induced hypertension, persistent polyhydramnios or persistent oligohydramnios, abruptio placenta, chorioamnionitis, known multiple gestation, intrauterine growth restriction, or substance abuse; and (d) Is appropriate for a setting where methods of anesthesia are limited.**

Sec. 3. Subsection 449.6114 is also amended as follows:

5. ~~[To operate in this State, an obstetric center must maintain current accreditation by a nationally recognized organization approved by the Division. Upon initial licensure, an~~

~~obstetric center shall, within 6 months after obtaining its license, submit proof to the Division of the accreditation of the obstetric center by such an organization. (a) Before issuing a license to an obstetric center, the Division shall conduct an on-site inspection of the center. (b) If an obstetric center fails to maintain current accreditation or if the accreditation is revoked or is otherwise no longer valid, the center shall immediately cease to operate.~~]. **An obstetric center that has been inspected and licensed by the Division and is accredited by an accrediting body approved by the board shall be granted license renewal based on that accreditation."**

Sec. 8 NAC Section 449.61148 is hereby amended to read as follows:

"2.(a)(1) a licensed physician, a licensed advanced practice nurse, **or a certified professional midwife who has been licensed or is otherwise practicing legally under Nevada law."**

"2 (a)(2) a registered nurse licensed pursuant to chapter 632 of NRS, a licensed practical nurse licensed pursuant to chapter 632, **or a certified midwifery assistant,** whom the director has deemed clinically competent, who is on the premises to provide care at the obstetric center during the time pre- and post-delivery care is provided.

"2 (b) At least one licensed physician, one licensed advanced practice nurse, **or a certified professional midwife who has been licensed or is otherwise practicing legally under Nevada law,** who is approved by the [~~medical~~] director to provide care at the obstetric center, is present at the time of delivery."

Sec. 8 (a-f) optional restatement in entirety: The Governing body shall ensure:
(a) The employment, contracting, or use of appropriately trained personnel and clinical staff, and
(b) Assure a physician, APRN or certified professional midwife is present at each birth. A second person who is an employee, student, certified midwife's assistant or a member of the clinical staff with evidence of current training in neonatal and adult resuscitation skills shall be immediately available in the birth center (obstetric center) during each birth.

2 (g)(1) **"or a certified professional midwife certified by the North American Registry of Midwives."**

2(g)(2) [~~"obstetric care"~~] **"maternity care,** including routinely delivering newborn babies and caring for **low risk maternal patients"**

2 (I) **"If the obstetric center, after making an attempt in good faith to enter into an agreement with a consulting physician as required by this subsection, is not able to secure a commitment from a consulting physician, then the obstetric center**

must have policies and procedures in place for obtaining such physician consultation as may be needed."
Hospitals and physicians may be unable or unwilling to create consulting relationships with midwives and birth centers in this area secondary to practice agreements or liability concerns. While this improves outcomes for mothers and babies, it must be obtainable, otherwise it unduly limits access to care through a freestanding birth center (obstetric center).

Sec. 9. NAC 449.61152 is also amended as follows:

Sec. 9(1) "or a midwife certified by the North American Registry of Midwives who is licensed or otherwise practicing legally in this State," who **"provides maternity care" or "practices obstetrics or midwifery"**

Sec. 9 subsection 4(b): **"If the obstetric center, after making an attempt in good faith to enter into an agreement with either an obstetrician and/or pediatrician, as indicated by this subsection, is not able to secure a commitment from such physician or physicians, then the obstetric center must have policies and procedures in place arranging for such physician consultation as may be needed."**

SEC. 13. NAC Sec. 449.6116 is also amended as follows:

(1): Have on the premises at least one registered nurse licensed pursuant to Chapter 632 of NRS **"or a certified professional midwife or certified midwife's assistant"**

Sec. 13 (2): **"or a midwife certified by the North American Registry of Midwives, either licensed or otherwise practicing legally in this State."**

Sec. 14 Are transports for pain relief or maternal request included in this section? AABC and ACOG worked together to include birth centers in the perinatal transport system, so as not to have to justify the reason for transport.

Sec. 16 (2) Laboratory services must be available **[~~during all hours of operation~~]** as necessary to meet the needs of maternal patients, newborn babies and clinical staff. 24 hour lab privileges are only required in a level I care facility, not in birth centers as per ACOG's Levels of Maternal Care report.

Sec. 16 subsection 4(b)
Notify the physician, **[~~or~~]** advanced practice registered nurse, **or certified professional midwife** who requested the report.....

Sec. 17. NAC 449.6117 is hereby amended to read as follows:

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

2. All drugs [~~and controlled substances~~] **administered [**~~distributed~~**]** at an obstetric center must [~~be possessed and distributed~~] by a licensed physician, a licensed advanced practice registered nurse**, or Certified Professional Midwife** in accordance with the **drug legend approved in their respective scopes of practice.** ~~his or her registration from the State Board of Pharmacy and the Drug Enforcement Administration of the Department of Justice.~~ **The distribution of controlled substances will be limited to those professionals with prescriptive authority 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, **or certified professional midwife** shall establish and maintain a list of drugs and/or controlled substances which are available for use **according to the regulations with govern their practice** ~~[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, **or certified professional midwife** [~~who made the order~~] **administered the medication.** An 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.

Currently in other states in which CPMs are licensed, they do not require prescriptive authority to procure and administer the medications listed on the drug legend in their state regulations. Prescriptive authority should not be a requirement to operate a birth center. A list of the medications that can be procured and administered would be listed in the Legend Drugs and Devices section of licensure regulations. Which controlled substances are currently legal to administer in a Freestanding Birth Center?

Journal of Midwifery & Women's Health www.jmwh.org
Original Review

Outcomes of Care in Birth Centers: Demonstration of a Durable Model

Susan Rutledge Stapleton, CNM, DNP, Cara Osborne, SD, CNM, Jessica Illuzzi, MD, MS

Introduction: The safety and effectiveness of birth center care have been demonstrated in previous studies, including the National Birth Center Study and the San Diego Birth Center Study. This study examines outcomes of birth center care in the present maternity care environment.

Methods: This was a prospective cohort study of women receiving care in 79 midwifery-led birth centers in 33 US states from 2007 to 2010. Data were entered into the American Association of Birth Centers Uniform Data Set after obtaining informed consent. Analysis was by intention to treat, with descriptive statistics calculated for maternal and neonatal outcomes for all women presenting to birth centers in labor including those requiring transfer to hospital care.

Results: Of 15,574 women who planned and were eligible for birth center birth at the onset of labor, 84% gave birth at the birth center. Four percent were transferred to a hospital prior to birth center admission, and 12% were transferred in labor after admission. Regardless of where they gave birth, 93% of women had a spontaneous vaginal birth, 1% an assisted vaginal birth, and 6% a cesarean birth. Of women giving birth in the birth center, 2.4% required transfer postpartum, whereas 2.6% of newborns were transferred after birth. Most transfers were nonemergent, with 1.9% of mothers or newborns requiring emergent transfer during labor or after birth. There were no maternal deaths. The intrapartum fetal mortality rate for women admitted to the birth center in labor was 0.47/1000. The neonatal mortality rate was 0.40/1000 excluding anomalies.

Discussion: This study demonstrates the safety of the midwifery-led birth center model of collaborative care as well as continued low obstetric intervention rates, similar to previous studies of birth center care. These findings are particularly remarkable in an era characterized by increases in obstetric intervention and cesarean birth nationwide.

J Midwifery Womens Health 2013;58:3–14 © 2013 by the American College of Nurse-Midwives.

Keywords: birth center, midwifery, perinatal outcomes

BACKGROUND

For 32 of the last 40 years, US health care costs have grown faster than the country's gross domestic product (GDP)[1] and are projected to be greater than $3 trillion in 2014, or 18% of the GDP.[2] Childbirth is the leading cause of hospitalization in the United States, with mothers and newborns accounting for 23% of all hospital discharges in 2008.[3] Five of the 10 most commonly performed procedures are associated with childbirth, and cesarean birth is the most common inpatient surgical procedure.[4] In 2008, hospitalization for pregnancy, birth, and care of the newborn resulted in total hospital charges of $97.4 billion, making it the single largest contributor as a health condition to the national hospital bill.[5] Average US payments for vaginal births are far higher than in many countries, including Canada, France, and Australia.[6]

At the same time, many other countries have better birth outcomes than the United States. In 2010, 33 countries had lower maternal mortality rates, 37 countries had lower neonatal mortality rates, 65 countries had lower rates of low birth weight, and 32 countries had higher rates of exclusive breastfeeding to at least 6 months than did the United States.[7]

Federal and state policy makers in the United States are working to identify and promote lower-cost, higher-quality models of care. This concept of better outcomes at lower costs, or "high-value" care, is a driving force in the Patient Protection and Affordable Care Act (PPACA).[8] Among several important provisions targeted to the care of pregnant women that the act mandates are payments for facility services to birth centers across the United States (Section 2301 [S.3590]).[9] The Centers for Medicare and Medicaid Services underscored the importance of examining the birth center model as means of providing high-quality care by including birth center care as one of 3 options for enhanced prenatal care under the Strong Start Initiative in 2012.[10] In addition, both the Institute of Medicine and Childbirth Connection have called for further research about the birth center model of care.[11,12] The birth center model was established as a high-value model of care by the landmark National Birth Center Study (NBCS, 1985-1987) and the San Diego Birth Center study (1994-1996).[13,14] These studies demonstrated that birth centers could provide maternity care to low-risk pregnant women, who make up approximately 85% of pregnant women in the United States,[15] safely, effectively, with less resource utilization, and with a resultant high level of patient satisfaction.

The American Association of Birth Centers (AABC) defines the birth center as "a homelike facility existing within the health care system with a program of care designed in the wellness model of pregnancy and birth. Birth centers provide family-centered care for healthy women before, during, and after normal pregnancy, labor, and birth."[16] The birth center is a collaborative model. Most birth centers have midwives as the primary care providers working with physicians and hospitals in a team approach to maternity care. The AABC has established national *Standards for Birth Centers* that are

Address correspondence to Susan Stapleton, CNM, DNP, 7 Hickens Way, #12, Kennebunk, ME 04043. E-mail: susanstapleton71@gmail.com

Quick Points

- Of 15,574 women planning and eligible for a birth center birth at the onset of labor, 93% experienced a spontaneous vaginal birth regardless of where they ultimately gave birth, whereas 6% had a cesarean birth.
- Eighty-four percent of women planning a birth center birth at the onset of labor gave birth there, with approximately 2.5% of mothers or newborns requiring transfer to the hospital after birth. Emergent transfer before or after birth was required for 1.9% of women in labor or for their newborns.
- There were no maternal deaths. The intrapartum fetal mortality rate for women who were admitted to the birth center in labor was 0.47/1000, and the neonatal mortality rate was 0.40/1000 excluding anomalies.
- The study provides important information for childbearing families for informed decision making regarding their choice of maternity care provider and birth location.
- This study demonstrates the safety of birth centers and consistency in outcomes over time despite a national maternity care environment with increasing rates of intervention.

used by the Commission for the Accreditation of Birth Centers (CABC), an independent authority that accredits birth centers in the United States.[17,18] Most birth centers are located outside of hospitals. Some birth centers are physically located inside a hospital building but meet AABC standards for autonomy and are separate from the hospital's acute care obstetric services. In its 1982 policy statement, the American Public Health Association issued guidelines for licensure of birth centers,[19] and birth centers are now licensed in 41 states.[20] This infrastructure of standards, accreditation, and licensure provides the foundation for US birth centers and may influence birth center outcomes. According to Centers for Disease Control and Prevention (CDC) data, 0.3% of all US births in 2010 occurred in freestanding birth centers.[21]

In the years since the national and San Diego birth center studies were conducted, maternity care in the United States has become increasingly interventional. A 2005 national survey reported that 90% of women had continuous electronic fetal monitoring, and 76% of women received epidural analgesia during labor.[22] According to CDC data, induction of labor was performed in 22.8% of all births in 2007, an increase of 140% since 1990 (9.5%).[23] The cesarean birth rate increased from 4.5% in 1965 to 22.7% in 1985 and to 32.8% in 2010.[21,24,25] In light of these changes in the overall US maternity care environment, this study aimed to describe the outcomes of birth center care in the current era so that consumers, providers, policy makers, and insurers have up-to-date, evidence-based information.

METHODOLOGY

Data Collection

Data were collected using the AABC Uniform Data Set (UDS), an online data registry developed by the AABC with a task force of maternity care and research experts. The UDS was developed in accordance with the guidelines for data registries developed by the Agency for Healthcare Research and Quality.[26,27] Participation in the registry is voluntary, and 78% of AABC-member birth centers contribute to the registry. Forty-one percent of all US birth centers known to the AABC are members.

Written informed consent is obtained from all participants prior to entry into the registry. The data are stored securely in a password-protected database. The AABC maintains a data access policy that requires investigators to request access to the data. Requests are reviewed by the AABC Research Committee, and determinations of appropriate access to and use of data are made in accordance with the Federal Policy for the Protection of Human Subjects.[28] The University of Arkansas institutional review board determined this descriptive study using registry data to be exempt from approval because the data do not include any personal identifiers.

The AABC UDS collects data on 189 variables that describe the demographics, risk factors, processes of care, and maternal-infant outcomes of women receiving care in birth centers. Data are collected prospectively, with the patient record created during the initial prenatal visit. Data on the patient's antenatal course are summarized when she either terminates prenatal care prior to labor or is admitted for intrapartum care. Data to describe intrapartum, immediate postpartum, and neonatal courses are entered after the birth. Data to describe the postpartum and neonatal course are entered following a visit 4 to 6 weeks after the birth. Outcome data are collected on all mothers and infants who remain in care, regardless of place of birth. All data are collected by the woman's primary care provider. Providers enter data directly, or trained clerical staff enters data from paper forms completed by providers via a secure Web-based portal, and the data are stored in a MySQL database.

Those entering data were provided with a detailed *UDS Instruction Manual* that includes data definitions, use of the Web-based collection tool, data collection procedures, and implementation of a data entry system within the practice.[29] Training workshops were presented by the AABC Research Committee throughout the study period. Research team members were available to provide support such as interpretation of data definitions and coding decisions in specific cases. AABC newsletters and e-mails were used to communicate with birth centers regarding any common data quality issues identified.

Once the data have been entered, a designated on-site UDS coordinator reviews entries, and errors are corrected prior to final submission of the data to the database. The UDS online form includes required fields to ensure that the form cannot be submitted without certain critical data such as transfer information and important perinatal outcome data. The UDS data are monitored by the AABC research team for records that have not been completed by established deadlines, coding errors, and unexpected discrepancies, using established validation parameters such as logical consistency to other data fields for the same patient. Birth centers are queried via e-mail or phone to obtain correct information. A log is maintained of all data modifications for correction of errors.

A validation study of the UDS was conducted in 2010 and found a high level of consistency between UDS registry data and matched medical records in 5 birth centers that were representative of those contributing data to the registry. Registration and birth logs were reviewed to confirm that all women who registered for care in each practice and consented for data collection had been entered in the UDS. At least 2% of each practice's records were randomly selected and audited for 25 key variables, with the medical record as the criterion standard. All variables audited showed at least 90% consistency between the 2 data sources, and there was 100% consistency for 10 variables.[30] All women in the audited practices were presented the option of participating in the UDS data registry. Women declined participation very rarely, and there were no recorded instances of women choosing to withdraw.[31] All study variables used in the current analysis are among the variables included in the validation study.

Inclusion Criteria

This report examines intrapartum care and perinatal outcomes of women who received care in birth centers that contributed to the UDS, entered labor eligible for and planning a birth center birth, and had estimated dates of birth during 2007 through 2010. Eligibility criteria for birth center birth were established by the AABC and CABC and included singleton, full-term gestation in vertex presentation with no medical or obstetric risk factors precluding a normal vaginal birth or necessitating interventions such as continuous electronic fetal monitoring or induction of labor.[17] Estimated date of birth, rather than actual date of birth, was used for establishing eligibility to ensure the inclusion of participants who transferred care during the antepartum period for whom date of birth was less likely to be available. All study variables (Appendix 1) were analyzed for both those women who gave birth in the birth center and those who required transfer to hospital care after onset of labor.

Data Analysis

Data were transferred from the MySQL database to SAS version 9.1 (Cary, North Carolina) for analysis. Descriptive statistics for demographic variables and perinatal outcomes were calculated, and frequencies are reported. Denominators were adjusted to account for missing data and are reported with frequencies.

RESULTS

A total of 79 birth centers in 33 US states (Appendix 2) contributed data to the AABC UDS during the study period of January 1, 2007, to December 31, 2010. Birth centers participating in this study were representative of overall AABC-member birth centers in terms of provider type, geographic distribution, payer mix, volume, and demographics of women served.[32] No birth centers were excluded from the study, as all had acceptable data, which was defined as no more than 5% incomplete records. Fifty-nine birth centers (75%) contributed data throughout the study period, 15 (19%) began contributing data after 2007, and 5 (6%) closed during the study period. Fifty of the birth centers contributing data (63%) were accredited by the CABC, 3 of those were accredited by both the CABC and the Joint Commission, and 29 (37%) were not accredited. Certified nurse-midwives (CNMs) were the primary care providers in 63 of the birth centers (80%). Certified professional midwives (CPMs) or licensed midwives (LMs) provided care in 11 participating birth centers (14%). In 5 participating centers (6%), care was provided by teams of CNMs, CPMs, and LMs. A comparison of the professional midwifery credentials in the United States is available from the American College of Nurse-Midwives.[33]

There were 22,403 complete client records in the UDS for women with an estimated date of birth between January 1, 2007, and December 31, 2010, who intended to give birth in a birth center when registering for prenatal care (Figure 1). The most common reasons for leaving birth center care during pregnancy were nonmedical (15.1%), such as moving to another area or changing provider or planned birth location. Nearly a thousand women (4.2%) did not remain pregnant past the first trimester because of spontaneous or induced abortion or ectopic pregnancy. Of the 18,084 women who continued in birth center care, 2474 women (13.7%) were referred to physician care for medical or obstetric complications precluding birth center care. Of these antepartum medical referrals, the most common indications were postdates (10.7%), malpresentation (10.4%), preeclampsia (9.3%), and nonreassuring fetal testing (8.6%). Thirty-six women (0.2%) never presented to the birth center in labor because of nonmedical reasons such as choosing to present at a hospital en route or giving birth at home because of precipitous labor. The remaining 15,574 women planned and were eligible for birth center birth at the onset of labor and make up the study sample presented in the results that follow.

