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Evaluation of the Quality of Care and Outcomes for Services Provided in Licensed Birth Centers

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I. Executive Summary

During the 2010 Legislative Session, Minnesota Statutes §144.615 was passed which directed the Minnesota Department of Health to license free-standing birth centers beginning January 1, 2011. The law also required the Department to evaluate the quality of care and outcomes in services provided in licensed birth centers and report findings of that evaluation to the legislature by January 15, 2014. As part of the evaluation, the Department was to consult with several organizations including the Minnesota Department of Human Services, representatives of the licensed birth centers, American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, the Minnesota Hospital Association, and the Minnesota Ambulance Association.

This report includes the finding of that evaluation. It also provides a brief overview of birth centers, explains the accreditation and licensure process, and includes national data on the safety and quality of birth centers.

Since the law was enacted, only five birth centers have been licensed by the Department. Two of those five birth centers, were recently licensed. The five licensed birth centers include: Alicia's Care Center in Eagle Bend, MN; Health Foundations Family Health and Birth Center in St. Paul, MN; Minnesota Birth Center in South Minneapolis, MN; Morning Star Women's Health and Birth Center in St. Louis Park, MN; and, Morning Star Women's Health and Birth Center in Duluth, MN.

One of the five birth centers, MDH withheld a license pending full accreditation by the Commission for the Accreditation of Birth Centers (CABC), and compliance with the licensure law which included evidence of no actions by the birth center that could be considered detrimental to the health and welfare of birth center clients.

MDH also reviewed complaint records from the Office of Health Facility Complaints, and found that only one complaint was received against a birth center. That complaint did not involve actual harm done to a birthing center client, but rather the complaint was related to a staffing concern which was investigated and determined that no violation had occurred and no further action was needed.

Regarding data on quality of care and outcomes in services provided in Minnesota licensed birth centers, MDH learned early on in the evaluation that such data is limited, in part because some of the birth centers were just recently licensed and others have only been licensed for a few years. Also, much of the data is voluntary and/or self-reported. The most comprehensive data available

at this time is the birth record information that is maintained by the MDH Centers for Health Statistics. However, that data had limitations too as it did not include reasons for transfer of mother or baby as directed by the legislation.

Data that was obtained from Minnesota birth records seems to support the national studies that were published in 1989 and more recently in 2013 on the quality and safety of birth centers. Those studies showed that birth centers can be a safe and effective option for low-risk women choosing to give birth in a non-hospital setting. The Minnesota birth record data suggests that mothers using licensed birth centers are more likely than other mothers to have received adequate prenatal care and were far less likely to give birth prematurely or to have a low birth weight baby. However, it's important to note that, the numbers of mothers using birth centers is small in comparison to total births and thus percentages may fluctuate widely from year to year. To yield more meaningful results it is not only recommended, but common statistical practice, to use five years of data to analyze small numbers of data. Unfortunately that was not possible with this study because birthing centers have been licensed in Minnesota for fewer than four years. Also, according to Minnesota Stats. §144.615,, Sub. 1, birth centers are only allowed to serve low risk pregnant women, whereas hospitals serve low risk and high risk pregnant women. This makes it difficult to make accurate comparisons between the two without further data collection and analysis.

In the future, better data should be available because the Commission for the Accreditation of Birth Centers is going to start requiring all accredited birth centers to participate in the American Association of Birth Centers (AABC) Perinatal Data Registry (PDR), (formerly called the Uniform Data Set or UDS), beginning with the birth center's next site visit. The PDR is an online data registry for the ongoing collection of perinatal data in all settings (hospital, birth centers, home) and by all providers (Certified Nurse Midwives, Certified Professional Midwives, OBGYNs, Family Physicians) who provide maternity services. The AABC PDR 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. MDH believes that this new requirement should help to provide more comprehensive and meaningful data on the quality of care and outcomes in services provided in Minnesota licensed birth centers and nationally.

Besides analyzing data for this report, the Department also consulted with a variety of stakeholders regarding their experiences with birth centers and requested comments and recommendations. Those comments are included in detail within the report.

With the licensure of birth centers in Minnesota being fairly new, data on quality of care and outcomes in services provided in licensed birth centers is limited. As more data becomes available on birth centers, MDH will have a better sense of the true quality of care and safety that is provided in all Minnesota licensed birth centers. The CABC's new requirement that all

accredited birth centers participate in a national data registry should be able to provide that picture for MDH, as Minnesota licensed birth centers will be included in that data base. Until then, MDH can only rely on data obtained from Minnesota birth records, complaints received by the Office of Health Facility Complaints, and concerns from stakeholders.

II. Introduction

A. Report Requirements

Minnesota Statutes §144.615 was passed in 2010 which directed the Minnesota Department of Health to license free-standing birth centers beginning January 1, 2011. The law also required the Department to evaluate the quality of care and outcomes in services provided in licensed birth centers and report findings of that evaluation to the legislature by January 15, 2014. Below is the legislative language regarding the evaluation and report requirement. A copy of the entire birthing center licensing law is available at https://www.revisor.mn.gov/statutes/?id=144.615

Subd. 11. Report.

(a) The commissioner of health, in consultation with the commissioner of human services and representatives of the licensed birth centers, the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, the Minnesota Hospital Association, and the Minnesota Ambulance Association, shall evaluate the quality of care and outcomes for services provided in licensed birth centers, including, but not limited to, the utilization of services provided at a birth center, the outcomes of care provided to both mothers and newborns, and the numbers of transfers to other health care facilities that are required and the reasons for the transfers. The commissioner shall work with the birth centers to establish a process to gather and analyze the data within protocols that protect the confidentiality of patient identification.

(b) The commissioner of health shall report the findings of the evaluation to the legislature by January 15, 2014

This report, prepared by staff in the Compliance Monitoring Division at MDH, includes the finding of that evaluation. It also provides a brief overview of birth centers, explains the accreditation and licensure process, and includes national data on the safety and quality of birth centers.

B. Background Information on Birth Centers

1. <u>Birth Center Definition and Concept</u>

The American Association of Birth Centers (AABC) defines a birth center as "a home-like-setting where care providers, usually midwives, provide family-centered care to healthy women before, during and after normal pregnancy, labor and birth". ¹

Minn. Stat. §144.615, subd. 1(b), defines a birth center as a "facility licensed for the primary purpose of performing low-risk deliveries that is not a hospital or licensed as part of a hospital and where births are planned to occur away from the mother's usual residence following a low-risk pregnancy." A low-risk pregnancy, as defined in Minn. Stats. §144.615, subd. 1. (d), is "a normal, uncomplicated prenatal course as determined by documentation of adequate prenatal care and the anticipation of a normal, uncomplicated labor and birth, as defined by reasonable and generally accepted criteria adopted by professional groups for maternal, fetal, and neonatal health care." All birth centers are required to have procedures in place specifying criteria by which risk status will be established and applied to each woman at admission and during labor (See Minn. Stat. §144.615, subd. 6.) The law limits services in a birth center to those surgical procedures that are normally performed during an uncomplicated birth, including episiotomy and repair. No abortions may be administered and no general or regional anesthesia may be administered. Local anesthesia may be administered at a birth center if the administration of the anesthetic is performed within the scope of practice of a health care professional (See Minn. Stat. §144.615, subd. 7.)

Birth centers screen their clients to ensure the mother remains healthy and low-risk during pregnancy. They also offer extensive education throughout pregnancy to empower women to feel confident making informed decisions about their own and their baby's health care. Staff hold to the "wellness" model of birth, which means that they provide continuous, supportive care and interventions are used only when medically necessary. During labor, interventions that may be considered standard routine in a hospital, such as IV's, continuous electronic fetal monitoring, induction of labor, or epidurals, are not routine interventions found in a birth center. Birth centers encourage active birth with frequent position changes, hydrotherapy in the tub or shower including water birth, eating and drinking while in labor, wearing one's own clothing, immediate skin-to-skin contact with the baby, and breastfeeding, among other things. The freestanding birth center setting encourages specialized care to each woman's individual needs and concerns. ²

¹ American Association of Birth Centers, What is a birth center. Available at http://www.birthcenters.org/forparents/what-is-birth-center.