Demographic Characteristics

Demographics for the study participants are presented in Table 1. Federal or state government programs (Medicaid, Medicare, Children's Health Insurance Program [CHIP], or TRICARE) were the primary payers for nearly a third of births. The majority of the study population was white, non-Hispanic; aged between 18 and 34 years; and had a college degree. Slightly fewer than half were nulliparous. The most common issue from medical history was overweight/obesity (5.7%), followed by depression or psychiatric disease requiring treatment (3.3%). The reported rates of smoking (1.5%) and substance abuse (0.5%) were very low. Problems in the

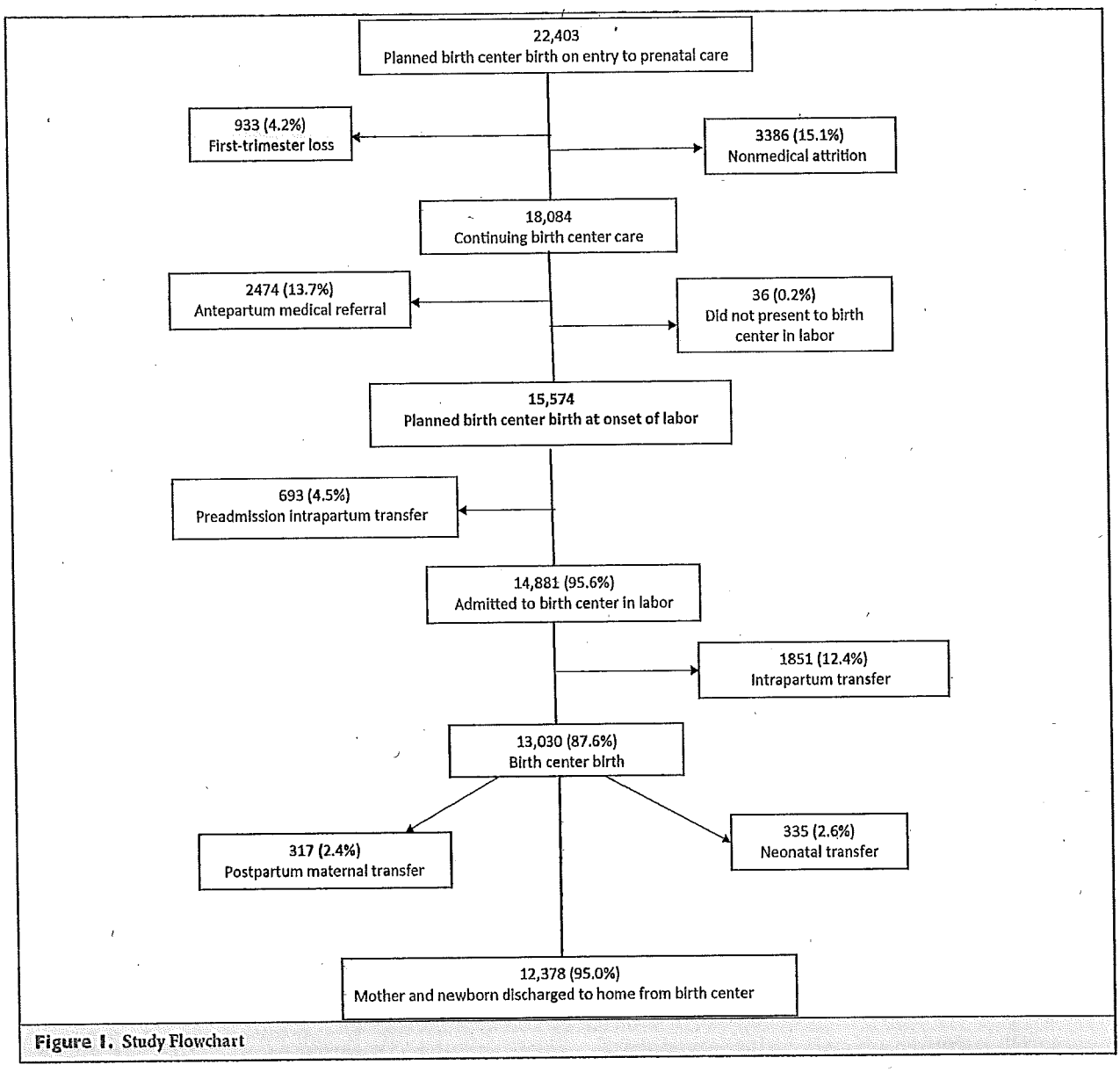


Figure 1. Study Flowchart

current pregnancy occurred in 17.5% of women, the most common of which were infections (4.6%), anemia (2.9%), and postdates (2.6%).

Intrapartum Admissions and Transfers

Of the 15,574 women who planned birth center birth at the onset of labor, 95.6% were admitted to the birth center in labor, and 4.5% were referred to hospital care before being admitted to the birth center. Among those referred to the hospital prior to admission, the most common reasons were term rupture of membranes without labor (20.4%), client choice (10.0%), and malpresentation (9.1%).

Of the 14,881 women who were admitted to the birth center in labor, 87.6% gave birth there, whereas 12.4% were transferred to the hospital prior to giving birth, with 11.5% referred to the hospital nonemergently. The majority (63.6%) of the nonemergent intrapartum referrals after admission to the birth center in labor were for prolonged labor or arrest of labor. Arrest during the first stage of labor occurred 3 times more frequently than arrest in the second stage of labor. Fewer than 1% of the women (0.9%) required emergent intrapartum transfers. Half the emergency intrapartum transfers were responses to nonreassuring fetal heart rate patterns noted with intermittent auscultation (Table 2). Nulliparas accounted for 81.6% of the intrapartum referrals and transfers. The AABC's definitions of referral and transfer with examples of each type can be found in Appendix 3.

Mode of Birth

Cephalic spontaneous vaginal births were the most common (92.3%), cesarean births and operative vaginal births were uncommon, and spontaneous breech vaginal births were the least common (Table 3). Trial of labor after cesarean (TOLAC) was infrequent in this population, as few birth centers were allowing TOLACs during the study period. Seventy percent of the 56 TOLACs were successful. Of the 1851 women who

Table 1. Demographic Characteristics of Women Planning Birth Center Birth at Onset of Labor (N = 15,574)

	n (%)
Age, y[a]	
<18	171 (1.1)
18-34	13,218 (85.4)
≥35	2093 (13.5)
Race[b]	
Non-Hispanic White	11,810 (77.4)
Hispanic	1711 (11.2)
Black	840 (5.5)
Asian or Pacific Islander	349 (2.3)
Native American or Native Alaskan	101 (0.7)
Unknown or other	440 (2.9)
Marital status[c]	
Married	12,109 (80.1)
Unmarried	3015 (19.9)
Parity at onset of labor	
Nulliparous	7355 (47.2)
Parous	8219 (52.8)
Payment method	
Private insurance	8325 (53.5)
Medicaid	3701 (23.8)
Self-pay	2261 (14.5)
Military coverage	411 (2.6)
Other insurance/grants	406 (2.6)
Medicare	374 (2.4)
Unknown	96 (0.6)
Education, y[d]	
<12	1184 (8.7)
12	2669 (19.6)
13-15	2727 (20.0)
≥16	7067 (51.8)

[a] n = 15,482 due to missing data.
[b] n = 15,251 due to missing data.
[c] n = 15,124 due to missing data.
[d] n = 13,647 due to missing data.

Table 2. Emergency Transfer Indications

	n (%)
Intrapartum, n = 140	
Nonreassuring fetal heart rate pattern[a]	72(51.4)
Arrest of labor[b]	24 (17.1)
Malpresentation[c]	14 (10.0)
Abnormal intrapartum bleeding[d]	7 (5.0)
Pregnancy-induced hypertension/preeclampsia[e]	6 (4.3)
Cord prolapse[f]	4 (2.9)
Seizure	1 (0.7)
Other	12 (8.6)
Postpartum, n = 67	
Postpartum hemorrhage[g]	36 (53.7)
Retained placenta[h]	23 (34.3)
Pregnancy-induced hypertension/preeclampsia[e]	1 (1.5)
Other	5 (7.5)
Unknown	2 (3.0)
Newborn, n = 94	
Respiratory issues[i]	66 (70.2)
5-Minute Apgar <7	11 (11.7)
Birth trauma[j]	3 (3.2)
Small for gestational age[k]	1 (1.1)
Prematurity[l]	1 (1.1)
Other	12 (12.8)

[a] Nonreassuring fetal heart rate pattern: includes prolonged bradycardia, severe variables, and late decelerations.
[b] First-stage prolonged/arrest of labor: slower than expected labor progress *or* patient in active labor who has had cervical change, then has no further progress for at least 2 hours. Second-stage prolonged/arrest of labor: slower than expected descent *or* no descent after 2 hours for primigravida or one hour for multigravida without epidural or after 3 hours for primigravida or 2 hours for multigravida with epidural.
[c] Malpresentation: breech, face, brow, compound, transverse lie.
[d] Intrapartum bleeding: greater than expected for "bloody show."
[e] Pregnancy-induced hypertension/preeclampsia: systolic blood pressure ≥ 140 mmHg or diastolic blood pressure ≥ 90 mmHg with or without signs and symptoms of preeclampsia.
[f] Cord prolapse: cord is presenting in front of the presenting part, including frank or occult prolapse.
[g] Postpartum hemorrhage: estimated blood loss >500 mL for vaginal birth and >1000 mL for cesarean birth.
[h] Retained placenta: placenta requiring manual removal or other out-of-the-ordinary third-stage interventions, regardless of the length of third stage.
[i] Respiratory distress: respiratory rate ≥ 60/minute accompanied by grunting and/or retractions. Includes apnea. Transient tachypnea: respiratory rate ≥ 60/minute without retractions or grunting.
[j] Birth trauma: fetal injury related to the process of birth or obstetric interventions, includes cephalohematoma, abscess at site of scalp lead or scalp blood sampling, subgaleal hematoma, significant caput succedaneum, abrasions and lacerations, brachial plexus injury, cranial nerve injury, laryngeal nerve injury, clavicular or long-bone fracture, hepatic rupture, and hypoxic-ischemic insult (confirmed by cord blood gases and other testing).
[k] Small for gestational age: weight <10th percentile for gestational age.
[l] Prematurity: less than 37 weeks' gestation by gestational age exam.

presented in labor and were transferred to hospitals, more than half (54.7%) had spontaneous vaginal births, 37.8% had cesarean births, and 7.5% had operative vaginal births.

Postpartum and Neonatal Complications

The immediate postpartum course was uncomplicated for 91% of the study population, regardless of where they gave birth. The majority of women experiencing postpartum complications had postpartum hemorrhage (68.2%). Most postpartum hemorrhages (92.6%) were managed in the birth center. Postpartum transfer to the hospital was required for 2.4% of women who gave birth in the birth center, with 1.9% referred nonemergently and 0.5% of women requiring emergent postpartum transfer. Postpartum hemorrhage was the most common reason for nonemergent referral and emergent transfers (Table 2).

Transport to the hospital was required for 2.6% of neonates born at birth centers, with 1.9% nonemergent referrals and 0.7% requiring emergent transfer. The most common indications for nonemergent referral and emergency transfer were respiratory issues (Table 2).

Overall, 79.4% of women who entered labor planning a birth center birth gave birth in the birth center and were

Table 3. Mode of Birth for All Women Planning a Birth Center Birth at Onset of Labor Regardless of Site of Birth (N = 15,574)

	n (%)
Spontaneous vaginal birth	14,437 (92.8)
Cephalic	14,373 (92.3)
VBAC	39 (0.3)
Breech	25 (0.2)
Assisted vaginal birth	188 (1.2)
Vacuum	148 (1.0)
Forceps	40 (0.3)
Cesarean birth	949 (6.1)
Primary	930 (6.0)
Repeat	19 (0.1)
With trial of labor	17 (0.1)
Without trial of labor[a]	2 (0.0)

Abbreviation: VBAC, vaginal birth after cesarean.
[a]Changed mind at onset of labor and presented at hospital for repeat cesarean birth.

discharged from there to home with their newborns. Fewer than 2% (1.9%) of the study sample required emergent transfer during labor or after birth of either the mother or newborn.

Mortality

There were no maternal deaths in the study population. There were 14 fetal deaths and 9 neonatal deaths. Seven of the fetal deaths (50%) occurred before women arrived at the birth center. Of these, 5 were diagnosed with intrauterine fetal demise (IUFD) on arrival at the birth center and then transferred directly to a hospital, whereas 2 were diagnosed with IUFD on arrival, but with birth imminent and no time to transfer. Seven fetal deaths (50%) occurred after women were admitted to the birth center in labor. Four of these occurred to women who were transferred emergently for nonreassuring fetal heart tones on auscultation and 3 to women who labored and had unexpected stillbirths at the birth center.

There were 9 neonatal deaths, of which 7 were unexpected. Two women whose infants had been prenatally diagnosed with lethal anomalies chose to give birth at a birth center, where one infant died shortly after birth and the other was discharged home with the family and died there. A third infant, transferred after birth, had a previously undiagnosed diaphragmatic hernia despite having had a second trimester fetal anatomy survey. Of the remaining 6 deaths, 3 were among infants whose mothers were transferred intrapartum. Two were emergent transfers for nonreassuring fetal status, and the respective causes of death were avulsion of a velamentous cord insertion and chronic fetal-maternal transfusion antenatally. The third was a nonemergent transfer for arrest of the first stage of labor with a subsequent cesarean for failed oxytocin augmentation; meconium aspiration was the probable cause of death. The other 3 infants were transferred emergently after birth: 2 had respiratory distress syndrome and one had hypoxic ischemic encephalopathy attributed to a prenatal insult documented on neuroimaging. All died within 7 days of birth. The intrapartum fetal mortality rate for the women who were admitted to the birth center in labor was 0.47/1000. The neonatal mortality rate was 0.40/1000 excluding anomalies.

DISCUSSION

These findings are consistent with those from Cochrane reviews of place of birth and midwifery-led care,[34,35] British studies of place of birth,[36,37] and US studies comparing midwifery and obstetric care,[38–40] which suggest that midwifery-led birth center care is a safe and effective option for medically low-risk women.

The intrapartum fetal and neonatal mortality rates found in this study are comparable to those reported in many studies of low-risk women. Women starting care in labor with midwives in a primary care setting in the Netherlands experienced an intrapartum fetal death rate of 0.96/1000 and a perinatal mortality rate of 1.39/1000, excluding newborns with congenital anomalies.[41] The US neonatal mortality rate in 2007 was 0.75/1000 for newborns weighing 2500 g or greater.[42] A study in Scotland of neonatal death rates by time of birth for term infants without anomalies reported an overall neonatal mortality rate of approximately 0.5/1000.[43] A National Perinatal Epidemiology Unit study of low-risk women in England found a neonatal mortality rate of 1.78/1000.[37] A comparison of outcomes for low-risk women under midwifery-led care and obstetrician care in Ireland found perinatal mortality rates of 2.76/1000 and 3.66/1000, respectively.[44] In a comparison of outcomes of planned home births attended by registered midwives, hospital births attended by registered midwives, and low-risk hospital births attended by obstetricians in British Columbia, Canada, perinatal death rates were 0.35/1000, 0.64/1000, and 0.57/1000, respectively.[45]

The findings of this study are also strikingly similar to those of the National Birth Center Study, which was based on data collected from mid-1985 through 1987. The authors reported an intrapartum fetal mortality rate of 0.3/1000 and neonatal mortality rate of 0.3/1000, excluding anomalies. Mortality, transfer, complication, and operative birth rates were similar despite differences in the 2 study populations that might be expected to contribute to more adverse outcomes in the current study; a higher proportion of women in the current study were aged 35 or older, black, unmarried, and nulliparous than the women in the National Birth Center Study.[13,46] This consistency speaks to the durability of the birth center model over time, despite increases in the rates of intervention and cesarean birth nationwide during the same period.

Strengths of the study include a relatively large sample size, geographic diversity of birth centers contributing data, and data collection over a period of 4 years. As with many multicenter studies, data were collected and entered by care providers. Although this creates a potential for bias and error, findings from the validation study[30] and the consistency of data across birth centers suggest that the data are reliable. Although there were missing demographic data, all other variables reported here are required fields in the UDS without which the form cannot be submitted; therefore, there were no incomplete data for other variables for this cohort.

The birth centers contributing data to the AABC UDS may have been different from those birth centers not contributing data. The study birth centers are AABC members and thus have access to continuing education activities and support the organization's model and *Standards for Birth Centers*.[17] This potential difference means that the findings may not be generalizable to all birth centers.

The provider made all coding decisions based on their interpretation of the data definitions, including the decision to designate a transfer as emergent. Review of the indications for emergency intrapartum transfer showed that some did not appear to be actual medical emergencies. For example, 24 women were transferred emergently for arrest of labor, which is unlikely to be a true medical emergency. Consequently, the incidence of actual medical emergencies requiring transfer is likely to have been lower than reported here.

The decreased direct and indirect costs to the health care system associated with birth center care make it a model that warrants thorough examination. Given that nearly half of all births in the United States (42.9%) are currently funded by Medicaid and CHIP programs,[47] it is worth considering the potential savings if more pregnant women receiving government-supported care gave birth in birth centers.

Despite the PPACA federal mandate, the AABC Legislative Committee reports that many states have not yet implemented appropriate birth center facility reimbursement. Medicaid facility reimbursement for birth centers varies widely across states in which birth centers are reimbursed; however, in 2011, the average Medicaid reimbursements in general were similar to national Medicare reimbursement rates.[48] The Medicare facility reimbursement for care of mother and newborn for an uncomplicated vaginal birth in a hospital in 2011 was $3998,[49] compared with $1907 in a birth center.[32] Thus, the 13,030 birth center births in this cohort saved an estimated $27,245,469 in payments for facility services compared with hospital vaginal births at current Medicare rates. Even with birth center facility reimbursement rates increased to more equitable levels, cost savings would remain significant.

The cesarean birth rate in this cohort was 6% versus the estimated rate of 25% for similarly low-risk women in a hospital setting.[21] Had this same group of 15,574 low-risk women been cared for in a hospital, an additional 2934 cesarean births could be expected. The Medicare facility reimbursement for an uncomplicated cesarean birth in a hospital in 2011 was $4465.[49] Given the increased payments for facility services for cesarean birth compared with vaginal birth in the hospital, the lower cesarean birth rate potentially saved an additional $4,487,524. In total, one could expect a potential savings in costs for facility services of more than $30 million for these 15,574 births.

The potential savings from the cost of care and lower intervention rates highlight birth centers as an important option for providing high-value maternity care. Cost analysis of birth center care is therefore an important area for future research, and fair and timely reimbursement for birth center care is important to the sustainability and further dissemination of the model.

The findings of this study also provide information to families considering birthing at a birth center. Among women who entered labor planning a birth center birth in this study, 83.7% gave birth there, and 79.4% ultimately were discharged from there to home with their newborns. Fewer than 2% (1.9%) required emergent transfer to a hospital for either mother or newborn. The total cesarean birth rate in the study sample was 6% regardless of where birth occurred. The fetal and neonatal mortality rates were consistent with those of births among low-risk women in previous studies including hospital settings. This information is helpful to families in making informed choices about their birth setting and maternity care provider.

This data set is rich and includes information on the elements of birth center care that have contributed to these outcomes. Future research should be carried out to describe the cost components of birth center care and strategies for optimizing and expanding this high-value care model. Qualitative studies exploring the experiences of childbearing women and families in birth center and hospital models of care are also critical.

Birth centers and their midwifery-led, collaborative model of maternity care continue to offer an important solution to many of the issues affecting the quality and cost of maternity care in the United States. This study confirms the findings of the National Birth Center Study and other studies of the birth center model of care and adds to the evidence demonstrating excellent maternal and infant outcomes for women receiving midwifery-led care in birth centers.

AUTHORS

Susan Stapleton, CNM, DNP, FACNM, is Research Committee Chair of the American Association of Birth Centers and has 25 years' experience owning and practicing in a birth center.

Cara Osborne, CNM, SD, is a midwife and perinatal epidemiologist and is assistant professor at the Eleanor Mann School of Nursing at the University of Arkansas.

Jessica Illuzzi, MD, MS, FACOG, is Associate Professor of Obstetrics, Gynecology, and Reproductive Sciences at Yale University School of Medicine and serves on the board of directors and is Standards Committee Chair of the American Association of Birth Centers.

CONFLICT OF INTEREST

The authors have no conflicts of interest to disclose

ACKNOWLEDGMENTS

The authors are deeply grateful to the American Association of Birth Centers (AABC) Foundation for their generous, unwavering support and recognition of the value of the AABC *Uniform Data Set*. They wish to thank Frontier Nursing Service Foundation for their significant support. They also thank the American College of Nurse-Midwives Foundation, Inc., and Childbirth Connection for their support of the project in the form of the 2010 Hazel Corbin Award.

The authors express their gratitude to the members of the AABC Research Advisory Committee who have contributed invaluable wisdom and expertise: Kenneth Blau, MD,

FACOG; Eunice K.M. Ernst, MPH, DSc(Hon), FACNM; Phyllis Leppert, MD, PhD; Evan Meyers, MD, MPH; SeanMulvenon, PhD; Judith Rooks, CNM, MPH, MS, FACNM; Mark Shwer, MD; and Nan Smith-Blair, PhD, RN, MSN.

Kate Bauer, Executive Director of the American Association of Birth Centers, has been instrumental in this project, providing invaluable administrative and technical support to the birth centers and the research team.

Jennifer Wright, MA, Research Associate, played an essential role on the research team by conducting data quality procedures and interacting with birth centers to verify and edit the data.

This study would not have been possible without the commitment of birth center midwives and staff to ongoing data collection and data quality. The authors especially thank providers and staff at the birth centers who collected data and responded to numerous requests from the research team (see Appendix 2).

REFERENCES

1. Centers for Medicare and Medicaid Services. *National Health Expenditure Data*. 2012. Available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and Reports/NationalHealthExpendData/downloads/tables.pdf. Accessed June 25, 2012.
2. Keehan S, Sisko A, Truffer C, et al. National health spending projections through 2020: Economic recovery and reform drive faster spending growth. *Health Aff*. 2011;30:1-12.
3. Podulka J., Stranges E., Steiner C. *Hospitalizations Related to Childbirth, 2008*. HCUP Statistical Brief #110. Rockville, MD: Agency for Healthcare Research and Quality; 2011. Available at: http://www.hcup-us.ahrq.gov/reports/statbriefs/sb110.pdf. Accessed February 25, 2012.
4. Wier LM, Pfuntner A, Maeda J, Stranges E, et al. *HCUP Facts and Figures: Statistics on Hospital-Based Care in the United States, 2009*. Rockville, MD: Agency for Healthcare Research and Quality; 2011. Available at: http://www.hcup-us.ahrq.gov/reports.jsp. Accessed July 21, 2012.
5. Wier, LM, Andrews RM. *The National Hospital Bill: The Most Expensive Conditions by Payer, 2008*. HCUP Statistical Brief #107. Rockville, MD: Agency for Healthcare Research and Quality; 2011. Available at: http://www.hcup-us.ahrq.gov/reports/statbriefs/sb107.pdf. Accessed February 25, 2012.
6. International Federation of Health Plans. *2010 Comparative Price Report: Medical and Hospital Fees by Country*. Available at: http://ifhp.com/documents/IFHP_Price_Report2010ComparativePriceReport29112010.pdf. Accessed February 25, 2012.
7. World Health Organization. *World Health Statistics 2010*. Geneva, Switzerland. Available at: http://www.who.int/whosis/whostat/EN_WHS10_Full.pdf. Accessed October 12, 2011.
8. Cosgrove D, Fisher M, Gabow P, et al. *A CEO Checklist for High-Value Health Care*. Institute of Medicine. June 2012. Available at: http://www.iom.edu/media/Files/Perspectives-Files/2012/Discussion-Papers/CEOHighValueChecklist.pdf. Accessed June 28, 2012.
9. Patient Protection and Affordable Care Act. Section 2301, S.3590, 11th Congress, 2nd Session. 2010.
10. Center for Medicare & Medicaid Services. *Strong Start for Mothers and Newborns*. 2012. Available at: http://innovations.cms.gov/ initiatives/strong-start/index.html. Accessed June 25, 2012.
11. Institute of Medicine (IOM). *Initial National Priorities for Comparative Effectiveness Research*. Washington, DC: National Academies Press; 2009. Available at: http://www.iom.edu/~/media/Files/Report%20Files/2009/ComparativeEffectivenessResearchPriorities/Stand%20Alone%20List%20of%20100%20CER%20Priorities%20-%20for%20web.ashx. Accessed October 12, 2011.
12. The Transforming Maternity Care Steering Committee. Blueprint for action: Steps toward a high-quality, high-value maternity care system. *Womens Health Issues*. 2010;20:S18-S49. Available at: http://www.whijournal.com/article/PIIS1049386709001406/fulltext. Accessed October 12, 2011.
13. Rooks J, Weatherby N, Ernst E, Stapleton S, Rosen D, Rosenfield, A. Outcomes of care in birth centers: the National Birth Center Study. *N Engl J Med*. 1989;321:1804-1811.
14. Jackson DJ, Lang JM, Swartz WH, et al. Outcomes, safety, and resource utilization in a collaborative care birth center program compared with traditional physician-based perinatal care. *Am J Pub Health*. 2003;93:999-1006. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1447883/pdf/0930999.pdf. Accessed September 8, 2011.
15. Martin JA, Hamilton BE, Sutton PD, et al. Births: final data for 2006. *Natl Vital Stat Rep*. 2009;57:1-101. Available at: http://www.cdc.gov/nchs/data/nvsr/nvsr57/nvsr57_07.pdf. Accessed September 17, 2012.
16. American Association of Birth Centers. *Definition of a Birth Center*. Available at: http://www.birthcenters.org/about-aabc/ position-statements/definition-of-birth-center. Accessed October 14, 2012.
17. American Association of Birth Centers. *Standards for Birth Centers*. Perkionmenville, PA; 2007. Available at: http://www.birthcenters.org/open-a-birth-center/birth-center-standards.
18. Commission for the Accreditation of Birth Centers. Available at: http://www.birthcenteraccreditation.org/.
19. American Public Health Association. *Guidelines for Regulating and Licensing Birth Centers*. 1982. Available at: http://www.birthcenters.org/sites/default/files/aabc/apha_guidelines.pdf. Accessed October 12, 2012.
20. American Association of Birth Centers. Birth Center Regulations. Available at: http://www.birthcenters.org/ open-a-birth-center/birth-center-regulations. Accessed October 12, 2012.
21. Martin JA, Hamilton BE, Ventura SJ, Osterman MJK, Wilson EC, Mathews TJ. Births: Final data for 2010. *Natl Vital Stat Rep*. 2012;61:1-100. Available at http://www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61_01.pdf. Accessed November 1, 2012.
22. Declercq E, Sakala C, Corry M, Applebaum, S. *Listening to Mothers II: Report of the Second National U.S. Survey of Women's Childbearing Experiences*. New York: Childbirth Connection; 2006. Available at: http://www.childbirthconnection.org/pdfs/LTMII_report.pdf. Accessed December 10, 2011.
23. Martin J, Hamilton B, Sutton P, et al. Births: Final data for 2007. *Natl Vital Stat Rep*. 2010;58:1-87. Available at: http://www.cdc.gov/nchs/data/nvsr/nvsr58/nvsr58_24.pdf. Accessed July 21, 2012.
24. Taffel S, Placek P, Liss T. Trends in the United States cesarean section rate and reasons for the 1980–85 rise. *Am J Pub Health*. 1987;77:955-959.
25. Taffel SM, Placek PJ, Moien M, Kosary CL. 1989. U.S. cesarean section rate steadies–VBAC rate rises to nearly one in five. *Birth*. 1991;18:73-77. Available at: http://www.cdc.gov/nchs/data/mvsr/supp/mv40_12s.pdf. Accessed July 24, 2012.
26. Gliklich RE, Dreyer NA, eds. *Registries for Evaluating Patient Outcomes: A User's Guide*. (Prepared by Outcome DEcIDE Center [Outcome Sciences, Inc. dba Outcome] under Contract No. HHSA29020050035ITO1.) AHRQ Publication No. 07-EHC001-1. Rockville, MD: Agency for Healthcare Research and Quality; 2007.
27. Gliklich RE, Dreyer NA, eds. *Registries for Evaluating Patient Outcomes: A User's Guide*. 2nd ed. (Prepared by Outcome DEcIDE Center [Outcome Sciences, Inc. d/b/a Outcome] under Contract No.HHSA290200500351 TO3.) AHRQ Publication No.10-EHC049. Rockville, MD: Agency for Healthcare Research and Quality; 2010. Available at: http://www.effectivehealthcare.ahrq.gov/ehc/products/74/531/Registries%202nd%20ed%20final%20to%20Eisenberg%209-15-10.pdf. Accessed September 7, 2010.

28.U.S. Department of Health and Human Services. *Federal Policy for the Protection of Human Subjects ('Common Rule')*. Available at: http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html.
29.American Association of Birth Centers. *Uniform Data Set Instruction Manual & Data Definitions*. Perkiomenville, PA; 2007.
30.Stapleton S. Validation of an online data registry: a pilot project. *J Midwifery Womens Health*. 2011;56:452-460.
31.Stapleton, S. (Unpublished doctoral project). *Defining Optimal Birth Using an Online Data Registry: A Pilot Project*. Hyden, KY: Frontier School of Midwifery & Family Nursing; 2007.
32.American Association of Birth Centers. *Uniform Data Set Practice Profile Report*. Perkiomenville, PA; 2012.
33.American College of Nurse-Midwives. *Comparison of Certified Nurse-Midwives, Certified Midwives and Certified Professional Midwives: Clarifying the Distinctions Among Professional Midwifery Credentials in the US*. Silver Spring, MD; 2011. Available at: http://midwife.org/ACNM/files/ACNMLibraryData/UPLOADFILENAME/000000000268/CNM%20CM%20CPM%20ComparisonChart%20082511.pdf. Accessed November 1, 2012.
34.Hatem M, Sandall J, Devane D, Soltani H, Gates S. Midwife-led versus other models of care for childbearing women. *Cochrane Database Syst Rev*. 2008;4:CD004667. Available at: http://apps.who.int/rhl/reviews/CD004667.pdf. Accessed June 7, 2011.
35.Hodnett ED, Downe S, Waksh D, Weston J. Alternative versus conventional institutional settings for birth. *Cochrane Database Syst Rev*. 2010;8:CD000012. Available at: http://www.update-software.com/BCP/WileyPDF/EN/CD000012.pdf. Accessed December 17, 2011.
36.Stewart M, McCandlish R, Henderson J, Brockhurst P. *Review of Evidence About Clinical, Psychosocial and Economic Outcomes for Women With Straightforward Pregnancies Who Plan to Give Birth in a Midwife-Led Birth Centre, and Outcomes for Their Babies. Report of a Structured Review of Birth Centre Outcomes*. Oxford, UK: National Perinatal Epidemiology Unit; 2005. Available at: https://www.npeu.ox.ac.uk/files/downloads/reports/Birth-Centre-Review.pdf. Accessed December 17, 2011.
37.Hollowell J, Puddicombe D, Rowe R, et al. *The Birthplace National Prospective Cohort Study: Perinatal and Maternal Outcomes by Planned Place of Birth*. Final report part 4: NIHR service delivery and organisation programme. Oxford, UK: Birthplace in England Collaborative Group; National Perinatal Epidemiology Unit, University of Oxford; 2011. Available at: www.sdo.nihr.ac.uk/projdetails.php?ref=08-1604-140. Accessed December 17, 2011.
38.Greulich B, Paine LL, McLain C, Barger MK, Edwards N, Paul, R. Twelve years and more than 30,000 nurse-midwife-attended births: The Los Angeles County and University of California women's hospital birth center experience. *J Nurse Midwifery*. 1994;39:185-196.
39.Blanchette H. Comparison of obstetric outcome of a primary care access clinic staffed by certified nurse-midwives and a private practice group of obstetricians in the same community. *Am J Obstet Gynecol*. 1995;172:1864-1870.
40.MacDorman MF, Singh GK. Midwifery care, social and medical risk factors and birth outcomes in the USA. *J Epidemiol Community Health*. 1998;52:310-317. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1756707/pdf/v052p00310.pdf. Accessed June 10, 2011.
41.Ever A, Brouwers H, Hukkelhoven C, Nikkels P, et al. Perinatal mortality and severe morbidity in low and high risk term pregnancies in the Netherlands: prospective cohort study. *BMJ*. 2010;341:c5639. Available at: http://www.bmj.com/highwire/filestream/397700/field_highwire_article_pdf/0/bmj.c5639.full.pdf. Accessed September 19, 2012.
42.Mathews TJ, MacDorman MF. Infant mortality statistics from the 2007 period linked birth/infant death data set. *Natl Vital Stat Rep*. 2011;59:1-30. Available at: http://www.cdc.gov/nchs/data/nvsr/nvsr59/nvsr59_06.pdf. Accessed September 19, 2012.
43.Pasupathy D, Wood A, Pell A, Mechan H, Fleming M, Smith G. Time of birth and risk of neonatal death at term: retrospective cohort study. *BMJ*. 2010;341:c3498. Available at: http://www.bmj.com/highwire/filestream/382672/field_highwire_article_pdf/0/bmj.c3498.full.pdf. Accessed September 19, 2012.
44.Begley C, Devane D, Clarke M, et al. Comparison of midwife-led and consultant-led care of healthy women at low risk of childbirth complications in the Republic of Ireland: a randomised trial. *BMC Pregnancy Childbirth* 2011;11:85. Available at: http://www.biomedcentral.com/1471–2393/11/85. Accessed September 19, 2011.
45.Janssen P, PhD, Saxell L, Page L, Klein M, Liston R, Lee S. Outcomes of planned home birth with registered midwife versus planned hospital birth with midwife or physician. *CMAJ*. 2009;181: 377-383. Available at: http://www.cmaj.ca/content/181/6-7/377.full.pdf+html. Accessed September 19, 2012.
46.Rooks J, Weatherby N, Ernst, E. The National Birth Center Study Part III-Intrapartum and immediate postpartum and neonatal complications and transfers, postpartum and neonatal care, outcomes and client satisfaction. *J Nurse Midwifery*. 1992;37:361-397.
47.National Governor's Association Center for Best Practices. *2010 Maternal and Child Health Update: States Make Progress Towards Improving Systems of Care*. January 19, 2012. Available at: http://www.nga.org/files/live/sites/NGA/files/pdf/MCHUPDATE2010.PDF. Accessed November 3, 2012.
48.Shatto JD, Clemens MK. *Projected Medicare Expenditures Under an Illustrative Scenario With Alternative Payment Updates to Medicare Providers*. Baltimore, MD: Centers for Medicare and Medicaid Services; 2010:1-20.
49.Sarpong E, Chevarley FR. *Health Care Expenditures for Uncomplicated Pregnancies, 2009*. Research Findings No. 32. Rockville, MD: Agency for Healthcare Research and Quality; 2012. Available at: http://www.meps.ahrq.gov/mepsweb/data_files/publications/rf32/rf32.pdf. Accessed June 12, 2012.