² From Minnesota Birth Center website, available at http://theminnesotabirthcenter.com/

2. Birthing Center Staff

Most birth centers have midwives as the primary care providers working with physicians and hospitals in a team approach to maternity care. Midwifery, as practiced by Certified Nurse Midwives (CNM) and Certified Midwives (CM), encompasses a full range of primary health care services for women from adolescence to beyond menopause. These services include primary care, gynecological and family planning services, preconception services, care during pregnancy, childbirth, and the postpartum period, care of the normal newborn during the first 28 days of life and treatment of male partners for sexually transmitted diseases. Midwives provide initial and ongoing comprehensive assessments, diagnosis and treatment. They conduct physical examinations; prescribe medications including controlled substances and contraceptive methods; admit, manage and discharge patients; order and interpret laboratory and diagnostic tests and order the use of medical devices. Midwifery care also includes health promotion, disease prevention, and individualized wellness education and counseling. Besides birth centers, midwifes can practice in ambulatory care clinics, private offices, community and public health systems, homes, and hospitals.³

There are different types of midwives with varying degrees of education and scopes of practices working in licensed birth centers. The Certified Nurse Midwives is the most common type of midwife providing care in birth centers, but some have a mix of Certified Nurse Midwives (CNM), Certified Midwife (CM), and Certified Professional Midwife (CPM). The following link provides a chart that compares CNM, CM and CMP, including their education and training level and scope of practice:

http://www.midwife.org/acnm/files/cclibraryfiles/filename/00000001031/cnm%20cm%20cpm %20comparison%20chart%20march%202011.pdf. 4

The Commission for the Accreditation of Birth Centers (CABC) requires midwifes working in birth centers to be licensed according to the state's licensing laws, and MDH's application for licensure of a birth center requires applicants to list the names and license numbers of health professionals on staff at the birth center. In Minnesota CNMs are licensed by the Minnesota Board of Nursing and CPMs are licensed by the Minnesota Board of Medical Practice. According to data from the Board of Nursing, as of December 31, 2013 there were 263 Certified Nurse-Midwives licensed in the state. Licensing statistics from the Board of Medical Practice,

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³ American College of Nurse Midwives, (2011) Definition of Midwifery and Scope of Practice of Certified Nurse Midwives and Certified Midwives.

⁴ American College of Nurse Midwives website, Comparison of Certified Nurse-Midwives, Certified Midwives, and Certified Professional Midwives, available at http://www.midwife.org/acnm/files/cclibraryfiles/filename/00000001031/cnm%20cm%20cpm%20comparison%20chart%20march%202011.pdf

⁵ Minnesota Board of Nursing, available at https://www.hlb.state.mn.us/mbn/reports/current_statistics.pdf

dated November 5, 2013, states that there are only 22 Traditional Midwifes/Certified Professional Midwives licensed in the state (20 located in MN).⁶

Besides Midwives, other staff who may work in birth centers include registered nurses, physician assistants, an MD/obstetrician who may also serve as a medical director, nutritionists, certified medical assistants, and administrative staff.

3. How Hospitals and Birth Centers Work Together

Most birth centers are considered free-standing birth centers which are located separately from a hospital. There are a few in-hospital birth centers which are required to meet certain standards for independence and must be separate from the Labor and Delivery Unit in a hospital in order to be considered a legal birth center. For example, Hennepin County Medical Center has a midwifery led unit within its hospital which is licensed by the Minnesota Department of Health and is accredited by the Joint Commission on the Accreditation of Health Care Organizations. This report will focus on free-standing birth centers only, as directed by the legislation and as licensed by the Minnesota Department of Health.

Even though hospitals and birth centers operate independently, birth centers that are accredited by the Commission for the Accreditation of Birth Centers (CABC) and meet the standards of the American Association of Birth Centers, are integrated within the health care system. They may refer clients to physician care or transfer to a hospital if medical needs arise. Some midwives in birth centers also have hospital privileges, so there is no interruption in care if a woman needs to be transferred. In other cases, the midwives will stay with the mother through the transfer and provide support. ⁷

4. Number of Women Who Give Birth in Hospitals and Birth Centers

According to statistics from the National Vital Statistics Reports (data from 2010), there are nearly 4 million births each year in the U.S. Approximately 99% of births take place in hospital labor and delivery units, with physicians attending 86% of those births. In contrast, only 0.3% of births take place in birth centers, where certified nurse midwives (86%) and midwives provide

⁶ Minnesota Board of Medical Practice, http://mn.gov/health-licensing-boards/medical-practice/licensees/statistical-data/

⁷ American Association of Birth Centers. What is a birth center. Available at http://www.birthcenters.org/for-parents/what-is-birth-center.

most of the care. ⁸ Among the women who give birth in hospitals, approximately 85% are considered low-risk. ⁹ The number of births taking place in birth centers will likely grow as birth centers become more accepted and integrated into the health care system as a safe and cost effective model of maternity care.

5. History of Birth Centers in Minnesota

The first out of hospital birth center in Minnesota was the Stork's Nest, which was established in March of 2002, in north Moorhead, Minnesota. It was a one-bed birthing center that was developed out of consumers' need for a non-hospital, non-home, birth place. The center was managed by a licensed traditional midwife who had 20 years of experience providing home births. It was at that time that the debate started about whether the center needed to be licensed, what state agency had jurisdiction, how it should be licensed, etc. The Stork's Nest was considered unique in that it did not fit the typical hospital licensure laws, in part because it did not have 5 or more beds. The Stork's Nest has since closed due to the high cost of medical liability insurance.

III. Licensure of Birth Centers in Minnesota

A. State Licensure Requirements

As stated previously, Minn. Stats. §144.615 requiring MDH to license birth centers was enacted in 2010. In order to be eligible for licensure in Minnesota, a birth center must be accredited by the Commission for the Accreditation of Birth Centers (CABC), a national accrediting organization, or it must obtain accreditation within six months of the date of their application for licensure. MDH may grant a temporary license for up to six months while a birth center seeks accreditation. If the accreditation has not been completed within six months, the Department may extend that temporary license for an additional six months. During the licensure review

⁸ Goer H, Romano AM. Optimal care in childbirth: The case for a physiologic approach. Seattle, WA: Classic Day Publishing: 2012. Available at http://www.optimalcare inchildbirth.com/

⁹ Martin JA, Hamilton BE, Ventura SF, et al. Births: Final data for 2010. National Vital Statistics Reports. 2012;16, Available at http://www.cdc.gove/nchs/data/nvsr/nvsr61 01.pdf.

process, the Department may request that the birth center provide the Department materials submitted to the CABC as part of the accreditation process, including the accreditation application, self-evaluation report, the accreditation decision letter, and any reports following the CABC's site visits. ¹⁰

B. National Accreditation Process

The CABC's accreditation process involves an extensive review of all aspects of business and clinical operations of the applicant birth center, including but not limited to:

- 1. A detailed self-evaluation report from the birth center.
- 2. A 2-day site visit to verify the materials in that report. The site visitors do not make the accreditation decision, but serve to verify, amplify and clarify materials and findings from the site visit and self-evaluation report. This process includes:
 - A complete review of all birth center clinical and administrative policies and procedures
 - Assessment for good business practices to enhance birth center viability and continuity for consumers;
 - Review of personnel files to confirm appropriate credentials and certifications;
 - Review of risk criteria and transfer procedures;
 - Evaluation of risk management and Continuous Quality Improvement programs for thoroughness and implementation;
 - Detailed chart reviews;
 - Review of required birth center clinical outcome statistics;
 - Meticulous facility inspection; and,
- Interviews with birth center staff, collaborative physicians and hospital personnel.
- 3. A team of panelists then review all materials and make the final decision regarding accreditation. 11

There are times when the CABC decision is to "Accredit with Requirements," which means the birth center has to meet certain standards or conditions before they are fully accredited. Birth centers have 90 days to meet those standards before being fully accredited.