Appendix 1. Study Variables for Outcomes of Birth Center Care

- Demographics
  - Maternal age at presentation to prenatal care
  - Payment method
  - Education level
  - Maternal race/ethnicity
  - Marital status
  - Gravidity and parity
  - Medical history
  - Psychosocial history
  - Intended place of birth at onset of prenatal care
  - Estimated date of birth
- Antepartum referral
  - Antepartum complications
  - Type of antepartum referral
  - Primary indication for antepartum referral
- Intrapartum
  - Type of intrapartum transfer
  - Primary indication for intrapartum transfer
- Pregnancy outcome
  - Place of first admission to intrapartum care
  - Place of birth
  - Type of birth
  - Live birth
  - Intrapartum fetal death
- Postpartum
  - Type of postpartum transfer
  - Primary indication for postpartum transfer
  - Postpartum hemorrhage
- Neonatal
  - Type of neonatal transfer
  - Primary indication for neonatal transfer
  - Neonatal death
- Provider characteristics
  - Primary provider for prenatal care
  - Birth attendant

Appendix 2. Participating Birth Centers

Alaska Family Health and Birth Clinic, Fairbanks, Alaska
Allen Birthing Center, Allen, Texas
Auburn Birthing Center LLC, Auburn, Indiana
Austin Area Birthing Center, Austin, Texas
Babymoon Inn, LLC, Phoenix, Arizona
Bay Area Midwifery Center, Annapolis, Maryland
Best Start Birth Center, San Diego, California
Birth & Women's Health Center, Tucson, Arizona
Birth and Beyond, Grandin, Florida
Birth Care and Family Health Service, Bart, Pennsylvania
Birth Care and Women's Health, Alexandria, Virginia
Birth Center of Gainesville, Gainesville, Florida
BirthWise, Appleton, Wisconsin
Breath of Life Women's Health Services and Birth Center, Largo, Florida
Brooklyn Birthing Center, Brooklyn, New York
Cambridge Birth Center, Cambridge, Massachusetts
Central Montana Birth Center, Great Falls, Montana
Charleston Birth Place Charleston, Charleston, South Carolina
Columbia Birth Center Kennewick, Kennewick, Washington
Columbia Community Birth Center, Columbus, Missouri
Connecticut Childbirth and Women's Center, Danbury, Connecticut
Edenway Birth Center, Cleburne, Texas
Family Beginnings Birth Center at Miami Valley Hospital, Dayton, Ohio
Family Birth Center of Naples, Naples, Florida
Family Birth Center, LLC, Great Falls, Montana
Family Health and Birth Center, Washington, District of Columbia
Family Health and Birth Center, Savannah, Georgia
Family Maternity Center of the Northern Neck, Kilmarnock, Virginia
Footprints In Time Midwifery Services, Black River Falls, Wisconsin
Geneva Woods Birth Center, Anchorage, Alaska
Goshen Birth Center, Goshen, Indiana
Healing Passages Birth & Wellness Center, Des Moines, Iowa
Health Foundations Family Health and Birth Center, St. Paul, Minnesota
Heart 2 Heart Birth Center LLC, Sanford, Florida
Holy Family Birth Center, Weslaco, Texas
Infinity Birthing Center-Nashville, Nashville, Tennessee
Inland Midwife Services, Redlands, California
Juneau Family Birth Center, Juneau, Alaska
Katy Birth Center, Katy, Texas
Labor of Love Birth Center, Lakeland, Florida
Labor of Love Birth Center Dunedin, Dunedin, Florida

Continued

Appendix 2. Participating Birth Centers
Labor of Love Birth Center for Tampa, Tampa, Florida
Lisa Ross Birth and Women's Center, Knoxville, Tennessee
Madison Birth Center, Madison, Wisconsin
Mamatoto Resource and Birth Centre, Port of Spain, Trinidad and Tobago
Mat-Su Midwifery, Wasilla, Alaska
Memorial Hospital Family Birthing Center, North Conway, New Hampshire
Midwife Center for Birth and Women's Health, Pittsburgh, Pennsylvania
Midwifery Center at DePaul, Norfolk, Virginia
Morning Star Women's Health and Birth Center, Menomonie, Wisconsin
Morning Star Women's Health and Birth Center, St. Louis Park, Minnesota
Motherly Way Maternity Service, Midland, Texas
Mother's Own Birth and Women's Center, Temperance, Michigan
Mountain Midwifery Center, Englewood, Colorado
Natchez Trace Maternity Center, Waynesboro, Tennessee
Nativiti Women's Health and Birth Center, The Woodlands, Texas
Natural Beginnings Birth & Wellness Center, Whittier, California
North Houston Birth Center, Houston, Texas
Park Nicollet, St. Louis Park, Minnesota
Nurse-Midwifery Birth Center, Springfield, Oregon
Reading Birth & Women's Center, Reading, Pennsylvania
Rite of Passage Women's Health and Birth Center, Pearland, Texas
Sage Femme Birth Center of Kansas City, Kansas City, Kansas
Sage Femme Midwifery Service/Community Childbearing Institute, San Francisco, California
San Antonio Birth Center, San Antonio, Texas
South Coast Midwifery and Women's Health Care, Irvine, California
Special Beginnings Birth & Women's Center, Arundel, Maryland
The Baby Place, Meridian, Idaho
The Birth Center, Bryn Mawr, Pennsylvania
The Birth Center, Missoula, Montana
The Birth Center, A Nursing Corporation, Sacramento, California
The Birth Center: Holistic Women's Health Care, Wilmington, Delaware
The Birth Place, Taylor, Michigan
The Midwife's Place, Bellevue, Nebraska
Valley Birthplace and Woman Care, Huntingdon Valley, Pennsylvania
Women's Birth & Wellness Center, Chapel Hill, North Carolina
Women's Health and Birth Center, Santa Rosa, California
Women's Health & Birth Options, Missoula, Montana
Women's Wellness and Maternity Center, Madisonville, Tennessee

Appendix 3. American Association of Birth Centers Transfer Definitions[27]

Type of Transfer	Definition	Examples
Medical attrition	No birth after 20 weeks' gestation is expected.	SAB Induced abortion Ectopic pregnancy
Nonmedical attrition	Changed from practice or original decision for intended birth site for nonmedical reasons.	Moved out of area Client wanted another provider or place of birth
Antepartum medical referral	Risk factor develops during pregnancy that makes birth in intended location or with intended provider inappropriate.	Hypertension Postdates Multiple gestation Gestational diabetes Malpresentation IUGR Nonreassuring fetal testing
Preadmit intrapartum referral	Risk factor identified on initial evaluation in labor that makes birth in intended location or with intended provider inappropriate.	Malpresentation MSAF Elective or client choice Prolonged prodromal labor Nonreassuring FHR pattern Preterm labor Term prelabor ROM
Intrapartum referral	Risk factor identified after admission in labor that makes birth in intended location or with intended provider inappropriate.	Arrest of labor/prolonged labor Psychological factors MSAF Malpresentation Hypertension/preeclampsia Abnormal intrapartum bleeding Prolonged ruptured of membranes
Emergency intrapartum transfer[a]	Risk factor is identified in labor that requires transfer to acute care setting or to another provider. Situation is urgent, and rapid transport is required.	Cord prolapse Nonreassuring FHR pattern Seizure Abruption
Postpartum referral	Risk factor is identified during postpartum requiring referral to acute care or to another provider. Not an emergency situation; transport time is not a significant factor.	Maternal fever Laceration requiring repair by physician Retained placenta Mild/moderate PPH
Emergency postpartum transfer[a]	Risk factor during postpartum which requires transfer to acute care setting or to another provider Situation is urgent and rapid transport time is required.	Maternal seizure Severe PPH Retained placenta with PPH
Newborn referral	Newborn risk factor is identified that requires referral to acute care setting or another provider. Not an emergency; transport time is not a significant factor.	Transient tachypnea Temperature instability Congenital anomaly Suspected infection Mild respiratory distress
Emergency newborn transfer[a]	Newborn risk factor is identified that requires transport to acute care setting or to another provider. Situation is urgent, and rapid transport is required.	Significant respiratory distress Major congenital anomaly Resuscitation >5 minutes

Abbreviations: FHR, fetal heart rate; IUGR, intrauterine growth restriction; MSAF, meconium-stained amniotic fluid; PPH, postpartum hemorrhage; ROM, rupture of membranes; SAB, spontaneous abortion.
[a]Determination of whether transfer is emergency is made by provider.

The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

Society for Maternal-Fetal Medicine

OBSTETRIC CARE CONSENSUS

Number 2 • February 2015

Levels of Maternal Care

Abstract: In the 1970s, studies demonstrated that timely access to risk-appropriate neonatal and obstetric care could reduce perinatal mortality. Since the publication of the *Toward Improving the Outcome of Pregnancy* report, more than three decades ago, the conceptual framework of regionalization of care of the woman and the newborn has been gradually separated with recent focus almost entirely on the newborn. In this current document, maternal care refers to all aspects of antepartum, intrapartum, and postpartum care of the pregnant woman. The proposed classification system for levels of maternal care pertains to birth centers, basic care (level I), specialty care (level II), subspecialty care (level III), and regional perinatal health care centers (level IV). The goal of regionalized maternal care is for pregnant women at high risk to receive care in facilities that are prepared to provide the required level of specialized care, thereby reducing maternal morbidity and mortality in the United States.

This document was developed jointly by the American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine with the assistance of M. Kathryn Menard, MD, MPH; Sarah Kilpatrick, MD, PhD; George Saade, MD; Lisa M. Hollier, MD, MPH; Gerald F. Joseph Jr, MD; Wanda Barfield, MD; William Callaghan, MD; John Jennings, MD; and Jeanne Conry, MD, PhD. The information reflects emerging clinical and scientific advances as of the date issued, is subject to change, and should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

This document has been endorsed by the following organizations:
American Association of Birth Centers
American College of Nurse-Midwives
Association of Women's Health, Obstetric and Neonatal Nurses
Commission for the Accreditation of Birth Centers
The American Academy of Pediatrics leadership, the American Society of Anesthesiologists leadership, and the Society for Obstetric Anesthesia and Perinatology leadership have reviewed the opinion and are supportive of the Levels of Maternal Care.

Objectives

- To introduce uniform designations for levels of maternal care that are complementary but distinct from levels of neonatal care and that address maternal health needs, thereby reducing maternal morbidity and mortality in the United States
- To develop standardized definitions and nomenclature for facilities that provide each level of maternal care
- To provide consistent guidelines according to level of maternal care for use in quality improvement and health promotion
- To foster the development and equitable geographic distribution of full-service maternal care facilities and systems that promote proactive integration of risk-appropriate antepartum, intrapartum, and postpartum services

Background

In the 1970s, studies demonstrated that timely access to risk-appropriate neonatal and obstetric care could reduce perinatal mortality. In 1976, the March of Dimes and its partners first articulated the concept of an integrated system for regionalized perinatal care in a report titled *Toward Improving the Outcome of Pregnancy* (1). This report included criteria that stratified maternal and neonatal care into three levels of complexity, and recommended referral of high-risk patients to higher-level centers with the appropriate resources and personnel needed to address their increased complexity of care.

After the publication of the March of Dimes report, most states developed coordinated regional systems for perinatal care. The designated regional or tertiary care centers provided the highest levels of obstetric and neonatal care, while serving

smaller facilities' needs through education and transport services. Numerous studies have validated the concept that improved neonatal outcomes were achieved through application of risk-appropriate maternal transport systems (2, 3). A comprehensive meta-analysis has shown increased odds of neonatal mortality for very low birth weight (very LBW, also commonly known as VLBW) infants (less than 1,500 g) born outside of a level III hospital (38% versus 23%; adjusted odds ratio, 1.62; 95% confidence interval, 1.44–1.83) (4). Data indicate higher neonatal mortality for very LBW infants born in hospitals that are staffed by neonatologists in the absence of a more complete multidisciplinary team (level II), compared with those born in level III centers (5).

Since the March of Dimes report was published, the conceptual framework of regionalization of care of the woman and the newborn has changed to focus almost entirely on the newborn (6, 7). The American College of Obstetricians and Gynecologists (the College) and the American Academy of Pediatrics (AAP) outline the capabilities of health care providers in hospitals delivering basic, specialty, subspecialty, and regional obstetric care in *Guidelines for Perinatal Care*, Seventh Edition (6). With 39% of hospital births in the United States occurring at hospitals that deliver less than 500 newborns each year and an additional 20% occurring at hospitals that deliver between 501 newborns and 1,000 newborns each year (8), it likely is that the majority of maternal care in the United States is provided at basic-care and specialty-care hospitals. However, a recent commentary noted the need to readdress "perinatal levels of care" to focus specifically on maternal health conditions that warrant designation as high risk, and to define specific clinical and systems criteria to manage such conditions (9). This document is a call for an integrated, regionalized framework to identify when transfer of care may be necessary to provide risk-appropriate maternal care.

Although maternal mortality in high resource countries improved substantially during the 20th century, maternal mortality rates in the United States have worsened in the past 14 years (10). Currently, the United States is ranked 60th in the world for maternal mortality (11). According to a Centers for Disease Control and Prevention study, the leading causes of maternal mortality are associated with chronic conditions that affect women of reproductive age, and common obstetric complications such as hemorrhage (12). Moreover, maternal mortality in the United States represents a small component of the larger emerging problem of maternal severe morbidities and near-miss mortality that increased by 75% between 1998–99 and 2008–09 (13). National increases in obesity, hypertensive disorders, and diabetes among women of reproductive age increase the risk of maternal morbidity and mortality, as does the increasing cesarean delivery rate (14, 15). Although specific modifications in the clinical management of these conditions have been instituted (eg, the use of thromboembolism prophylaxis and bariatric beds in obstetrics), more can be done to improve the system of care for high-risk women at facility and population levels.

Although there is strong evidence of more favorable neonatal outcomes with regionalized perinatal care, evidence of a beneficial effect on maternal outcome is limited. Maternal mortality is an uncommon event, and methods for tracking severe morbidity only have been proposed recently (13). Data indicate that obstetric complications are significantly more frequent in hospitals with low delivery volume (16), and that obstetric providers with the lowest patient volume have significantly increased rates of obstetric complications compared with high-volume providers (17). Hospital clinical volume likely is a proxy measure for institutional and individual experience that may not be available at hospitals with lower volumes (18). Also, data indicate that outcomes are better if certain conditions, such as placenta previa or placenta accreta, are managed in a high-volume hospital (19, 20). It also has been noted that maternal mortality is inversely related to the population density of maternal–fetal medicine subspecialists at the state level (21), although other factors, such as the presence of obstetrician–gynecologists, nurses, and anesthesiologists who have experience in high-risk maternity care, also may contribute to this trend. Although these findings provide support for an association between availability of resources and favorable maternal outcomes, they do not prove a direct cause and effect relationship between levels of care and outcomes.

A number of states have incorporated maternal care criteria into perinatal guidelines. Indiana, Arizona, and Maryland emphasize the need for stratification of facilities based on levels of maternal care that are distinct from neonatal needs, but use inconsistent definitions and nomenclature: the Indiana Perinatal Networks guideline is modeled after the March of Dimes report and uses levels I, II, and III (22); the Arizona system defines levels I, II, IIE, and III of maternal care (23); and the Maryland Perinatal System uses levels I, II, III, and IV (24). Despite their differences, an essential component of each of these guidelines is the concept of an integrated system in which, just as with neonatal care, level III and level IV maternal centers serve level I and level II centers by providing educational resources, consultation services, and streamlined systems for maternal and neonatal transport when necessary.

This document has four objectives: 1) introduce uniform designations for levels of maternal care that are complementary but distinct from levels of neonatal care and that address maternal health needs, thereby preventing further increases in maternal morbidity and mortality in the United States; 2) develop standardized definitions and nomenclature for facilities that provide each level of maternal care, including birth centers; 3) provide consistent guidelines of service according to level of maternal care for use in quality improvement and health promotion; and 4) foster the development and equitable geographic distribution of full-service maternal care facilities and

systems that promote proactive integration of risk-appropriate antepartum, intrapartum, and postpartum services. This document focuses on maternal care and does not include an in-depth discussion about high-risk neonatal care capability based on gestational age or birth weight. Nevertheless, optimal perinatal care requires synergy in institutional capabilities for the woman and the fetus or neonate.

Definitions of Levels of Maternal Care

In this document, maternal care refers to all aspects of antepartum, intrapartum, and postpartum care of the pregnant woman. In order to standardize a complete and integrated system of perinatal regionalization and risk-appropriate maternal care, a classification system should be established for levels of maternal care that pertain to birth centers (as defined in the Birth Centers section of this document), basic care (level I), specialty care (level II), subspecialty care (level III), and regional perinatal health care centers (level IV) (see Table 1 and Table 2). This system is in concert with the College and AAP *Guidelines for Perinatal Care*, Seventh Edition (6). Although data on which to base these distinctions in resources and capacity for maternal care are limited, the definitions were created from the characteristics of successful regionalized perinatal systems in a number of states (see Background). In this context, regionalized perinatal systems represent a combination of maternal and neonatal services. Establishing clear, uniform criteria for designation of maternal centers that are integrated with emergency response systems will help ensure that the appropriate personnel, physical space, equipment, and technology are available to achieve optimal outcomes, as well as to facilitate subsequent data collection regarding risk-appropriate care. Trauma is not integrated into the levels of maternal care because trauma levels are already established. Pregnant women should receive the same level of trauma care as nonpregnant patients. This document addresses the care provided at birth centers and hospitals, but home birth is not included.

Table 1. Levels of Maternal Care: Definitions, Capabilities, and Types of Health Care Providers *

Birth Center	
Definition	Peripartum care of low-risk women with uncomplicated singleton term pregnancies with a vertex presentation who are expected to have an uncomplicated birth
Capabilities	• Capability and equipment to provide low-risk maternal care and a readiness at all times to initiate emergency procedures to meet unexpected needs of the woman and newborn within the center, and to facilitate transport to an acute care setting when necessary. • An established agreement with a receiving hospital with policies and procedures for timely transport. • Data collection, storage, and retrieval. • Ability to initiate quality improvement programs that include efforts to maximize patient safety. • Medical consultation available at all times.
Types of health care providers	Every birth attended by at least two professionals: • Primary maternal care providers. This includes CNMs, CMs, CPMs, and licensed midwives who are legally recognized to practice within the jurisdiction of the birth center; family physicians; and ob-gyns. • Availability of adequate numbers of qualified professionals with competence in level I care criteria and ability to stabilize and transfer high-risk women and newborns.
Examples of appropriate patients (not requirements)	• Term, singleton, vertex presentation
Level I (Basic Care)	
Definition	Care of uncomplicated pregnancies with the ability to detect, stabilize, and initiate management of unanticipated maternal–fetal or neonatal problems that occur during the antepartum, intrapartum, or postpartum period until patient can be transferred to a facility at which specialty maternal care is available
Capabilities	Birth center capabilities plus • ability to begin emergency cesarean delivery within a time interval that best incorporates maternal and fetal risks and benefits with the provision of emergency care. • available support services, including access to obstetric ultrasonography, laboratory testing, and blood bank supplies at all times.

(continued)

Table 1. Levels of Maternal Care: Definitions, Capabilities, and Types of Health Care Providers * *(continued)*

Level I (Basic Care) *(continued)*	
Capabilities *(continued)*	• protocols and capabilities for massive transfusion, emergency release of blood products, and management of multiple component therapy. • ability to establish formal transfer plans in partnership with a higher-level receiving facility. • ability to initiate education and quality improvement programs to maximize patient safety, and/or collaborate with higher-level facilities to do so.
Types of health care providers	Birthing center providers plus • continuous availability of adequate number of RNs with competence in level I care criteria and ability to stabilize and transfer high-risk women and newborns. • nursing leadership has expertise in perinatal nursing care. • obstetric provider with privileges to perform emergency cesarean available to attend all deliveries. • anesthesia services available to provide labor analgesia and surgical anesthesia.
Examples of appropriate patients (not requirements)	Any patient appropriate for a birth center, plus capable of managing higher-risk conditions such as • term twin gestation • trial of labor after cesarean delivery • uncomplicated cesarean delivery • preeclampsia without severe features at term
Level II (Specialty Care)	
Definition	Level I facility plus care of appropriate high-risk antepartum, intrapartum, or postpartum conditions, both directly admitted and transferred from another facility
Capabilities	Level I facility capabilities plus • computed tomography scan and ideally magnetic resonance imaging with interpretation available. • basic ultrasonographic imaging services for maternal and fetal assessment. • special equipment needed to accommodate the care and services needed for obese women.
Types of health care providers	Level I facility health care providers plus • continuous availability of adequate numbers of RNs with competence in level II care criteria and ability to stabilize and transfer high-risk women and newborns who exceed level II care criteria. • nursing leadership and staff have formal training and experience in the provision of perinatal nursing care and should coordinate with respective neonatal care services. • ob-gyn available at all times. • director of obstetric service is a board-certified ob-gyn with special interest and experience in obstetric care. • MFM available for consultation onsite, by phone, or by telemedicine, as needed. • anesthesia services available at all times to provide labor analgesia and surgical anesthesia. • board-certified anesthesiologist with special training or experience in obstetric anesthesia available for consultation. • medical and surgical consultants available to stabilize obstetric patients who have been admitted to the facility or transferred from other facilities.
Examples of appropriate patients (not requirements)	Any patient appropriate for level I care, plus higher-risk conditions such as • severe preeclampsia • placenta previa with no prior uterine surgery

(continued)

Table 1. Levels of Maternal Care: Definitions, Capabilities, and Types of Health Care Providers * *(continued)*

Level III (Subspecialty Care)	
Definition	Level II facility plus care of more complex maternal medical conditions, obstetric complications, and fetal conditions
Capabilities	Level II facility capabilities plus • advanced imaging services available at all times. • ability to assist level I and level II centers with quality improvement and safety programs. • provide perinatal system leadership if acting as a regional center in areas where level IV facilities are not available (see level IV). • medical and surgical ICUs accept pregnant women and have critical care providers onsite to actively collaborate with MFMs at all times. • appropriate equipment and personnel available onsite to ventilate and monitor women in labor and delivery until they can be safely transferred to the ICU.
Types of health care providers	Level II health care providers plus • continuous availability of adequate numbers of nursing leaders and RNs with competence in level III care criteria and ability to transfer and stabilize high-risk women and newborns who exceed level III care criteria, and with special training and experience in the management of women with complex maternal illnesses and obstetric complications. • ob-gyn available onsite at all times. • MFM with inpatient privileges available at all times, either onsite, by phone, or by telemedicine. • director of MFM service is a board-certified MFM. • director of obstetric service is a board-certified ob-gyn with special interest and experience in obstetric care. • anesthesia services available at all times onsite. • board-certified anesthesiologist with special training or experience in obstetric anesthesia in charge of obstetric anesthesia services. • full complement of subspecialists available for inpatient consultations.
Examples of appropriate patients (not requirements)	Any patient appropriate for level II care, plus higher-risk conditions such as • suspected placenta accreta or placenta previa with prior uterine surgery • suspected placenta percreta • adult respiratory syndrome • expectant management of early severe preeclampsia at less than 34 weeks of gestation
Level IV (Regional Perinatal Health Care Centers)	
Definition	Level III facility plus on-site medical and surgical care of the most complex maternal conditions and critically ill pregnant women and fetuses throughout antepartum, intrapartum, and postpartum care
Capabilities	Level III facility capabilities plus • on-site ICU care for obstetric patients. • on-site medical and surgical care of complex maternal conditions with the availability of critical care unit or ICU beds. • Perinatal system leadership, including facilitation of maternal referral and transport, outreach education for facilities and health care providers in the region, and analysis and evaluation of regional data, including perinatal complications and outcomes and quality improvement.

(continued)

Table 1. Levels of Maternal Care: Definitions, Capabilities, and Types of Health Care Providers * *(continued)*

Level IV (Regional Perinatal Health Care Centers) *(continued)*

Types of health care providers	Level III health care providers plus • MFM care team with expertise to assume responsibility for pregnant women and women in the postpartum period who are in critical condition or have complex medical conditions. This includes comanagement of ICU-admitted obstetric patients. An MFM team member with full privileges is available at all times for on-site consultation and management. The team is led by a board-certified MFM with expertise in critical care obstetrics. • physician and nursing leaders with expertise in maternal critical care. • continuous availability of adequate numbers of RNs who have experience in the care of women with complex medical illnesses and obstetric complications; this includes competence in level IV care criteria. • director of obstetric service is a board-certified MFM, or board-certified ob-gyn with expertise in critical care obstetrics. • anesthesia services are available at all times onsite. • board-certified anesthesiologist with special training or experience in obstetric anesthesia in charge of obstetric anesthesia services. • adult medical and surgical specialty and subspecialty consultants available onsite at all times to collaborate with MFM care team.
Examples of appropriate patients (not requirements)	Any patient appropriate for level III care, plus higher-risk conditions such as • severe maternal cardiac conditions • severe pulmonary hypertension or liver failure • pregnant women requiring neurosurgery or cardiac surgery • pregnant women in unstable condition and in need of an organ transplant

Abbreviations: CMs, certified midwives; CNMs, certified nurse–midwives; CPMs, certified professional midwives; ICU, intensive care unit; MFM, maternal–fetal medicine subspecialists; ob-gyns, obstetrician–gynecologists; RNs, registered nurses;.

*These guidelines are limited to the maternal needs. Consideration of perinatal needs and the appropriate level of care should occur following existing guidelines. In fact, levels of maternal care and levels of neonatal care may not match within facilities. Additionally, these are guidelines, and local issues will affect systems of implementation for regionalized maternal care, perinatal care, or both. Data from Levels of Neonatal Care. American Academy of Pediatrics Committee on Fetus and Newborn. Pediatrics 2012;130:587–97.

Table 2. Levels of Maternal Care by Services

Required Service	Level of Maternal Care				
	Birth Centers	Level I	Level II	Level III	Level IV
Nursing	Adequate numbers of qualified professionals with competence in level I care criteria	Continuously available RNs with competence in level I care criteria Nursing leadership has expertise in perinatal nursing care	Continuously available RNs with competence in level II care criteria Nursing leadership has formal training and experience in perinatal nursing care and coordinates with respective neonatal care services	Continuously available nursing leaders and RNs with competence in level III care criteria and have special training and experience in the management of women with complex maternal illnesses and obstetric complications	Continuously available RNs with competence in level IV care criteria Nursing leadership has expertise in maternal intensive and critical care

(continued)

Table 2. Levels of Maternal Care by Services *(continued)*

Required Service	Level of Maternal Care				
	Birth Centers	Level I	Level II	Level III	Level IV
Minimum primary delivery provider to be available	CNMs, CMs, CPMs, and licensed midwives	Obstetric provider with privileges to perform emergency cesarean delivery	Ob-gyns or MFMs	Ob-gyns or MFMs	Ob-gyns or MFMs
Obstetrics surgeon		Available for emergency cesarean delivery	Ob-gyn available at all times	Ob-gyn onsite at all times	Ob-gyn onsite at all times
MFMs			Available for consultation onsite, by phone, or by telemedicine, as needed	Available at all times onsite, by phone, or by telemedicine with inpatient privileges	Available at all times for on-site consultation and management
Director of obstetric services			Board-certified ob-gyn with experience and interest in obstetrics	Board-certified ob-gyn with experience and interest in obstetrics	Board-certified MFM or board-certified ob-gyn with expertise in critical care obstetrics
Anesthesia		Anesthesia services available	Anesthesia services available at all times Board-certified anesthesiologist with special training or experience in obstetrics, available for consultation	Anesthesia services available at all times Board-certified anesthesiologist with special training or experience in obstetrics is in charge of obstetric anesthesia services	Anesthesia services available at all times Board-certified anesthesiologist with special training or experience in obstetrics is in charge of obstetric anesthesia services
Consultants	Established agreement with a receiving hospital for timely transport, including determination of conditions necessitating consultation and referral	Established agreement with a higher-level receiving hospital for timely transport, including determination of conditions necessitating consultation and referral	Medical and surgical consultants available to stabilize	Full complement of subspecialists available for inpatient consultation, including critical care, general surgery, infectious disease, hematology, cardiology, nephrology, neurology, and neonatology	Adult medical and surgical specialty and subspecialty consultants available onsite at all times, including those indicated in level III and advanced neurosurgery, transplant, or cardiac surgery
ICU				Appropriate equipment and personnel available onsite to ventilate and monitor women in labor and delivery until safely transferred to ICU Accepts pregnant women	Collaborates actively with the MFM care team in the management of all pregnant women and women in the postpartum period who are in critical condition or have complex medical conditions Comanages ICU-admitted obstetric patients with MFM team

Abbreviations: CMs, certified midwives; CNMs, certified nurse–midwives; CPMs, certified professional midwives; ICU, intensive care unit; MFMs, maternal–fetal medicine specialists; ob-gyns, obstetrician–gynecologists; RNs, registered nurses.

Once levels of maternal care are established, analysis of data collected from all facilities and regional systems will inform future updates to the levels of maternal care. Consistent with the levels of neonatal care published by the AAP (7), each level reflects required minimal capabilities, physical facilities, and medical and support personnel. Note that each higher level of care includes and builds on the capabilities of the lower levels. As with the AAP-defined levels of neonatal care, the system will be modified as analysis is completed.

The goal of regionalized maternal care is for pregnant women at high risk to receive care in facilities that are prepared to provide the required level of specialized care. Each facility should have a clear understanding of its capability to handle increasingly complex levels of maternal care, and should have a well-defined threshold for transferring women to health care facilities that offer a higher level of care. These proposed categories of maternal care are meant to facilitate this process. These guidelines also are intended to foster the development of equitably distributed resources throughout the country. These are guidelines, not mandates, and geographic and local issues will affect systems of implementation for regionalized perinatal care. In fact, levels of maternal and neonatal care may not match within facilities. However, a pregnant woman should be cared for at the facility that best meets her needs as well as her neonate's needs. Because all facilities cannot maintain the breadth of resources available at subspecialty centers, interfacility transport of pregnant women or women in the postpartum period is an essential component of a regionalized perinatal health care system. To ensure optimal care of all pregnant women, all birth centers, hospitals, and higher-level facilities should collaborate to develop and maintain maternal and neonatal transport plans and cooperative agreements capable of managing the health care needs of women who develop complications; receiving hospitals should openly accept transfers. The appropriate care level for patients should be driven by their medical need for that care and not limited by financial constraint. Because of the importance of accurate data for the assessment of outcomes, all facilities should have requirements for data collection, storage, and retrieval.

An important goal of regionalized maternal care is for higher-level facilities to provide training for quality improvement initiatives, educational support, and severe morbidity and mortality case review for lower-level hospitals. In those regions that do not have a facility that qualifies as a level IV center, any level III facilities in the region should provide the educational and consultation function (see Table 3).

Birth Centers

In 1995, the American Association of Birth Centers (www.birthcenters.org) defined *birth centers* as "a home-like facility existing within a healthcare system with a program of care designed in the wellness model of pregnancy and birth. Birth centers provide family-centered care for healthy women before, during and after normal pregnancy, labor and birth." This common definition is used in this document and includes birth centers regardless of their location. Birth centers provide peripartum care to low-risk women with uncomplicated singleton term pregnancies with a vertex presentation who are expected to have an uncomplicated birth. Cesarean delivery or operative vaginal delivery are not offered at birth centers.

In a freestanding birth center, every birth should be attended by at least two professionals. The primary maternity care provider that attends each birth is educated and licensed to provide birthing services. Primary maternity care providers include certified nurse–midwives (CNMs), certified midwives, certified professional midwives, and licensed midwives who are legally recognized to practice within the jurisdiction of the birth center; family physicians; and obstetrician–gynecologists. In addition, there should be adequate numbers of qualified professionals available who have completed orientation and demonstrated competence in the care of obstetric patients (women and fetuses) consistent with level I care criteria and are able to stabilize and transfer high-risk women and newborns. Medical consultation should be available at all times. These facilities should be ready to initiate emergency procedures (including cardiopulmonary and newborn resuscitation and stabilization) at all times (7), to meet unexpected needs of the woman and newborn within the center, and to facilitate transport to an acute care setting when necessary. To ensure optimal care of all women, a birth center should have a clear understanding of its capability to provide maternal and neonatal care and the threshold at which it should transfer women to a facility with a higher level of care. A birth center should have an established agreement with a receiving hospital and have policies and procedures in place for timely transport. These transfer plans should include risk identification; determination of conditions necessitating consultation; referral and transfer; and a reliable, accurate, and comprehensive communication system between participating facilities and transport teams. All facilities should have quality improvement programs that include efforts to maximize patient safety.

Birth center facility licenses currently are available in more than 80% of states in the United States and state requirements for accreditation for birth centers vary. Three national agencies (Accreditation Association for Ambulatory Health Care [www.aaahc.org], The Joint Commission [www.jointcommission.org], and The Commission for the Accreditation of Birth Centers [www.birthcenteraccreditation.org]) provide accreditation of birth centers. The Commission for the Accreditation of Birth Centers is the only accrediting agency that chooses to use the national American Association of Birth Centers Standards for Birth Centers in its accreditation process.