11 From the Commission for the Accreditation of Birth Centers website available at https://www.birthcenteraccreditation.org/find-accredited-birth-centers/cabc-accreditation-process/

¹⁰ Office of the Revisor of Statutes, Minn. Stat. 144.615, website available at https://www.revisor.mn.gov/statutes/?id=144.615

After a birth center has been accredited, the birth center provides MDH with a copy of the accreditation decision letter. The Department then issues a permanent license to the birth center which is effective for two years. The birth center must renew its license with the Department every two years.

As part of the CABC accrediting process, the CABC conducts site visits of accredited birth centers every three years to check compliance with standards. At least annually, birth centers are required to submit an Interim Report to the CABC that includes information such as new policies and procedures, changes in ownership or administration, and any adverse outcomes.

With the CABC's standards for accreditation and monitoring of birth centers, MDH relies on the CABC for monitoring and surveying birth centers. MDH may refuse to grant or renew, or may suspend or revoke a license according to any of the grounds described under section 144.55, subd. 6., or upon the loss of accreditation by the CABC.

There was one instance when MDH used its authority granted in the above mentioned law and refused to grant a license to a birth center until it had achieved full accreditation by the CABC and provided evidence of no actions that could be considered detrimental to the health and welfare of the birth center clients. For several months, the birth center had to suspend deliveries while it worked with the CABC and the Department to meet standards for accreditation and licensure.

While the CABC conducts most of the monitoring of licensed birth centers, MDH does investigate complaints regarding the quality of care provided to birth center clients. MDH received its first complaint against a birth center in November 2013. The complaint was in regard to a free-standing birth center that allegedly employed unlicensed midwives. The complainant stated that there was no harm done to clients, but that they were concerned about proper staffing levels. MDH's investigation into this matter revealed that the unlicensed midwife was licensed in another state but not yet in Minnesota, and was only providing administrative and training assistance to the birth center. She was not providing care to birth center clients. It was determined that no further action was needed and the complaint file was closed.

More information about MDH's licensing of birth centers can be found on the Department's website at http://www.health.state.mn.us/divs/fpc/profinfo/lic/licbirthcenter.html. Information about CABC and the accrediting process can be found on the CABC's website at: http://www.birthcenteraccreditation.org/find-accredited-birth-centers/cabc-accreditation-process/

C. Number and Type of Licensed Birth Centers in Minnesota

Since Minnesota Stat. 144.615 was enacted in 2010, which required free-standing birth centers to be licensed by MDH, five birth centers have been licensed. Two of the five were just recently licensed. Below is a table that describes the 5 licensed birth centers including the name, location, date of licensure, services provided beyond the standard services provided in a birth center, transfer hospital, and other information about that particular birth center. More specific information on birth centers, including client demographics, utilization of services, transfer and outcomes data, will be provided in Section IV, B, of this report.

Name and Address	Date Established/ Licensed	Services Provided Beyond Prenatal, Delivery and Post-Partum Services	Transfer Hospital(s)	Other Unique Info.
Alicia's Care Center 12550 County Road #38 Eden Valley	Est. 2009 Temp. Lic. 1/12/12 Perm. Lic. 08/05/13	Offers home births	CentraCare Health in Long Prairie	First rural birth center in MN. Serves low-income, uninsured & Amish comm.
Health Foundations Family Health and Birth Center 968 Grand Ave., St. Paul	Est. 2/1/2010 Temp. Lic. 01/01/11 Perm. Lic. 06/01/11	Full service midwifery and integrative clinic. Offers home birth delivery options, naturopathic medicine; chiropractic care; yoga, acupuncture; pediatric service, breastfeeding & educational classes	St. Joseph's Hospital/ Regions Hosp./ United Children's Hospital	First birth center to be licensed in Minnesota.
MN Birth Center 2606 Chicago Ave. S., Mpls.	Est. 12/2011 Lic. 12/03/11		Abbott Northwestern Hospital & Children's Mother and Baby Center	CNM's have hospital privileges at ABNW and Children's Mother Baby Ctr.
Morning Star Birth Center 6111 Excelsior Blvd., St. Louis Park	Est. 3/2010 Lic. 01/26/11	Multidisciplinary clinic group that provides a variety of services, beyond the standard maternity and delivery services.	Patient preference or nearest Twin Cities hospital w/open bed	Closed Clinic Model with most services in house via the Morning Star Health Assoc.
Morning Star Birth Center 1730 E. Superior St., Duluth	Est. 9/2013 Lic.10/21/13		Patient preference or nearest Duluth hospital w/open bed	Second rural birth center. Recently opened.

Alisha's Care Center, Eagle Bend Minnesota

Alisha's Care Center was established in 2009. It is located in Central Minnesota, in Eagle Bend, Minnesota (12550 County Road #38) approximately 12 miles west of Long Prairie, Minnesota. CentraCare Health – Long Prairie is the closest transfer hospital to Alisha's Care Center. The Center provides maternity and prenatal care, well woman care, well child care and birthing services. The majority of their clients are low income and uninsured, and they serve a growing Amish community. Alisha's care center is the first rural birth center to be licensed and was developed as a result of consumer demand for a center that serves women who would typically give birth at home assisted by a midwife.

Alisha's Care Center was issued a temporary license by MDH effective January 12, 2012, while awaiting full accreditation by the CABC. Accreditation was obtained and a permanent license was issued on August 5, 2013. From the time the law went into effect to the time Alisha's was accredited and licensed, they had to suspend deliveries at the center. However, they were able to continue providing prenatal exams, well baby checks, and women's health checks. ¹²

Health Foundations Family Health and Birth Center, St. Paul, Minnesota

Health Foundations, LLC first opened for business on February 1, 2010. The birth center is located on Grand Ave. in St. Paul, Minnesota (968, Grand Ave.) and serves the Twin Cities Metro Area. Health Foundations, LLC is a full-service midwifery practice and integrative clinic offering a variety of services including, but not limited to the following: birth center and home birth delivery options; well-woman care; comprehensive midwifery care (including family planning, preconception counseling, maternity care, postpartum care, and breastfeeding support); lactation center; naturopathic medicine; chiropractic care; acupuncture; pediatric service, new mama and breastfeeding groups, yoga, and educational classes. There are three hospitals nearby that serve as transfer hospitals; St. Joseph's Hospital, Regions Hospital, and United/Children's Hospital.

MDH issued a temporary license to Health Foundations, LLC on January 1, 2011, while the center pursued full accreditation by CABC. The center was accredited and a permanent license was issued on June 6, 2011. The license was recently renewed on June 6, 2013 for an additional two years. ¹³

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¹² Alicia's Care Center website available at http://www.alishascarecenter.com/. Also MDH's licensing records.

¹³ Health Foundations website available at http://www.health-foundations.com/ and MDH's licensing records.