Table 3. Summary and Recommendations for Levels of Maternal Care

Summary and Recommendations	Grade of Recommendations
In order to standardize a complete and integrated system of perinatal regionalization and risk-appropriate maternal care, a classification system should be established for levels of maternal care that pertain to birth centers (as defined in the Birth Centers section of this document), basic care (level I), specialty care (level II), subspecialty care (level III), and regional perinatal health care centers (level IV).	1C Strong recommendation, low quality evidence
Introduce uniform designations for levels of maternal care that are complementary but distinct from levels of neonatal care.	1C Strong recommendation, low quality evidence
Establishing clear, uniform criteria for designation of maternal centers that are integrated with emergency response systems will help ensure that the appropriate personnel, physical space, equipment, and technology are available to achieve optimal outcomes, as well as to facilitate subsequent data collection regarding risk-appropriate care.	1C Strong recommendation, low quality evidence
Each facility should have a clear understanding of its capability to handle increasingly complex levels of maternal care, and should have a well-defined threshold for transferring women to health care facilities that offer a higher level of care. To ensure optimal care of all pregnant women, all birth centers, hospitals, and higher-level facilities should collaborate to develop and maintain maternal and neonatal transport plans and cooperative agreements capable of managing the health care needs of women who develop complications; receiving hospitals should openly accept transfers.	1C Strong recommendation, low quality evidence
Higher-level facilities should provide training for quality improvement initiatives, educational support, and severe morbidity and mortality case review for lower-level hospitals. In those regions that do not have a facility that qualifies as a level IV center, any level III facilities in the region should provide the educational and consultation function.	1C Strong recommendation, low quality evidence
Facilities and regional systems should develop methods to track severe maternal morbidity and mortality to assess the efficacy of utilizing maternal levels of care.	1C Strong recommendation, low quality evidence
Analysis of data collected from all facilities and regional systems will inform future updates to the levels of maternal care.	1C Strong recommendation, low quality evidence
Follow-up interdisciplinary work groups are needed to further explore the implementation needs to adopt the proposed classification system for levels of maternal care in all facilities that provide maternal care.	1C Strong recommendation, low quality evidence

Level I Facilities (Basic Care)

Level I facilities (basic care) provide care to women who are low risk and are expected to have an uncomplicated birth (Table 1). Level I facilities have the capability to perform routine intrapartum and postpartum care that is anticipated to be uncomplicated (6). As in birth centers, maternity care providers, midwives, family physicians, or obstetrician–gynecologists should be available to attend all births. Adequate numbers of registered nurses (RNs) are available who have completed orientation, demonstrated competence in the care of obstetric patients (women and fetuses) consistent with level I care criteria, and are able to stabilize and transfer high-risk women and newborns. Nursing leadership should have expertise in perinatal nursing care. An obstetric provider with privileges to perform an emergency cesarean delivery should be available to attend deliveries. Anesthesia services should be available to provide labor analgesia and surgical anesthesia. Level I facilities have the capability to begin an emergency cesarean delivery within a time interval that best incorporates maternal and fetal risks and benefits with the provision of emergency care (6, 25). Support services include access to obstetric ultrasonography, laboratory testing, and blood bank supplies at all times. All hospitals with obstetric services should have protocols and capabilities in place for massive transfusion, emergency release of blood products (before full compatibility testing is complete), and for management of multiple component therapy. These facilities and health care providers can appropriately detect, stabilize, and initiate management of unanticipated maternal, fetal, or neonatal problems that occur during the antepartum, intrapartum, or postpartum period until the patient can be transferred to a facility at which specialty maternal care is available. To ensure optimal care of all pregnant women, formal transfer plans should be established in partnership with a higher-level receiving facility. These plans should include risk identification; determination of conditions

necessitating consultation; referral and transfer; and a reliable, accurate, and comprehensive communication system between participating hospitals and transport teams (6). All facilities should have education and quality improvement programs to maximize patient safety, provide such programs through collaboration with facilities with higher levels of care that receive transfers, or both. Examples of women who need at least level I care include women with term twin gestation; women attempting trial of labor after cesarean delivery; women expecting an uncomplicated cesarean delivery; and women with preeclampsia without severe features at term.

Level II Facilities (Specialty Care)

Level II facilities (specialty care) provide care to appropriate high-risk pregnant women, both admitted and transferred to the facility. In addition to the capabilities of a level I (basic care) facility, level II facilities should have the infrastructure for continuous availability of adequate numbers of RNs who have demonstrated competence in the care of obstetric patients (women and fetuses). Orientation and demonstrated competence should be consistent with level II care criteria and include stabilization and transfer of high-risk women and newborns who exceed level II care criteria. The nursing leaders and staff at a level II facility should have formal training and experience in the provision of perinatal nursing care and should coordinate with respective neonatal care services. Although midwives and family physicians may practice in level II facilities, an attending obstetrician–gynecologist should be available at all times. A board-certified obstetrician–gynecologist with special interest and experience in obstetric care should be the director of obstetric services. Access to a maternal–fetal medicine subspecialist for consultation should be available onsite, by phone, or by telemedicine as needed. Anesthesia services should be available at all times to provide labor analgesia and surgical anesthesia. A board-certified anesthesiologist with special training or experience in obstetric anesthesia should be available for consultation. Support services include level I capabilities plus computed tomography scan and, ideally, magnetic resonance imaging with interpretation available; basic ultrasonographic imaging services for maternal and fetal assessment; and special equipment needed to accommodate the care and services needed for obese women (6). Medical and surgical consultants should be available to stabilize obstetric patients who have been admitted to the facility or transferred from other facilities. Examples of women who need at least level II care include women with severe preeclampsia and women with placenta previa with no prior uterine surgery.

Level III Facilities (Subspecialty Care)

Level III facilities (subspecialty care) provide all level I (basic care) and level II (specialty care) services, and have subspecialists available onsite, by phone, or by telemedicine to assist in providing care for more complex maternal and fetal conditions. Level III facilities will function as the regional perinatal health care centers for some areas of the United States if there are no level IV facilities available. In these areas, the level III facilities will be responsible for the leadership, facilitation of transport and referral, educational outreach, and data collection and analysis outlined in the Regionalization section discussed later in this document.

Designation of level III should be based on the demonstrated experience and capability of the facility to provide comprehensive management of severe maternal and fetal complications. An obstetrician–gynecologist is available onsite at all times and a maternal–fetal medicine subspecialist is available at all times, either onsite, by phone, or by telemedicine, and should have inpatient privileges. The director of the maternal–fetal medicine service should be a board-certified maternal–fetal medicine subspecialist. A board-certified obstetrician–gynecologist with special interest and experience in obstetric care should direct obstetric services. Anesthesia services should be available at all times onsite. A board-certified anesthesiologist with special training or experience in obstetric anesthesia should be in charge of obstetric anesthesia services. A full complement of subspecialists, including subspecialists in critical care, general surgery, infectious disease, hematology, cardiology, nephrology, neurology, and neonatology should be available for inpatient consultations. An on-site intensive care unit (ICU) should accept pregnant women and have critical care providers onsite to actively collaborate with maternal–fetal specialists at all times. Equipment and personnel with expertise must be available onsite to ventilate and monitor women in the labor and delivery unit until they can be safely transferred to the ICU.

Level III facilities have nursing leaders and adequate numbers of RNs who have completed orientation and demonstrated competence in the care of obstetric patients (women and fetuses) consistent with level III care criteria, including transfer of high-risk women and newborns who exceed level III care criteria, and who have special training and experience in the management of women with complex maternal illnesses and obstetric complications. These nursing personnel continuously are available. Level III facilities should be able to provide imaging services including basic interventional radiology, maternal echocardiography, computed tomography, magnetic resonance imaging, and nuclear medicine imaging with interpretation should be available at all times. Level III facilities should have the ability to perform detailed obstetric ultrasonography and fetal assessment, including Doppler studies. These facilities also should provide evaluation of new technologies and therapies. Examples of women who need at least level III care include those women with extreme risk of massive hemorrhage at delivery, such as those with suspected placenta accreta or placenta previa with prior uterine surgery; women with

suspected placenta percreta; women with adult respiratory distress syndrome; and women with rapidly evolving disease, such as planned expectant management of severe preeclampsia at less than 34 weeks of gestation.

Level IV Facilities (Regional Perinatal Health Care Centers)

Level IV facilities (regional perinatal health care centers) include the capabilities of level I, level II, and level III facilities with additional capabilities and considerable experience in the care of the most complex and critically ill pregnant women throughout antepartum, intrapartum, and postpartum care. Although level III and level IV may seem to overlap, a level IV facility is distinct from a level III facility in the approach to the care of pregnant women and women in the postpartum period with complex and critical illnesses. In addition to having ICU care onsite for obstetric patients, a level IV facility must have evidence of a maternal–fetal medicine care team that has the expertise to assume responsibility for pregnant women and women in the postpartum period who are in critical condition or have complex medical conditions. The maternal–fetal medicine team collaborates actively in the comanagement of all obstetric patients who require critical care and ICU services. This includes comanagement of ICU-admitted obstetric patients. A maternal–fetal medicine team member with full privileges is available at all times for on-site consultation and management. The team should be led by a board-certified maternal–fetal medicine subspecialist with expertise in critical care obstetrics. The maternal–fetal medicine team must have expertise in critical care at the physician level, nursing level, and ancillary services level. A key principle of caring for critically ill pregnant and peripartum women is the facility's recognition of the need for seamless communication between maternal–fetal medicine subspecialists and other subspecialists in the planning and facilitation of care for women with the most high-risk complications of pregnancy. There should be institutional support for the routine involvement of a maternal–fetal medicine care team with the critical care units and specialists. There also should be a commitment to having physician and nursing leaders with expertise in maternal intensive and critical care, as well as adequate numbers of available RNs in level IV facilities who have experience in the care of women with complex medical illnesses and obstetric complications; this includes completed orientation, demonstrated competence in the care of obstetric patients (women and fetuses) consistent with level IV care criteria. The director of obstetric services is a board-certified maternal–fetal medicine subspecialist or a board-certified obstetrician–gynecologist with expertise in critical care obstetrics. As in level III facilities, anesthesia services are available onsite at all times. A board-certified anesthesiologist with special training or experience in obstetric anesthesia should be in charge of obstetric anesthesia services. Level IV facilities should include the capability for on-site medical and surgical care of complex maternal conditions (eg, congenital maternal cardiac lesions, vascular injuries, neurosurgical emergencies, and transplants) with the availability of critical (or intensive) care unit beds. There should be adult medical and surgical specialty and subspecialty consultants (a minimum of those listed in level III) available onsite at all times to collaborate with the maternal–fetal medicine care team. The designation of level IV also may pertain only to a particular specialty in that advanced neurosurgery, transplant, and cardiovascular capabilities may not all be available in the same regional facility. Examples of women who would need level IV care (at least at the time of delivery) include pregnant women with severe maternal cardiac conditions, severe pulmonary hypertension, or liver failure; pregnant women in need of neurosurgery or cardiac surgery; or pregnant women in unstable condition and in need of an organ transplant.

Regionalization

Regional centers, which include any level III facility that functions in this capacity and all level IV facilities, should coordinate regional perinatal health care services; provide outreach education to facilities and health care providers in their region; and provide analysis and evaluation of regional data, including perinatal complications and outcomes, as part of collaboration with lower-level care facilities in the region. Community outreach and data analysis and evaluation will require additional resources in personnel and equipment within these facilities.

Although specific supporting data are not currently available in maternal health, it is believed that concentrating the care of women with the most complex pregnancies at designated regional perinatal health care centers will allow these centers to maintain the expertise needed to achieve optimal outcomes. Regionalization of maternal health care services requires that there be available and coordinated specialized services, professional continuing education to maintain competency, facilitation of opportunities for transport and back-transport, and collection of data on long-term outcomes to evaluate the effectiveness of delivery of perinatal health care services and the safety and efficacy of new therapies. Because the health statuses of women and fetuses may differ, referral should be organized to meet the needs of both. In some cases with specific care needs, optimal coordination of care will not be delineated by geographic area, but rather by availability of specific expertise (eg, transplant services or fetal surgery).

Measurement and Evaluation of Regionalized Maternal Care

Implicit in the effort to establish levels of maternal care is the goal to provide the best possible maternal outcomes, as well as ongoing quality improvement. If levels of maternal care improve care, then ensuring that appropriate

transfer of women occurs should be associated with a decrease in preventable maternal severe morbidities and mortality. There also should be a shift toward less severe morbidity in lower-level care facilities. Therefore, facilities and regional systems should develop methods to track severe maternal morbidity and mortality to assess the efficacy of utilizing maternal levels of care.

Operational definitions are needed to compare data and outcomes between levels of maternal care. However, waiting for the precise measure before establishing tiered levels of care invites unnecessary delay. Therefore, two constructs to implement with the utilization of levels of maternal care are proposed: 1) identify women at extreme risk of morbidity and 2) identify severe morbidity outcomes that may improve with appropriate use of maternal levels of care. Some women at extreme risk of severe morbidities, such as stroke, cardiopulmonary failure, or massive hemorrhage, can be identified during the antepartum period and should give birth in the appropriate level hospital. Examples of such women include those with suspected placenta accreta or placenta percreta; prior cesarean birth and current anterior previa; severe heart disease such as complex cardiac malformations and pulmonary hypertension, coronary artery disease, or cardiomyopathy; severe preeclampsia with uncontrollable hypertension; and preterm HELLP syndrome.

Outcome morbidities that may improve with appropriate use of levels of maternal care include stroke, returns to the operating room, massive transfusions, severe maternal morbidity, and potential ICU admissions. The incidence of these outcomes could decrease or be shifted from lower-level to higher-level hospitals. For example, known placenta accreta has the potential for massive blood loss and need for advanced surgical services, which are best available at facilities with a high designated level of care. Expectant management of severe early preeclampsia, septic shock, and pulmonary hypertension are other examples of conditions that require considerable resources likely best available at facilities with a high designated level of care. Although the development of comprehensive lists of what conditions comprise extreme morbidity risks and what outcomes ought to be measured currently is an evolving process, prospective measurement with continuous monitoring and evaluation of any regionalized maternal care system is critical to improvement in care processes and outcomes.

Determination and Implementation of Levels of Maternal Care

Many barriers to the implementation of levels of maternal care may need to be overcome. The development of the classification system is the first step; the next step, is the implementation of this concept in all facilities that provide maternal care. The questions of whether to have state-level or national-level accrediting bodies establish and set these proposed levels of maternal care, as well as how to provide the financing needed to run them, are unanswered. Follow-up interdisciplinary work groups are needed to further explore the implementation needs to adopt the proposed classification system for levels of maternal care in all facilities that provide maternal care.

The determination of the appropriate level of care to be provided by a given facility should be guided by local and state health care regulations, national accreditation and professional organization guidelines, and identified regional perinatal health care service needs (6). State and regional authorities should work together with the multiple institutions within a region to determine the appropriate coordinated system of care.

References

1. March of Dimes. Toward improving the outcome of pregnancy III: enhancing perinatal health through quality, safety and performance initiatives. White Plains (NY): March of Dimes; 2010. ⇦
2. Paneth N, Kiely JL, Wallenstein S, Marcus M, Pakter J, Susser M. Newborn intensive care and neonatal mortality in low-birth-weight infants: a population study. N Engl J Med 1982;307:149–55. [PubMed] [Full Text] ⇦
3. Gortmaker S, Sobol A, Clark C, Walker DK, Geronimus A. The survival of very low-birth weight infants by level of hospital of birth: a population study of perinatal systems in four states. Am J Obstet Gynecol 1985;152:517–24. [PubMed] ⇦
4. Lasswell SM, Barfield WD, Rochat RW, Blackmon L. Perinatal regionalization for very low-birth-weight and very preterm infants: a meta-analysis. JAMA 2010;304:992–1000. [PubMed] [Full Text] ⇦
5. Menard MK, Liu Q, Holgren EA, Sappenfield WM. Neonatal mortality for very low birth weight deliveries in South Carolina by level of hospital perinatal service. Am J Obstet Gynecol 1998;179:374–81. [PubMed] ⇦
6. Guidelines for perinatal care. 7th ed. Elk Grove Village (IL): AAP; Washington, DC: American College of Obstetricians and Gynecologists; 2012. ⇦
7. Levels of neonatal care. American Academy of Pediatrics Committee on Fetus and Newborn. Pediatrics 2012;130:587–97. [PubMed] [Full Text] ⇦
8. American Hospital Association. AHA guide to the health care field. 2015 ed. Chicago (IL): AHA; 2014. ⇦
9. Hankins GD, Clark SL, Pacheco LD, O'Keeffe D, D'Alton M, Saade GR. Maternal mortality, near misses, and severe morbidity: lowering rates through designated levels of maternity care. Obstet Gynecol 2012;120:929–34. [PubMed] [*Obstetrics & Gynecology*] ⇦
10. Main EK. Maternal mortality: new strategies for measurement and prevention. Curr Opin Obstet Gynecol 2010;22:511–6. [PubMed] [Full Text] ⇦
11. Kassebaum NJ, Bertozzi-Villa A, Coggeshall MS, Shackelford KA, Steiner C, Heuton KR, et al. Global, regional, and national levels and causes of maternal mortality during 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013 [published erratum appears in Lancet 2014;384:956]. Lancet 2014;384:980–1004. [PubMed] [Full Text] ⇦

12. Berg CJ, Callaghan WM, Syverson C, Henderson Z. Pregnancy-related mortality in the United States, 1998 to 2005. Obstet Gynecol 2010;116:1302–9. [PubMed] [*Obstetrics & Gynecology*] ⇦

13. Callaghan WM, Creanga AA, Kuklina EV. Severe maternal morbidity among delivery and postpartum hospitalizations in the United States. Obstet Gynecol 2012;120:1029–36. [PubMed] [*Obstetrics & Gynecology*] ⇦

14. Burlingame J, Horiuchi B, Ohana P, Onaka A, Sauvage LM. The contribution of heart disease to pregnancy-related mortality according to the pregnancy mortality surveillance system. J Perinatol 2012;32:163–9. [PubMed] ⇦

15. May AL, Freedman D, Sherry B, Blanck HM. Obesity - United States, 1999–2010. Centers for Disease Control and Prevention (CDC). MMWR Surveill Summ 2013;62(suppl 3):120–8. [PubMed] [Full Text] ⇦

16. Kyser KL, Lu X, Santillan DA, Santillan MK, Hunter SK, Cahill AG, et al. The association between hospital obstetrical volume and maternal postpartum complications. Am J Obstet Gynecol 2012;207:42.e1–42.17. [PubMed] [Full Text] ⇦