Minnesota Birth Center, South Minneapolis, Minnesota

Minnesota Birth Center is located in South Minneapolis (2606 Chicago Ave.) across the street from Abbott Northwestern Hospital (ABNW) and Minneapolis Children's Hospital's Mother and Baby Center. Minnesota Birth Center provides a unique model of care with Certified Nurse Midwives (CNM) providing the care. All of the CNMs have hospital privileges at the Mother and Baby Center, should a transfer be necessary. They can admit, deliver, and discharge patients independently. The midwives also have the ability to consult with their collaborative physician group, Associates in Women's Health/Mother Baby Center, as needed and call upon an obstetrician on staff for specific physician type services. Minnesota Birth Center provides an array of services including midwifery care, prenatal care, labor and delivery care, water births, postpartum care, and breastfeeding support. They do not provide home births.

The Birth Center was accredited and received a permanent license from MDH effective December 3, 2011through December 2, 2013. Minnesota Birth Center just recently renewed their license for an additional two years effective December 3, 2013. 14

Morning Star Women's Health and Birth Center in St. Louis Park and Duluth, Minnesota

Morning Star Women's Health and Birth Center has three locations; two in Minnesota and one in Menomonie, Wisconsin. The two in Minnesota include one in St. Louis Park (6111 Excelsior Boulevard) and one that just recently opened in Duluth in September of 2013. The Birth Centers provide a variety of services including initial consultations; nutritional care; comprehensive prenatal care; labor and delivery options; medical referral; breast feeding support and counseling; post-partum follow-up care; and, well woman care and family care. The center uses a midwifery model of care.

If hospital care is necessary, women are transferred to their hospital of choice or according to their insurance coverage. If there is an emergency, patients are transferred to the nearest hospital with an open bed (e.g. Methodist Hospital, Fairview Southdale Hospital, Hennepin County Medical Center, and Regions Hospital). Women are encouraged to have a back-up physician identified should the need for a physician arise. An OBGYN, practicing in Hudson, WI, is available for consultation and physician related care when necessary.

Besides the birth center itself, the Center has a multidisciplinary clinic group which is Morning Star Health Associates. The staff at Morning Star Women's Health and Birth Center includes

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¹⁴ Minnesota Birth Center's website available at http://theminnesotabirthcenter.com/ and MDH's licensing records.

nurse midwives, professional midwives, and an RN. They would like to hire a dietician and family physician's assistant eventually and maybe a pediatrician. However, they have explained that the Birth Center license limits the services they may provide. Morning Star Women's Health and Birth Center operates under a "closed clinic model," where most of the services to clients are provided in-house and staff are employees of Morning Star Health Associates or have the ability to affiliate with them. This clinic model is different from the other birth centers which refer out to health care providers for services.

Morning Star Women's Health and Birth Center's St. Louis Park location opened in March 2010, it was accredited by the CABC in May of 2010 and received a license from MDH on January 26, 2011. The license was renewed June 15, 2013. The Duluth location was accredited in August 2013 and received a permanent license from MDH on October 21, 2013. ¹⁵

D. Predicted Growth of Birth Centers in Minnesota

According to 2012 data from the American Association of Birth Centers, the number of birth centers has grown 30% in the last five years, reaching 240 nationwide. Currently 82% of states have some type of regulation for birth centers. ¹⁶ There has been an increased interest in birth centers since the Affordable Care Act was passed which requires federal and state government programs to cover birth center deliveries. We understand from the licensed birth centers in Minnesota that more birth centers are being developed and some existing birth centers have plans for expansion.

¹⁵ Morning Star Women's Health and Birth Center website available at http://www.morningstarbirth.com/ and MDH licensing records.

¹⁶ American Association of Birth Centers website available at http://www.birthcenters.org/

IV. Birth Center Safety and Quality

A. National Data and Information on Birth Center Safety and Quality

Most of the studies published on the quality of care and outcomes in services provided in birth centers were conducted in the United Kingdom. The first national study in the United States was published in the New England Journal of Medicine, in 1989, titled, "Outcomes of Care in Birth Centers", the National Birth Center Study. The study was conducted in response to a 1982 Institute of Medicine committee recommendation that called for reliable information about the safety and efficacy of all birth settings. Prior to that study, the American Academy of Pediatrics and the American College of OB-GYN discouraged the use of birth centers until better data was available. This landmark study was a nationwide prospective descriptive study of the care provided in free-standing birth centers. The report examined the labor, delivery, follow-up care and outcomes of 11,814 women who were admitted in labor to 84 birth centers from 1985-1987. The study concluded that:

"few innovations in health service promise lower cost, greater availability, and a high degree of satisfaction with comparable degree of safety." "Birth centers offer a safe and acceptable alternative to hospital confinement for selected pregnant (low-risk) women, particularly those who have had children, and that such care leads to relatively few cesarean sections". ¹⁷

Since then, birth centers have been endorsed by the American College of Obstetrics and Gynecology (ACOG) as a safe alternative to home birth.

A more recent study of birth centers in the United States was published in 2013, by the American College of Nurse Midwives. The study was the second national birth study in the U.S (National Birth Center Study II) The study involved a prospective study of 79 midwifery-led birth centers in 33 U.S. states from 2007 to 2010. Data was entered into the American Association of Birth Centers Uniform Data Set, an online data registry for the ongoing collection of perinatal data in all settings (hospital, birth centers, home) and by all providers (Certified Nurse Midwives,

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¹⁷ Rooks JP, Weatherby NL, etal. 1989. Outcomes of care in birth centers, the national birth center study. The New England Journal of Medicine.

Certified Professional Midwives, OBGYNs, Family Physicians) who provide maternity services. More information about this data source will be provided later in the report.

Demographics of the women in the study included mostly white women, non-Hispanic; between the ages of 18 and 34 years; with college degrees. Most women were married and slightly fewer than half were nulliparous (no previous births). The reports of smoking and substance abuse were very low among the women studied. Private insurance and self-pay was the main payment source, with nearly a third of the births being paid by federal or state government programs.

Of the 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 (63% for prolonged labor or arrest of labor). Regardless of where they gave birth, 93% had a spontaneous vaginal birth, 1% an assisted vaginal birth, and 6% a cesarean birth. Of the women giving birth in the birth center, 2.4% required transfer postpartum, whereas 2.6% of newborns were transferred after birth. Most transfers were non-emergent, with 1.9% of mothers or newborns requiring emergent transfer during labor or after birth (50% related to fetal heart tones). There were no maternal deaths. The intrapartum fetal mortality rate for women admitted to the birth center in labor was 0.47/1000 (0.47 stillbirths per 1,000 women). The neonatal mortality rate was 0.40/1000 excluding anomalies (0.40 newborn deaths (first 28 days) per 1,000 women).

One of the most important findings of this study was that more than 9 out of 10 women (94%) who entered labor planning a birth at a birth center achieved a vaginal birth. In other words, the C-section rate for low-risk women who chose to give birth at a birth center was only 6% -- compared to the U.S. C-section rate of 27% for low-risk women. This is more than 4 times lower than what is seen among low-risk women in general in the U.S.

Another important finding is that the results of this study are similar to those found in the landmark national study of birth centers published in the New England Journal of Medicine in 1989, and described earlier. ¹⁸

B. State Data and Information on Birth Center Safety and Quality

As directed by the legislation, MDH was to evaluate the quality of care and outcomes in services provided in licensed birth centers, including, but not limited to, the utilization of services provided at a

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¹⁸ Stapleton SR, Osborne C, Illuzzi J (2013). Outcomes of care in birth centers. Demonstrations of durable model. Journal of Midwifery and Women's Health. Retrieved from http://onlinelibrary.wiley.com/doi/jmwh.12003/full.

birth center, the outcomes of care provided to both mothers and newborns, and the numbers of transfers to other health care facilities and the reasons for the transfers.

MDH was to consult with a variety of organizations listed in legislation including: representatives of the licensed birth centers, the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, the Minnesota Hospital Association, the Minnesota Ambulance Association, and Minnesota Department of Human Services. MDH contacted all of those organizations as well as others including the local chapters of the national organizations listed in legislation in order to obtain more specific information related to birth centers in Minnesota, the Minnesota Board of Nursing, the Minnesota Board of Medical Practice, the Commission for the Accreditation of Birth Centers, and MDH's Center for Health Statistics. Consultation was done via e-mail messages to identified organizations, follow-up phone calls, and some in person meetings. Additionally, MDH accepted invitations to tour two of the five licensed birth centers.

1. Sources of Data for Minnesota Licensed Birth Centers

MDH learned early on in the evaluation that data on Minnesota licensed birth centers is limited, in part because some of the birth centers were just recently licensed and others have only been licensed for a few years. Also, much of the data is voluntary and/or self-reported. Sources that do collect data on birth centers are described below.

1. Commission for the Accreditation of Birth Centers Data

As part of the accreditation process, the CABC requires birth centers to have a quality improvement program and systems in place to collect and analyze data and evaluate customer satisfaction. Standard VIII, Evaluation of Quality of Care, in the CABC's Indicators for Compliance document requires birth center to complete a Self-Evaluation Report (SER) which includes the type evaluative information requested by the legislature for this report including, but not limited to, utilization of services, the outcomes of care provided to both mothers and newborns, and the number of transfers to other health care facilities and reasons for transfers. ¹⁹ This information is required at the time a birth center applies for accreditation. MDH reviews the SER, as well as other information from the CABC, such as the Commission's accrediting decision letter, as part of its licensure process. More information about the CABC's Indicator's for Compliance is available at https://www.birthcenteraccreditation.org/get-accredited/buy-accreditation-manual/.

¹⁹ Commission for the Accreditation of Birth Centers website available at https://www.birthcenteraccreditation.org/

2. American Association of Birth Centers Perinatal Data Registry

The American Association of Birth Centers (AABC) has a Perinatal Data Registry (PDR), (formerly called the Uniform Data Set or UDS), which is an online data registry for the ongoing collection of perinatal data in all settings (hospital, birth centers, home) and by all providers (Certified Nurse Midwives, Certified Professional Midwives, OBGYNs, Family Physicians) who provide maternity services. This data registry is designed to provide comprehensive data on both the process and outcomes of the midwifery model of care. The AABC PDR 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. The large prospective data set generated from the registry can be used to evaluate and improve the delivery of care to childbearing women and their families. Currently, participation in this data set by birth centers is voluntary. However, the CABC recently instituted a policy requiring all accredited birth centers to participate in this data registry effective at the time of their next site visit by the CABC. More information about the PDR is available on the AABC's website at http://www.birthcenters.org/data-collection/pdr-features

3. Minnesota Department of Human Services Public Programs Payment Records

The Minnesota Department of Human Services (DHS) collects data from claims paid by Minnesota Health Care Programs (MHCP). The Affordable Care Act (ACA), that was passed in 2011, required government funded health plans to cover services provided in a licensed birth center by a licensed health professional if the service would otherwise be covered if provided in a hospital. Following the passage of the ACA, Minnesota Statute 256B.0625, Subd. 54 was passed which states that MHCP covers low risk pregnancy and delivery services provided in licensed, free-standing birth center if the service is covered when provided in a hospital by a licensed health professional. The legislation states further that facility services provided by a birth center shall be paid at the lower of billed charges or 70% of the statewide average for a facility. Nursery care services provided by a birth center shall be paid the lower of billed charges or 70% of statewide average for a facility.

MHCP reimburses Certified Nurse Midwives licensed by the Minnesota Board of Nursing as well as Certified Traditional Midwives licensed by the Minnesota Board of Medical Practice who work in licensed free-standing birth centers. Covered services include antepartum visits (prenatal care), uncomplicated vaginal births, newborn care services and the first post-partum visit. MHCP does not cover home births. If a home visit is done, MHCP does not cover travel time or a facility charge. More information about MHCP coverage for birth center services is available on DHS' website at

http://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION &RevisionSelectionMethod=LatestReleased&dDocName=dhs16_156145#

Since there are only five licensed birth centers in Minnesota, and two of the five birth centers were recently licensed, and since discussions with birth centers indicated that most of their clients were not MHCP clients, the evaluators decided not to pursue obtaining claims data from DHS as the data would not be representative of all clients receiving services from birth centers (e.g. self-pay, private insurance).

4. MDH Center for Health Statistics' Birth Record Data

The MDH Center for Health Statistics maintains records on all births that occur in Minnesota and to Minnesota residents. The birth record contains data on the demographics of the mother and father as well as medical information on the mother and infant. The birth record also includes information on whether the mother or infant were transferred from or to another facility and the name of that facility. Unfortunately, reasons for transfer are not specifically collected. The birth record establishes a person's legal identity and demographics and health data are used in multiple ways including assessment, identifying trends, establishing a need for programming, identifying clients for public health programs and establishing policy. A copy of the birth certificate form can be found in Appendix A of this report.

2. Birth Record Data Obtained from Minnesota Licensed Birth Centers

MDH used data from birth records maintained by the Centers for Health Statistics for the evaluation, since it appeared to be the most comprehensive data available on all Minnesota licensed birth centers at this time. Birth record data was used to provide a demographic profile of birth center women including their age and race. It was also used to compare transferred/non-transferred mothers and infants by selected medical risk factors and birth outcomes. The calendar years 2010-2013 were chosen because 2010 was the first year for which births occurring at a birth center could be positively identified in the birth dataset, and 2013 is the most recent year available (2013 data are preliminary). It should be noted that not all birth centers opened in 2010, and those that did open in 2010 opened on different dates (see table 1 for years in which the centers opened).

Table 1: Number of Births in Minnesota's Licensed Birth Centers

Birth Center Name	Number of Births								
		2010-2013							
Morning Star Birth									
Center, St. Louis Park		27	50	80	65	222			
Health Foundations		14	19	35	56	124			
Minnesota Birth Center		0	0	20	60	80			
Alisha's Care Center		2	10	15	10	37			
	Total	43	79	150	191	463			

Source: Minnesota Department of Health, Center for Health Statistics; 2013 data are preliminary

2010-2013 birth record data on clients who received services from Minnesota licensed birth centers provided the following demographic information:

- The majority were between the ages of 20 and 34 years and were U.S. born
- 91 percent of the mothers were Caucasian
- 86.4 percent had attended at least some college
- 84.0% were residents of the 7-County Twin Cities Metro Area

Table 2 compares prenatal care (PNC) visits and selected birth outcomes (premature births & low birth weight births) of birthing center clients to overall Minnesota birth data from 2010-2013.

Table 2: Prenatal Care, Gestational Age and Birth Outcomes

Prenatal Care Visits and Birth Outcomes, Minnesota 2010-2013									
	Birth Centers	Minnesota							
At least 10 PNC visits	84.7%	74.2%							
Premature births	0.6%	8.5%							
Low birth weight births	0.9%	6.4%							

Source: Minnesota Department of Health, Center for Health Statistics

The data indicates that:

- 87.3 percent of the mothers who were clients of Minnesota birth centers had at least 10 prenatal care visits during their pregnancy. During the same time period, 74.2 percent of all Minnesota resident mothers received at least 10 PNC visits.
- 0.6 percent of infants born at Minnesota licensed births centers were born prematurely (less than 37 weeks) and 0.9 percent of infants born at MN licensed birth centers were low birth weight (under 2500 grams). Comparatively, the overall percentages for Minnesota resident mothers were 8.5 percent premature and 6.4 percent low birth weight births.