17. Janakiraman V, Lazar J, Joynt KE, Jha AK. Hospital volume, provider volume, and complications after childbirth in U.S. hospitals. Obstet Gynecol 2011;118:521–7. [PubMed] [Full Text] ⇦

18. Eller AG, Bennett MA, Sharshiner M, Masheter C, Soisson AP, Dodson M, et al. Maternal morbidity in cases of placenta accreta managed by a multidisciplinary care team compared with standard obstetric care. Obstet Gynecol 2011;117:331–7. [PubMed] [*Obstetrics & Gynecology*] ⇦

19. Wright JD, Herzog TJ, Shah M, Bonanno C, Lewin SN, Cleary K, et al. Regionalization of care for obstetric hemorrhage and its effect on maternal mortality. Obstet Gynecol 2010;115:1194–200. [PubMed] [*Obstetrics & Gynecology*] ⇦

20. Olive EC, Roberts CL, Algert CS, Morris JM. Placenta praevia: maternal morbidity and place of birth. Aust N Z J Obstet Gynaecol 2005;45:499–504. [PubMed] [Full Text] ⇦

21. Sullivan SA, Hill EG, Newman RB, Menard MK. Maternal-fetal medicine specialist density is inversely associated with maternal mortality ratios. Am J Obstet Gynecol 2005;193:1083–8. [PubMed] [Full Text] ⇦

22. Indiana Perinatal Network. Indiana perinatal hospital standards. Indianapolis (IN): IPN; 2012. Available at: http://c.ymcdn.com/sites/www.indianaperinatal.org/resource/resmgr/policy_makers/final_indiana_perinatal_hosp.pdf. Retrieved October 24, 2014. ⇦

23. Arizona Perinatal Regional System Inc. Recommendations and guidelines for perinatal and freestanding neonatal care centers in Arizona. 3rd ed. Casa Grande (AZ): APRS; 2012. ⇦

24. Maryland Department of Health and Mental Hygiene. The Maryland perinatal system standards: recommendations of the Perinatal Clinical Advisory Committee. Baltimore (MD): DHMH; 2014. Available at: http://phpa.dhmh.maryland.gov/mch/Documents/Maryland_Perinatal_System_Standards_2013.pdf. Retrieved October 24, 2014. ⇦

25. Vaginal birth after previous cesarean delivery. ACOG Practice Bulletin No. 115. American College of Obstetricians and Gynecologists. Obstet Gynecol 2010;116:45–63. [PubMed] [*Obstetrics & Gynecology*] ⇦

Society for Maternal-Fetal Medicine Grading System: Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Recommendations

Obstetric Care Consensus documents will use Society for Maternal-Fetal Medicine's grading approach: http://www.ajog.org/article/S0002-9378%2813%2900744-8/fulltext. Recommendations are classified as either strong (Grade 1) or weak (Grade 2), and quality of evidence is classified as high (Grade A), moderate (Grade B), and low (Grade C)*. Thus, the recommendations can be 1 of the following 6 possibilities: 1A, 1B, 1C, 2A, 2B, 2C.

Grade of Recommendation	Clarity of Risk and Benefit	Quality of Supporting Evidence	Implications
1A. Strong recommendation, high quality evidence	Benefits clearly outweigh risk and burdens, or vice versa.	Consistent evidence from well performed randomized controlled trials or overwhelming evidence of some other form. Further research is unlikely to change confidence in the estimate of benefit and risk.	Strong recommendations, can apply to most patients in most circumstances without reservation. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
1B. Strong recommendation, moderate quality evidence	Benefits clearly outweigh risk and burdens, or vice versa.	Evidence from randomized controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on confidence in the estimate of benefit and risk and may change the estimate.	Strong recommendation, and applies to most patients. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
1C. Strong recommendation, low quality evidence	Benefits appear to outweigh risk and burdens, or vice versa.	Evidence from observational studies, unsystematic clinical experience, or from randomized controlled trials with serious flaws. Any estimate of effect is uncertain.	Strong recommendation, and applies to most patients. Some of the evidence base supporting the recommendation is, however, of low quality.
2A. Weak recommendation, high quality evidence	Benefits closely balanced with risks and burdens.	Consistent evidence from well-performed randomized controlled trials or overwhelming evidence of some other form. Further research is unlikely to change confidence in the estimate of benefit and risk.	Weak recommendation, best action may differ depending on circumstances or patients or societal values.
2B. Weak recommendation, moderate quality evidence	Benefits closely balanced with risks and burdens; some uncertainty in the estimates of benefits, risks, and burdens.	Evidence from randomized controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an effect on confidence in the estimate of benefit and risk and may change the estimate.	Weak recommendation, alternative approaches likely to be better for some patients under some circumstances.
2C. Weak recommendation, low quality evidence	Uncertainty in the estimates of benefits, risks, and burdens; benefits may be closely balanced with risks and burdens.	Evidence from observational studies, unsystematic clinical experience, or from randomized controlled trials with serious flaws. Any estimate of effect is uncertain.	Very weak recommendation, other alternatives may be equally reasonable
Best practice	Recommendation in which either (i) there is enormous amount of indirect evidence that clearly justifies strong recommendation (direct evidence would be challenging, and inefficient use of time and resources, to bring together and carefully summarize), or (ii) recommendation to contrary would be unethical.		

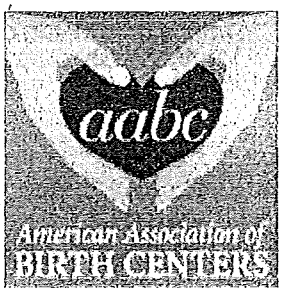
Modified from Grading guide. In: UpToDate, Basow, DS (Ed), UpToDate, Waltham, MA, 2013. Available at: http://www.uptodate.com/home/grading-guide. Retrieved October 9, 2013.

*Guyatt GH, Oxman AD, Vist GE, Kunz R, Falck-Ytter Y, Alonso-Coello P, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. GRADE Working Group. BMJ 2008;336:924–6.

Also published in the *American Journal of Obstetrics and Gynecology*.

Levels of maternal care. Obstetric Care Consensus No. 2. American College of Obstetricians and Gynecologists. Obstet Gynecol 2015;125:502–15.

STANDARDS FOR BIRTH CENTERS



American Association of Birth Centers

America's Birth Center Resource

The Standards for Birth Centers were approved by the Board of Directors of the American Association of Birth Centers on March 30, 1985.

Revisions recommended by the Standards Committee were approved by the Board of Directors and the membership on:

April 4, 1987

September 18, 1992

October 1, 1995

September 27, 1998

September 24, 2000

September 21, 2003

October 7, 2007

October 6, 2012

September 28, 2013

American Association of Birth Centers

America's Birth Center Resource

3123 Gottschall Road, Perkiomenville, PA 18074
Tel. (215) 234-8068 Fax (215) 234-8829
www.BirthCenters.org

Table of Contents

Introduction

National Standards were established to provide a tool for measuring the quality of services provided to childbearing families in birth centers. Quality is a relative term defined by predetermined characteristics, traits, properties or attributes. Therefore, quality improvement is a continuing process toward achieving the predetermined characteristics, traits, properties or attributes defined by the standards for birth centers.

Quality improvement is an ongoing function that is both external and internal to birth center operation. Licensure and accreditation constitute two arms of external evaluation of quality. Licensing agencies protect the public by monitoring compliance to codes, ordinances and a variety of regulations. This first level of external quality control requires that the birth center meet defined criteria for state licensure in order to operate as a business or health care facility. The level of quality required for licensure, however, may vary from one locality to another. Some states and municipalities are non-specific or uneven in their requirements for regulations, while other states may be very specific and uniform in the level of requirements for safe operation.

A second level of external quality evaluation is accreditation. The standards and attributes for accreditation are uniformly applied in all localities, thereby eliminating state and local inconsistency. It is a voluntary program that places the level of quality desired above that which an individual state requires.

The internal quality improvement program is an ongoing evaluation by birth center staff and childbearing families. It begins at the earliest stages of planning for a birth center and consists of a systems approach to evaluation of operation and services. With careful planning, new birth centers have the opportunity to build evaluation mechanisms into all facets of the organization and operation from the first day of operation. If attention is given to establishing a strong program of quality management during the planning of the birth center, application for licensure and accreditation are simply a form of external review – an opportunity to be evaluated or measured by established yardsticks for required and desired levels of excellence.

AABC Standards Development

The first standards of the American Association of Birth Centers (formerly the National Association of Childbearing Centers) represent an effort that evolved over more than a decade beginning with the design of the demonstration Childbearing Center in 1975 by Maternity Center Association (now known as Childbirth Connection) of New York. That demonstration included:

1. Identification of criteria for low risk pregnancy and birth (sample available through AABC).
2. Development of policies and procedures for operation of a birth center within the existing system of health care (sample available through AABC).
3. Design of record forms including an extensive informed consent (sample available through AABC).
4. A health record that reflects the physical care provided as well as the instruction of clients on health relating to pregnancy, birth, and early parenting.
5. Evaluation mechanism for all aspects of the program offered.

The Maternity Center Association also took the concept of the birth center through the official government agencies responsible for protecting the public's health and welfare and met all of the characteristics of quality assurance required by a certificate of need, the health code, building codes, fire and safety code, the federal requirements for controlled substance use and, in the absence of birth center-specific regulations, the regulations for a license to operate as a Diagnostic and Treatment Center in New York State.

In 1979 Maternity Center Association sponsored a national tour of fourteen operating birth centers in fourteen states. The tour was followed by a study of eleven of those centers by Anita Barbey, DrPH that was reported in the *Lancet* in 1982. The study brought attention to an urgent need for birth centers to be able to communicate on matters of common interest and concern.

In 1981 the Cooperative Birth Center Network was established as a program of Maternity Center Association under a grant from the John A. Hartford Foundation to promote quality assurance in the growth of birth centers and to communicate the development of the birth center concept at policy, provider and public levels. In view of the projections for growth and the lack of mechanism to assure quality of services, high priority was given to the development of the Recommendations and Rationale for Regulation of Birth Centers (CBCN News, Vol. 1, Nos. 2-3), support for the development of the American Public Health Association's Guidelines for Licensing and Regulating Birth Centers (CBCN News, Vol. 1, No. 4) and finally, development of national standards and a mechanism for accreditation.

The Childbearing Center of the Maternity Center Association was the first center to seek accreditation. It had been accredited since 1979 by the National League for Nursing/American Public Health Association (NLN/APHA) Council on Accreditation of Community Health Agencies. In 1982 and 1983 meetings were held with the staff of the NLN/APHA accrediting services to examine

the feasibility of birth center accreditation through the established mechanisms of NLN/APHA. Attempts were made to adapt the NLN/APHA standards to fit the special needs of birth centers. However, as the numbers of birth centers increased, it became apparent that obstetricians, family practice physicians and hospitals, as well as nurse-midwives and community health agencies, constituted an expanding market in the establishment of birth centers. Birth center-specific standards and criteria needed to be broadly developed to administer an accreditation program effectively and efficiently for all birth centers.

The possibility of accreditation by the Accreditation Association for Ambulatory Health Care, Inc. (AAAHC) and the Joint Commission on Accreditation of Health Organizations (JCAHO) was also explored. The structure of these organizations, the cost of their services and the fact they would only evaluate hospital or physician-owned centers did not seem to be a viable option for birth centers at that time.

It was decided that a multidisciplinary approach to standards was needed. Thus, the President of the Board of AABC, accompanied by representatives of concerned governmental agencies, consulted with the American College of Obstetricians and Gynecologists (ACOG). ACOG responded that they could not be involved in accreditation for legal reasons and would not be able to participate in writing standards.

The belief that birth centers should be involved in establishing national standards of excellence for their own operation and services motivated MCA to seek funds to work with AABC to establish standards specifically for birth centers and pilot test a cost effective mechanism for accreditation.

Partial funding for the project was obtained by Maternity Center Association from the Pew Charitable Trust. The Pew Grant funded the initial phase to develop the standards and pilot test the application of these standards in the evaluation of ten birth centers selected to reflect the variety of types of centers in terms of ownership, staffing, location and populations served.

The process of accreditation developed by AABC under the pilot program provided the foundation for establishing the independent Commission for the Accreditation of Birth Centers (CABC).

The Standards Committee of the AABC is responsible for periodically reviewing the Standards to assure that they remain consistent with evolving evidence-based maternity care. The Standards Committee, a standing committee of the AABC, has equal representation from the AABC and the CABC, with a Chair who is an AABC Board of Directors member.

The Standards are owned by the AABC, and require membership approval for revision. The CABC Board of Commissioners then develops specific indicators for assessment of compliance with the Standards.

The American Association of Birth Centers recognizes the many people, too numerous to identify, who participated in this effort. We are grateful for their commitment to developing quality services in birth centers.

Standard 1: Planning

STANDARD:

The birth center assesses the needs of the childbearing community in developing services and programs.

Attributes Required for Compliance with Standard:

1. The general geographical area served is defined.
2. Demographic data and vital statistics of the community served are assessed periodically.
   A. Availability of and access to maternal and newborn services including practitioners, hospital obstetrical and newborn services, home birth services, family centered maternity care programs, birth rooms/suites, clinics for disadvantaged families, laboratory services, supplementary social and welfare services, childbirth education and parent support programs are evaluated.
   B. The birth center periodically assesses its impact on the community and assesses the needs of childbearing families in the population served for purpose of program planning and development.
   C. Changes in the population, the environment, regulations, legislation, reimbursement, access to and availability of maternal and newborn services in the community are monitored for impact on the operation of the childbearing center.

Standard 2: Organization

STANDARD:

The birth center is, or is part of, a legally constituted organization with a governing body that establishes policy, lines of responsibility and accountability and, either directly or by delegated authority to qualified individuals, is responsible for fiscal management and operation of the center.

Attributes Required for Compliance with Standard:

1. The birth center is governed as an organization that is separate from other health, hospital or medical services and has its own governing body, or is part of a larger legally constituted healthcare organization and has representation to that governing body.
2. Governing body or the designated birth center directors meet regularly to execute responsibilities for operation of the center and maintains minutes of the meeting.
3. Names and addresses of all owners or controlling parties, directors and officers are maintained and there is a policy on conflict of interest disclosure.
4. Governing body responsibilities, direct or delegated, include but are not limited to:
    A. Formulation of missions, goals and a long range plan for the center
    B. Development of organizational structure and bylaws, which clearly delineate lines of authority and responsibility
    C. Appointment of qualified administrative director
    D. Appointment of qualified director of the professional staff
    E. Approval of policies and procedures for the operation of the center
    F. Approval of qualifications of applicants for professional staff
    G. Approval of a program of quality improvement for the operation of the center and the care provided
    H. Review and action on all legal matters relating to the operation of the center
    I. Financial management and accountability
    J. Establishing charges for services
    K. Prohibition of discrimination in operation and provision of services
    L. Approval of all contracts and agreements with individuals or service agencies, such as hospitals, laboratories, emergency transport, consulting specialists, teaching institutions, and organizations conducting research
    M. Access to and retrieval of all revenue and expense information specific to the birth center
5. The governing body establishes a mechanism for consumer advice on the services and functioning of the birth center.

Standard 3: Administration

STANDARD:

The birth center is administered according to the mission, goals and policies of the governing body in a manner that assures financial viability while promoting high quality services responsive to the needs of the population served.

Attributes Required for Compliance with Standard:

1. The mission, philosophy and goals of the birth center are clearly stated.
2. A qualified individual is designated by the governing body as administrative director with authority, responsibility and accountability for overall center administration. There is a plan for the operation of the center in the absence of the administrative director.
3. There is evidence of adherence to generally accepted accounting principles including but not limited to a review of financial statements every six (6) months and approval of the annual budget by documentation in minutes from meetings of the governing board or its directors.
4. Capital expenditures as may be required for the continued effective operation of the center are anticipated and planned for as documented in the minutes of the governing body. There is a plan for the investment of funds beyond what may be required for current operations.
5. There are policies and procedures for maintenance of equipment, building and grounds, as well as control of the use of the facility.
6. There is orderly maintenance and secure storage of official documents of the center.
7. Personnel policies and procedures are maintained (See section on Personnel).
8. Contracts for student education or field experience are approved by the governing body or its designee.
9. The center carries liability insurance. Where liability insurance is not available, the center notifies clients that the center does not carry liability insurance.
10. There are agreements and/or policies and procedures for interaction with other agencies, institutions and individuals for services to clients including but not limited to:
    A. Obstetric/newborn acute care in licensed hospitals
    B. Transport services
    C. Obstetric consultation services
    D. Pediatric consultation services
    E. Laboratory and diagnostic services
    F. Childbirth education/parent education support services
    G. Home health care services

11. All contracts, agreements, policies and procedures are reviewed annually and updated as needed.
12. There is a plan for informing the community of the services of the center.
13. The center complies with applicable local, state and federal regulations for protection of client privacy and safety.

Standard 4: Facility, Equipment and Supplies

STANDARD:

The birth center establishes and maintains a safe, home like environment for healthy women anticipating an uncomplicated labor and birth with space for furnishings, equipment and supplies commensurate to comfortable accommodation for the number of childbearing families served and the personnel providing services.