These data would suggest that mothers using licensed birth centers are more likely than other mothers to have received adequate prenatal care and were far less likely to give birth prematurely or to have a low birth weight baby. However, the numbers of mothers using birth centers is small in comparison to total births and thus percentages may fluctuate widely from year to year. To yield more meaningful results it is common statistical practice to use five years of data to analyze small number data. Unfortunately that was not possible with this study because birthing centers have been licensed in Minnesota for fewer than four years. Additionally, it should be noted that birth centers are only allowed to serve low-risk pregnant women, as defined in Minn. Stats. §144.616, Sub. 1(d). Hospitals on the other hand, serve low-risk and high risk pregnant women. Because of this difference in clientele served, it is difficult to make comparisons between the two and form any accurate conclusions without further data collection and analysis.

Birth data shows that 6.3 percent of mothers were transferred from a birthing center to another facility before giving birth.

Table 3: Number of Mothers Transferred from Licensed Birth Centers

				2013	
	2010	2011	2012	YTD	2010-2013
Transfers	1	6	14	10	31
Non Transfers	43	79	150	191	463
Total Births	44	85	164	201	494
Percent Transferred	2.3%	7.1%	8.5%	5.0%	6.3%

Source: Minnesota Department of Health, Center for Health Statistics

2013 data are preliminary

Additionally, data shows that 2.6 percent of infants were transferred to another facility following delivery at a birthing center.

Table 4: Number of Infants Transferred from Licensed Birth Centers

	2010	2011	2012	2013 YTD	2010-2013
Transfers	1	3	3	5	12
Non Transfers	42	76	147	186	451
Total	43	79	150	191	463
Percent Transferred	2.3%	3.8%	2.0%	2.6%	2.6%

Source: Minnesota Department of Health, Center for Health Statistics 2013 data are preliminary

Transfers and Risk Factors

As noted previously, the birth record does not specifically ask the reason(s) for a transfer. Additionally, transfer criteria vary somewhat from one facility to another. However, data on maternal risk factors and issues occurring at the time of birth may shed some light on factors involved in the decision to transfer. Table 5 compares risk factor indicators and birth issue indicators of mothers who were transferred to those of mothers who were not transferred using birth record data from 2010 -2013. The maternal risk factors include conditions such as diabetes, eclampsia (high blood pressure) and infections. Birth issues include factors such as fetal intolerance of labor, premature rupture of membranes, cord prolapse and prolonged labor. In all categories a higher percentage of mothers with at least one risk or issue were transferred than those that had none. It should be noted that the risk factors and birth issues listed on the birth certificate vary in severity— some may warrant a transfer, others may not. This analysis did not attempt to separate risk factors/birth issues by level of severity.

Table 5: Number of Maternal Transfers Due To Risk Factor(s), 2010-2013

	Maternal	Risks	Birth Issues			
	Not Transferred	Transferred	Not Transferred	Transferred		
None	305	14	314	11		
At least one Risk/Issue	114	16	109	21		
Percent with at least one	27.2%	53.3%	25.8%	65.6%		

Source: Minnesota Department of Health, Center for Health Statistics

Note that the counts in the above table do not include records where maternal risks or birth issues were listed as 'unknown'. Percentages are computed on the total number of records with 'known' data.

The data obtained from birth records, although limiting, appears to support the national data that has been published on birth centers which shows that birth centers can be a safe and effective option for low-risk women choosing to give birth in a non-hospital setting.

3. Comments and Recommendations from Organizations Consulted

American Academy of Pediatrics

The American Academy of Pediatrics informed MDH that they do not keep statistics on the utilization of services and outcomes in care provided in birth centers. MDH did have record of receiving a letter from the Minnesota Chapter of the American Academy of Pediatrics from May of 2012, which was written on behalf of several pediatricians inquiring about the safety standards that were being used by MDH in their licensing of birth centers. MDH's response to that letter pointed out Minnesota law, which requires birth centers to be accredited by the Commission for the Accreditation of Birth Centers before they are licensed or within six months of their application for licensure. MDH included a copy of the standards that are used by the CABC as well as the American Association of Birth Centers, the entity that established the CABC.

American Congress (formerly College) of Obstetricians and Gynecologists

MDH contacted the American Congress (College) of Obstetricians and Gynecologist (ACOG) for input. ACOG informed MDH that they did not have current guidelines on American Birth Centers. However, birth centers are covered in the general College guidelines on obstetric services which are available for purchase.

MDH also contacted the ACOG – District VI or the Central Chapter that includes Minnesota. The MN ACOG sent inquires out to their members, but members indicated a need to see data on birth centers before they could comment. MN ACOG members did provide some general comments on birth centers including the following:

"Birth centers were discussed at the annual state legislative meetings held by ACOG and that it was explained that state policy varies considerably. "Some states, such as Minnesota, have worked with their birth centers, while other states have worked to oppose them. In general Minnesota has done well. Patients seem to be transferred in a timely manner, and OBGYNs have good relationships with the midwives, both professional and certified nurse midwives, who work at the centers".

"I am not aware of any patients who have had serious complications that have been transferred to a hospital."

Minnesota Hospital Association

The Minnesota Hospital Association sent MDH a letter with their comments and recommendations (see Appendix B for a copy of the letter). Specific recommendations are listed below.

• Birth Centers should be required to establish risk criteria procedures and transfer and communication protocols with hospitals.

As noted above, the CABC requires birth centers to establish risk criteria and transfer protocols. They also require birth center operators to build relationships with consultants, hospitals and other providers within the community. CABC does not allow "ER dumping" and they conduct site visits of accredited birth centers every three years to assess how birth centers are managing their transfers. While the CABC standards require these relationships, that doesn't mean that some birth centers and hospitals couldn't do more to build relationships, and have clear communication and transfer protocols.

• Birth Centers should require patients to sign a form that designates transfer hospital preference.

The CABC's standards also require birth centers to orient the client to the birth center program which includes, but is not limited to, obtaining informed consent; explaining the limits of the program; discussing the emergency clause covering transfer of care (authorization to transfer); delineating risks and providing a glossary explaining terms used; and, securing a signature from the client that affirms their understanding and acceptance of the birth center program. The client record must include documentation of all of these discussions and the CABC reviews these records during their site visit to assure that the birth center is complying with standards.²⁰

Minnesota Ambulance Association

The Minnesota Ambulance Association/Metro Area EMS Systems was contacted and they offered to send a survey to their members in the counties that service the Minnesota licensed birth centers. MDH received one response to that survey, which indicated that they had not made any medical calls to the birth center in their county.

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²⁰ Commission for the Accreditation of Birth Centers, Indicators for Compliance with Standards document (10/22/11) available at https://www.birthcenteraccreditation.org/get-accredited/buy-accreditation-manual/

Minnesota Licensed Birth Centers

MDH sent the same letter that they sent to other organizations listed in legislation explaining the legislative report and requesting information, comments, concerns, recommendations, etc. for it. As mentioned previously, MDH also accepted invitations from two licensed birth centers to meet with them in person and tour their center. Comments and recommendations from the licensed birth centers are listed below.

• MDH/Minnesota Should Develop its Own Standards for Licensing Birth Centers and Streamline the Licensing Process.

It should be noted that this recommendation was not shared by all birth centers. Since there is a national and reputable accrediting organization that already exists (CABC), it would be duplicative and costly to create separate standards for Minnesota, given the small number of birth centers that currently exist.

• MDH/Minnesota Should Require Some Type of Incident Reporting and a Peer Review Committee Should Be Established.

The CABC collects adverse events information from licensed birth centers as part of Standard 8, Evaluation of Quality of Care, of the accreditation process. The MDH Center for Health Statistics also collects and maintains birth record data from birth certificates which could be used to develop quality improvement measures if need be. With these reporting systems in place, there is not a need for MDH to develop a separate incident reporting system for birth centers at this time.

• Advisory Committee for Birth Centers Should be Established. MDH should establish an advisory board or committee for birth centers to provide a forum for discussion, review data, and offer a unified voice. Currently no such forum exists at the state level.

Establishing an Advisory Committee for such few number of licensed birth centers at this time is not necessary and could be costly to the state. However, MDH could meet annually with representatives from birth centers to discuss issues and concerns.

• DHS Should Work with Birth Centers to Resolve Medicaid Reimbursement Issues. Some birth centers are experiencing problems receiving reimbursements for services provided. Under Minnesota Stats. §256 B, birth centers may only provide labor and delivery care and immediate newborn care until the mother is sent home. That appears to conflict with

a midwife's scope of practice which allows them to provide care to newborns up to 28 days postnatal. Also, some birth centers are not being paid for the newborn facility service fee

As noted in the concern stated, DHS is the agency which has jurisdiction over Minn. Stat. 256B and is responsible for paying Minnesota Health Care Program claims, and they should be engaged in finding the solution.

V. Conclusion

The data that MDH was able to obtain on Minnesota licensed birth centers, although limited, seems to support the national data which shows that birth centers can be a safe and effective option for low-risk women choosing to give birth in a non-hospital setting. However, it's important to note that the numbers of mothers using birth centers is small in comparison to total births and thus percentages may fluctuate widely from year to year. To yield more meaningful results it is not only recommended, but common statistical practice, to use five years of data to analyze small numbers of data. Unfortunately that was not possible with this study because birthing centers have been licensed in Minnesota for fewer than four years

As discussed earlier in the report, the CABC is going to start requiring all accredited birth centers to report to the PDR, a national data base, beginning with the birth centers' next site visit. Prior to this new requirement, a birth centers' participation in a national data base was voluntary and only some birth centers in Minnesota participated. MDH believes that this new requirement should help to provide more comprehensive and meaningful data on the quality of care and outcomes in services provided in Minnesota licensed birth centers and nationally.

VI. List of Appendices

APPENDIX A: Birth Certificate Worksheet Mother and Medical Portion

APPENDIX B: Minnesota Hospital Association's Letter

MINNESOTA DEPARTMENT OF HEALTH

Appendix A NAMING YOUR BABY AND BIRTH CERTIFICATE INFORMATION

The information provided on this worksheet will be used to create your child's birth certificate.

Please complete this information carefully and completely.

		MOTHER'S IN	IFORM	ATION				
CURRENT FIRST NA	AME	CURRENT N	1IDDLE N	IAME	C	CURRENT LAST NAME		
NAME BEFORE FIRST MAR	RIAGE (first)	NAME BEFORE FIRS	AGE (middle)	NAME BE	FORE FIRST MARRI	AGE (last)		
BIRTHPLACE – STATE OR FOR	EIGN COUNTRY	BIRTHPL	ACE - CI	ТҮ	DATE OF BIRTH			
				management of the second of th		/ /		
		RESIDENCE ADDRESS (in	iclude ci	ty and zip code)				
COUNTY OF RESIDE	ENCE	IF NOT WITHIN CITY I	lmits, n	NAME OF TOWNS	SHIP S	SOCIAL SECURITY N 	UMBER	
		MAILING AD	DRESS			SAME AS RESIDEN	ICE ADDRESS	
		BABY'S INF	ORMA	TION				
You can give your baby any								
or any name of your choos							be placed	
between two letters, but no		ning or end of a name BABY'S MID				e <i>rmitted.</i> BABY'S LAST NAME		
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DATE OF BIRTH	l	SEX		☐ SINGLE ☐ TV	WIN	IF NOT A SINGLE	:,	
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		n or any time between)	If you are single and would like the father's name on this birth					
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For birth research. The information on this page does not print on the birth certificate.

			ADDITIONAL INFORMATION
DID	YOU PART	ГІСІР	TE IN WIC NUTRITIONAL PROGRAM DURING SMOKING - Did you smoke cigarettes 3 months before or during
THI	S PREGNAN	CY?	☐ Yes ☐ No this pregnancy? ☐ Yes ☐ No
If ve	es, what mo	nth	f pregnancy did WIC begin?
(1 st	, 2 nd , 3 rd , etc	:.)	3 months before First trimester
			Second trimester Third trimester
		:	BOTH PARENTS' DEMOGRAPHICS – EDUCATION
			est describes your highest level of school completed at the time of this baby's birth
	THER	FAT	
			8 th grade or less
			9 th – 12 th grade, no diploma
			High school graduate or GED completed
			Some college credit, but no degree
			Associate degree (e.g. AA, AS)
			Bachelor's degree (e.g. GA, AB, BS)
			Master's degree (e.g. MA, MS, MEng, Med, MSW, MBA)
\Box	·		Doctorate (e.g. PhD, EdD) or Professional degree (e.g. MD, DDS, DVM, LLB, JD)
L			BOTH PARENTS' DEMOGRAPHICS – HISPANIC ORIGIN
	ck all that ap THER	<i>ply</i> FAT	IED .
	IIILIX		No, not Spanish/Hispanic /Latina/Latino
			Yes, Mexican, Mexican American
			Yes, Puerto Rican
			Yes, Cuban
			Yes, other Hispanic (e.g. Salvadoran, Dominican, Colombian) (specify)
			BOTH PARENTS' DEMOGRAPHICS – RACE/ETHNICITY
Che	ck all that a	vlaa	
	THER	FAT	IER CONTRACTOR OF THE PROPERTY
			White
			Black or African American
			□ Somali
			□ Liberian
			□ Kenyan
			□ Nigerian
			□ Ethiopian
			☐ Ghanaian
			☐ Other African (specify)
			American Indian or Alaska Native (specify name of enrolled or principal tribe)
			Asian
			☐ Asian Indian
			□ Chinese
			□ Filipino
			☐ Japanese
			□ Korean
			□ Cambodian
			□ Laotian
			□ Vietnamese
			□ Other Asian (specify)
	. <u></u>		Pacific Islander
			Native Hawaiian
			Guamanian or Chamorro
			□ Samoan
_		_	Other Pacific Islander (specify)
			Other Race (specify)



BIRTH CERTIFICATE INFORMATION – MEDICAL PORTION

This information is required by law and will be confidentially used by public health. The preferred source of this data is the medical professional in attendance at the time of delivery and/or newborn examination.