Attributes Required for Compliance with Standard:

FACILITY

1. Complies with regulations for licensure of birth centers if established for its jurisdiction.
2. Complies with applicable local, state and federal codes, regulations and ordinances for construction, fire prevention, public safety and access.
3. In the absence of community fire regulations the birth center maintains functioning smoke alarms, appropriately placed fire extinguishers to control limited fires and emergency fire lighting; identifies exits; protects stairwells with fire doors.
4. Maintains a record of routine periodic inspections by Health Department, Fire Department, Building inspectors and other officials concerned with public safety, as required by the center's local jurisdiction.
5. Provides instruction of all personnel on fire safety and conducts at least semiannual evacuation drills.
6. Prohibits smoking in the birth center.
7. Guards against environmental factors that may cause injury from falls, electrical shock, poisoning and burns; with particular attention to hazards to children such as uncovered electrical outlets, unsafe toys, unprotected stairs and unlocked storage cabinets as well as walkways, parking lots and outside play areas.
8. Provides adequate ventilation and lighting.
9. Provides adequate space for caseload and personnel and insures privacy for women and childbearing families including but not limited to:
    A. Business operations
    B. Secure medical records storage
    C. Waiting reception area
    D. Exam rooms
    E. Family room and play area for children
    F. Bath and toilet facilities for families, laboring women and staff

G. Birth rooms
H. Staff area
I. Educational facilities/library
J. Utility and work area
K. Storage
L. Area for emergency care of the newborn
M. Accommodation for a non-ambulatory family member (non-ambulatory childbearing women are not usually cared for in birth centers).

10. Provides adequate housekeeping services to maintain a sanitary, home like environment.
11. Provides adequate hand washing facilities for childbearing families and personnel.
12. Provides adequate space for coats, boots and umbrellas in inclement weather where appropriate.
13. Provides adequate sanitary trash storage and removal including biomedical waste and human tissue.
14. Has a disaster plan in place, including equipment or plan for snow removal where appropriate, and to secure the facility in the event of floods, major storms, etc.

EQUIPMENT

15. A readily accessible emergency cart or tray for the mother is equipped to carry out the written emergency procedures of the center and securely placed with a written log of routine maintenance for readiness.
16. A readily accessible emergency cart or tray for the newborn is equipped to carry out the written emergency procedures of the center and securely placed with a written log of routine maintenance for readiness.
17. Properly maintained equipment for routine care of women and neonates including but not limited to:
    A. A heat source for infant examination or resuscitation
    B. Transfer isolette or demonstrated capability of ready access to transport
    C. Sterilizer or demonstration of sterilizing capability
    D. Blood pressure equipment, thermometers, fetoscope/doptone, equipment for newborn exam and resuscitation
    E. Intravenous equipment
    F. Oxygen equipment for mother and newborn
    G. Instruments for delivery, episiotomy and repair

18. Provides properly maintained accessory equipment which includes but is not limited to:
    A. Conveniently placed telephones
    B. Portable lighting
    C. Kitchen equipment usually found in home for light refreshment
    D. Laundry equipment usually found in home or contracted laundry services

SUPPLIES

19. The inventory of supplies is sufficient to care for the number of childbearing women and families registered for care.
20. Shelf life of all medications, I.V. fluids and sterile supplies is monitored.
21. Supplies such as needles, syringes, and prescription pads are appropriately stored to avoid public access.
22. Controlled drugs are maintained in double-locked, secured cabinets with a written procedure for accountability.
23. Used hazardous supplies, such as needles and expired drugs, are disposed of properly.

Standard 5: Quality of Services

STANDARD:

The birth center provides high quality, family centered, maternal and newborn services to healthy women anticipating an uncomplicated pregnancy, labor and birth that reflect the following:

- Applicable professional standards for conduct of the practitioners responsible for services rendered;
- Available scientific evidence;
- Recognition of the basic human rights of the childbearing woman and her family.

Attributes Required for Compliance with Standard:

1. That the rights and responsibilities of the woman and her family, however she defines her family, are clearly delineated in the center's policies and procedures and communicated to the childbearing family on acceptance for care and that the client's rights include but not be limited to:
   A. Be treated with respect, dignity and consideration
   B. Be assured of confidentiality
   C. Be informed of the benefits, risks and eligibility requirements of an out of hospital labor and birth
   D. Be informed of those services provided by the center and those services provided by contract, consultation and referral
   E. Be informed of the identity and qualifications of care providers, consultants and related services and institutions
   F. Be informed of all diagnostic procedures and reports, all recommendations and treatments
   G. Participate in decisions relating to the plan for management of her care and all changes in that plan once established including referral or transfer to other practitioners or other levels of care
   H. Be provided with a written statement of fees for services and responsibilities for payment
   I. Be informed of the center's plan for provision of emergency and non-emergency care in the event of complications in mother and newborn
   J. Be informed of the client's rights with regards to participation in research or student education programs
   K. Be informed of the center's plan for hearing grievances

2. That the center provide or demonstrate availability of a range of services to meet physical, emotional, socio economic, informational and medical needs of the individual client while under care including but not limited to:
   A. An orientation to the facility fees and services of the center
   B. Written information, including a glossary of terms, on the established criteria for admission to, and continuation in, the birth center program of care as appropriate for the demographics of the center's client population
   C. Information about the risks and benefits of any test or procedure being offered or recommended
   D. Prenatal care (may be provided at related practitioner or clinic site)
   E. A program of education for pregnancy, labor, breastfeeding, infant care, early discharge, parenting, self care/self help, sibling preparation
   F. Laboratory services
   G. 24 hour telephone consultation and provider availability
   H Library resources
   I. Intrapartum Care
   J. Light nourishment during labor and postpartum
   K. Immediate postpartum care
   L. Referrals to meet the needs of each client outside the scope of birth center practice
   M. Home or office follow up for mother and newborn
   N. There shall be strong evidence that the birth center is addressing domestic violence as an issue with birth center clients.
   O. There shall be evidence of screening, education, and referral for postpartum mood disorders
   P. Family planning

   Additional Options:

   Q. Exercise programs
   R. Parent support groups
   S. Postpartum classes
   T. Well baby care
   U. Circumcision
   V. Nursing mother support program
   W. Well woman gynecologic care
   X. Public education
   Y. Professional education
   Z. Clinical investigation and/or research

3. That drugs for cervical ripening and induction are not appropriate for use in birth centers.
4. That drugs for augmentation of labor, vacuum extractors, forceps, and recorded electronic fetal monitors are not appropriate for use after admittance in active labor in birth centers. Clients requiring these interventions should be transferred to an appropriate facility.
5. That a policy and procedure manual meeting current standards of care is available to practitioners and support staff at all times and that it include all aspects of birth center practice and care to childbearing families, including but not limited to:
   A. Prenatal risk assessment and birth center eligibility
   B. Routine prenatal care
   C. Normal labor and birth
   D. Neonatal assessment and resuscitation
   E. Routine postpartum care of the mother and newborn
   F. Intrapartum, postpartum and neonatal management of deviations from normal and referral/transfer protocols
6. Practice protocols be provided to the consulting specialists and available to the hospital receiving transfers upon request.

Standard 6: Staffing and Personnel

STANDARD:

High-quality family centered maternal and newborn care is provided by qualified professional and clinical staff with access to and availability of consulting clinical specialists and support by administrative and ancillary personnel consonant with the volume of clients enrolled for care and reflective of the services and program offered.

Attributes Required for Compliance with Standard:

1. Professional staff and consulting specialists provide evidence of the knowledge and skills required to provide the services offered by the center.
2. Professional staff and consulting specialists are licensed to practice their profession in the jurisdiction of the birth center.
3. Professional staff and consulting specialists provide evidence of malpractice insurance coverage and if not available inform clients that they do not carry malpractice insurance.
4. There are adequate numbers of professional and support staff on duty and on call to meet demands for services routinely provided, and in periods of high demand or emergency, to assure client safety and satisfaction; and to assure that no mother in active labor shall remain unattended.
5. There is an established, posted schedule for clinical staff and consulting specialists.
6. At each birth there shall be two staff currently trained in:
    A. Adult cardiopulmonary resuscitation equivalent to American Heart Association Class C basic life support
    B. Neonatal resuscitation endorsed by American Academy of Pediatrics/American Heart Association
7. Personnel records are maintained and secured for confidentiality on all employed, attending, and contracted staff and include but are not limited to:
    A. Qualifications
    B. Current license where indicated
    C. Health examinations where required
    D. Malpractice insurance carrier or explanation of why malpractice insurance is not obtainable
    E. Evidence of malpractice claims
    F. Annual performance evaluations and/or peer review
    G. Evidence of current training in CPR and neonatal evaluation and resuscitation

8. There are written personnel policies available to all personnel that include but are not limited to:
    A. Conditions of employment
    B. Respective obligations of employer and employee
    C. Benefits
    D. Affirmative action
    E. Grievance procedures
    F. Sexual harassment and workplace violence
9. The birth center provides for professional and non-professional staff development including but not limited to:
    A. Orientation of new staff, including emergency drills.
    B. Reference library
    C. Current journal subscriptions or online resources
    D. In service education programs to maintain currency in knowledge and skills used infrequently in birth center practice
    E. Participation in continuing professional education programs
    F. Involvement in activities of professional organization
    G. Routine, periodic maternal and newborn medical emergency drills
10. All birth center employees who are exposed to blood should have full immunization against hepatitis B or documentation of refusal.
11. Birth center personnel shall have annual training that meets OSHA regulations and any other applicable infection control guidelines.
12. Training as required by state and federal law in the area of patient safety and privacy.

Standard 7: The Health Record

STANDARD:

Health records of the birth center provide a format for continuity and documentation of legible, uniform, complete and accurate maternal and newborn information readily accessible to health care practitioners and maintained in a system that protects confidentiality, provides for storage, retrieval and prevention of loss.

Attributes Required for Compliance with Standard:

1. The birth center adopts a record form appropriate for use by the practitioners in the birth center containing information required for transfer to the acute care maternal and newborn hospital service.
2. The health record on each client includes, but is not limited to, written documentation of:
   - A. Demographic information and client identification
   - B. Orientation to program and informed consent and including a plan for payment of services
   - C. Complete social, family, medical, reproductive, nutrition and behavioral history
   - D. Initial physical examination, laboratory tests and evaluation of risk status
   - E. Appropriate referral on ineligible clients with report of findings on initial screening
   - F. Continuous periodic prenatal examination and evaluation of risk factors
   - G. Instruction and education including nutritional counseling, changes in pregnancy, self-care in pregnancy, orientation to health record and understanding of findings on examinations and laboratory tests, preparation for labor, sibling preparation, preparation for early discharge, newborn assessment and care
   - H. History, physical examination and risk assessment on admission to the center
   - I. Monitoring of progress in labor with ongoing assessment of maternal and fetal reaction to the process of labor in accordance with accepted professional standards
   - J. Consultation, referral and transfer for maternal or neonatal problems including outcome of transfers.
   - K. Labor and birth summary
   - L. Physical assessment of newborn including Apgar scores, gestational age assessment, maternal newborn interaction, prophylactic procedures, and accommodation to extrauterine life and blood glucose when clinically indicated
   - M. Ongoing physical assessment of the mother and newborn during recovery
   - N. Discharge summary for mother and newborn
   - O. Plan for home care, follow up, referral to support groups
   - P. Plan for newborn health supervision and required screening tests

Q. Late postpartum evaluation of mother, counseling for family planning and other services

R. Screening and referral for postpartum mood disorders

3. Reports of laboratory tests, treatments and consultations are entered promptly on health records.

4. There is a mechanism for providing the birth center with a copy of the prenatal record before labor and for sending a copy of the health record with the mother and/or newborn on referral or transfer to other levels of care.

5. Health records are protected to insure safe confidentiality and prevent loss but are available to practitioners on a 24 hour basis.

6. There is a system for periodic review of individual client records and attention to problems identified.

7. A medical record system is established with periodic review, by a qualified individual, of the center's system and policies and procedures for the maintenance, storage, retrieval and retirement of health records consistent with regulatory requirements.

8. Responsibility and accountability for the processing of health records is assigned to an individual employed by or contracted with the center.

9. Disclosure of all protected health information is made in compliance with federal and state regulations.

Standard 8: Evaluation of Quality of Care

STANDARD:

There is an established program for evaluating the quality of direct care services to childbearing families, and the environment in which the services are provided, with an organizational plan to identify and resolve problems.

Attributes Required for Compliance with Standard:

1. The quality improvement program for direct maternal newborn care includes but is not limited to:
    A. At least annual review of protocols, policies and procedures relating to the maternal and newborn care
    B. The appropriateness of the risk criteria for determining eligibility for admission to and continuation in the birth center program of care
    C. The appropriateness of diagnostic and screening procedures, such as laboratory studies, sonography, and fetal surveillance tests as they impact on quality of care and cost to the client
    D. The appropriateness of medications prescribed, dispensed or administered in the birth center
    E. The evaluation of performance of clinical practitioners practicing in the center (including peer review and self-evaluation)
    F. Regular meetings of clinical practitioners to review the management of care of individual clients and make recommendations for improving the plan for care
    G. Regular review of all transfers of mothers and neonates to hospital care to determine the appropriateness and quality of the transfer
    H. Regular review and evaluation of all problems or complications of pregnancy, labor and postpartum and the appropriateness of the clinical judgment of the practitioner in obtaining consultation and managing the problem
    I. Evaluation of staff on ability to manage emergency situations by periodic drills for fire, maternal/newborn emergencies, power failures, and natural disasters, that are held regularly, and evaluation of management of actual emergencies
2. The quality improvement program for maintaining a safe, home like environment includes but is not limited to:
    A. Routine testing of the efficiency and effectiveness of all equipment (e.g. sphygmomanometer, doptones, sterilizers, resuscitation equipment, transport equipment, oxygen equipment, communication equipment, heat source for newborn, smoke alarms, fire extinguishers)
    B. Routine review of housekeeping procedures and infection control

C. Evaluation of maintenance policies and procedures for heat, ventilation, emergency lighting, waste disposal, water supply and laundry and kitchen equipment

3. The quality improvement program monitors and promotes quality of care to clients and the community through an effective system for collection and analysis of data which includes but is not limited to:

   A. Utilization of the following services:
      1) orientation sessions
      2) childbirth related educational programs
      3) time in birth center before birth
      4) time in center after birth
      5) home visits postpartum
      6) follow up office visits postpartum (mother)
      7) follow up office visits for newborn
      8) type of anesthesia/analgesia used

   B. Outcomes of care provided:
      1) women registered for care
      2) antepartum attrition rate
      3) antepartum transfer rate
      4) women admitted to center for intrapartum care
      5) births in the center
      6) births enroute to the center
      7) maternal intrapartum transfer rate
      8) maternal postpartum transfer rate
      9) newborn transfer rate
      10) type of delivery: NSVD or other
      11) episiotomies
      12) third and fourth degree lacerations
      13) cesarean and operative vaginal delivery rates
      14) infants with birth weight: less than 2500 grams or greater than 4500 grams
      15) Apgar scores less than 7 at five minutes
      16) neonatal mortality and morbidity
      17) maternal mortality and morbidity

   C. Reasons for transfers:
      1) antepartum
      2) intrapartum, including pre-admit transfers
      3) postpartum
      4) newborn

4. The quality improvement program evaluates client satisfaction with services provided, and demonstrates a plan to address issues/concerns raised by clients.

5. When appropriate, outside consultation/expertise is sought to review problems identified by the quality improvement program.

6. Action to resolve problems is initiated and includes but is not limited to:
   A. Administrative or supervisory action
   B. In-service education
   C. Modification of policies and procedures
   D. Revision of risk criteria
   E. Revision of health record or other record forms
7. The quality improvement program includes re-evaluation to determine the action taken has resolved the identified problem.

Standard 9: Research Activities

Preamble:

The term "research" could be used in reference to gathering and analyzing information on at least two levels of effort in a freestanding birth center. One level is the variety of investigations that relate to individual or multicenter studies in areas of market research, operation reporting, outcome analysis and reporting, or user evaluation of programs and services. Protocols must be established to protect the confidentiality of client information in these endeavors. Human subject protections as outlined by the U.S. Federal Office for Protection from Research Risks (OPRR) Guidelines should also be followed and documented as appropriate in either level/type of research mentioned in this document. This is especially important in that birth center research of any type usually involves subjects which are considered "vulnerable populations" (i.e. pregnant women and their infants).

This standard applies primarily to the second level of research that involves direct or hands on physical, emotional involvement of the birth center's clients when the center is involved in individual or multicenter trials of the use of:

A) Investigational drugs, devices or procedures deemed safe in the acute care setting such as, but not restricted to, medicines or procedures for altering the women's progress in labor, medicines or procedures for relief of pain or other interventions for use in the perinatal period;

or

B) Alternative therapies which may seem appropriate for use in birth centers such as, but not restricted to, water birth, homeopathic or herbal medicines, or other alternative interventions/therapies for use in the perinatal period ("alternative" is defined here as primarily low technology interventions which are not generally used in the mainstream medical/hospital setting). Alternative therapies must have some prior evidence which suggests they can be used safely in a birth center setting on pregnant or laboring women.

STANDARD:

When research is conducted by the birth center or by the employees or affiliates of the birth center or when the birth center is used as a research site, such that the birth center patients and/or staff are the subjects of research, the research must be conducted by qualified researchers (defined here as having evidence in formal training and/or experience in the conduct of clinical, epidemiologic, or sociologic research) in accordance with written approved research policies and procedures by staff trained to conduct such research and in a manner that protects the client's health, safety and right to privacy, and protects the birth center and its clients from unsafe practices.

Attributes Required for Compliance with Standard:

1. Protocols for conducting research are approved by an Institutional Review Board or Human Investigation Committee and the governing body of the birth center after review by professional staff and by appropriate birth center medical consultants.
2. Any research activities carried out within the organization are appropriate to the expertise of staff and the resources of the organization.
3. Rights and welfare of every research subject are adequately protected.
4. Research activity is monitored and progress periodically reported to the governing board.
5. Final results of research activity are reported to AABC, for consideration and dissemination to other birth centers, and for consideration by the AABC Standards Committee for possible incorporation in accepted birth center standards of practice.