		T		Child's Medic							
DATE OF BIRTH TIME □am □pm MOTHER'S NAME OR MED □24hr					DICAL				Congenital anomalies Anencephaly		
INFANT TRANSFERRED?					FNDA					cele /Spina bifida	
If so, WHERE?						☐ Hypospadias			·		
BABY'S MEDICAL RECORD NUMBER BIRTH WEIGHT ☐ Ib/oz					ES	T GESTATION				-	al anomalies
□ grams					s	W	eeks			_	nital heart disease hragmatic hernia
	APGA	R Scores		Abnormal co					Omphalo		in aginatic nerma
				Assisted ventilation imr		diately after birth Gastroschisis					
PLU	JRALITY / live bo	orn / baby's birth o	order	☐ Assisted ventilation > ☐ NICU admission					Limb red Polydact		defect ndactyly /adactyly
		HEP B STATUS		☐ Newborn surfactant tl☐ Antibiotics for suspect					Club foo		
		ositive Unkr		☐ Confirmed bacterial in						usculos	skeletal/integumental
	oy get Hep B vac Yes - when?	cine? □No □ Re	tused	☐ Seizure or neurologic					Cleft lip Cleft pal	ate	
		y? □ No □ Ref	fused	☐ Birth injury							e – confirmed?
	Yes - when?	,,		☐ Other					Other ch	romoso	omal – conf?
BRI	EASTEEDING or	fed breast milk [7 No	□ None INFANT ALIVE AT	IMF (DE EILING?				omalie	S
	☐ During sta			☐ Yes ☐ No	IIVIL C	or richto.			None		
		-		Mother's Medical In	form	ation I - Pre	natal				
Pr	enatal care?	First prenatal	visit	Date of last prenatal visit		al prenatal visi			h care b	egan	Mother's height
	Yes □ No	. / /		/ /						_	
		Risk factors t	his pre	gnancy	Pre	-preg. weight	Wei	ght at d	elivery	Las	st menstrual period
	Diabetes – p										/ /
	Diabetes – ge	estational n – pre pregnanc	٠.٧		1				Other outcomes		
		n – gestational (F		eeclampsia)	livii			dead)ata af	last ather autaems
	Eclampsia	,	, ,			Date of last live birth Date of last other outcom				/ / /	
	_	sulted from infe		reatments	Tox	cicology – were	toxico	ology te	ests adm	inister	ed to mother and/or
	-	enhancing drugs I reproductive te		omy /IV/E_GIET\	1	the newborn					
	Anemia	reproductive te	cilloic	ogy (IVF, GIFT)	Res	ults:					
	Previous pre	term birth						irce of			is delivery
				natal death, SGA, IUGR)		☐ Private insurance ☐ Medicaid ☐ Self pay ☐ Indian health service					
		arean birth. Num	nber of	prev. C/S		1 /	icaro				n nealth service r government
	Other None								_	Other	government
	NOTIC			Mother's Med	ical I						
	Infections p	resent/treated		Prenatal OB procedures	T			Ons	et of lab	or	
	Chlamydia	☐ Hep C		☐ Cerclage		PROM (> 12 i	nours)			Prolong	ged labor (>20 hours)
	Genital herp	•	ive	☐ Tocolysis		Precipitous la	bor (<			None	
	Gonorrhea	☐ Syphilis		☐ Version ☐ Successful ☐ No		E			od of bi		□ N-
	GBS Hep B	□ Other □ None		□ None		Forceps atter Vacuum atte			□ Succe □ Succe		□ No □ No
	Tiep B	Characteris	tics of			al presentation					☐ Other
	Induction]	⊐ Augr	mentation		Vaginal/spon					forceps
☐ Non-vertex presentation ☐ Steroids for fetal lung maturation						Vaginal/vacu			□ VB		
	Antibiotics du			rioamnionitis diagnosed		Cesarean					ed? 🗆 Yes 🗆 No
	Maternal tem Fetal intolerar			onium staining Mod-heavy ural or spinal anesthesia		Maternal tran			nal morb		perineal laceration
	Other		⊐ Lpiu ⊐ Non			Cord prolapse			Seizure		
						Placental abr			Placent		
		ed prior to delive	ery?	☐ Yes ☐ No		Ruptured ute	rus				terectomy
Fac	cility she was tr	ansferred from:				Admission to	ICU			ned Ope	erating Rm procedure
		חוח	TU ^7	TENDANT CICNATURE	(not	None	r bos		Other_		
	BIRTH ATTENDANT SIGNATURE (not required for hospital births)										

I certify this information is correct to the best of my knowledge:

Appendix B



| 2550 University Ave. W., Suite 350-S | St. Paul, MN 55114-1900 | phone: (651) 641-1121; fax: (651) 659-1477 | toll-free: (800) 462-5393; www.mnhospitals.org

October 15, 2014

Compliance Monitoring Division Minnesota Department of Health P.O. Box 64975 St. Paul, MN 55164-0975

Dear MDH:

Thank you for your recent message inviting the Minnesota Hospital Association (MHA) to provide input and information for the Minnesota Department of Health (MDH) to consider as it completes its evaluation of the quality of care and outcomes for services provided in birth centers. MHA appreciates the opportunity to share the following comments and attached information on behalf of our members, which include 144 hospitals and their health systems serving patients and communities throughout Minnesota.

MHA supports care delivery models that are designed to provide patients with the right care, in the right setting at the right time. Although such objectives may seem straightforward, patients' care needs can be difficult to predict or they can change quickly. The nature of labor and delivery inherently includes a degree of uncertainty and unpredictability of care needs for both the mother and the infant.

Accordingly, hospitals' labor and delivery services are designed, resourced and staffed to meet the mother's and infant's needs, whether the delivery turns out to be an uncomplicated, low-risk birth or, in some circumstances, unexpected complications or high-risk deliveries result in the need for significant medical intervention to save the life of the mother or child. Because hospitals must ensure the availability of this standby capacity if a low-risk delivery unexpectedly becomes high risk, we understand how people may question the costs for uncomplicated or low-risk births at hospitals. At the same time, we also understand the gratitude from those occasional patients whose lives and families are saved because a hospital's highly trained care teams, technology and sophisticated services are immediately available as an emergency arises.

By comparison, the few birth centers that have entered Minnesota's array of options for labor and delivery services do not offer the span of services, resources or staffing to meet the broad spectrum of care needs that patients may need. Instead, they are intended to be limited to low-risk deliveries that are expected to be normal and uncomplicated labor and birth. Because it remains impossible to know ahead of time whether a particular patient who appears to have an uncomplicated pregnancy will, in fact, have an uncomplicated labor and delivery, hospitals are effectively in the position of providing the standby capacity, staffing and resources for these birth centers when complications arise.

MDH October 15, 2013 Page 2

Since it is inevitable that birth centers will need to transfer patients to hospitals for life-saving care from time to time, MHA and our members believe that it is critical for birth centers to have transfer agreements, engage in advance planning and establish communication expectations with hospitals, and at times accompanying the laboring mother. Taking these proactive measures will make the emergency, life-and-death steps the birth center and hospital will need to coordinate during the highly stressful crises more predictable, streamlined and, most importantly, safer for the patients.

To respond to MDH's request for our input for this evaluation, MHA asked our members to provide information about their experiences. Thirty nine hospitals responded to our survey and six of those reported regularly receiving transfers from birth centers. The number of transfers ranged from hospitals that receive one to five transfers per year to one that receives up to twenty transfers in a year.

According to the six members who have the most experience with the birth centers operating in Minnesota, it appears that some centers have taken those proactive steps to promote safe, quality care. Feedback MHA received indicated that these birth centers work closely and coordinate with local hospitals to make the transfer and emergency care processes as safe, effective and successful as possible given the fact that meeting the patients' care needs will not occur as quickly as they would if the mother was in the hospital because of the need to relocate the patient when complications become apparent or expected.

However, MHA is troubled by feedback we received from hospitals indicating that some of the birth centers that appear to delay needed transfers and transfer patients in the midst of a crisis or life-threatening situation without having taken the reasonable steps of establishing transfer or communication protocols with the receiving hospital. Our members believe that such lack of due diligence can result in increased risk for patients, less than optimal hand-offs from the birth center to the hospital, and the potential for miscommunication or confusion among caregivers. It is unknown whether birth center patients, families or staff has reported concerns to MDH's Office of Health Facility Complaints.

The following are a representative sample the comments MHA members provided to us as we prepared to respond to MDH's request for comments related to this evaluation:

"We have had a few cases [of transfers from a birth center] over the last year and one over the weekend that raised some huge concerns."

"Relationships between hospitals and Birth Centers are quite variable and unique, formal and informal. For example, [Birth Center A] is a formal relationship including neonatal providers that will go to the Birth Center to check on babies if needed. [Birth Center B] has a very cordial and respectful relationship with their frequent referral hospital. [Birth Center C] has their formal hospital relationship in Wisconsin and has no formal or informal relationship with [Hospital 1] except as need[ed] for 911 type care."

"It is helpful to have an agreement and credentialed providers who can follow the patient from the birth center to the hospital."

"[W]e have had nothing but great things to say about [Birth Center B], always appropriate and timely transfers with well-prepared patients, great pre-natal records and reports from the midwife who accompanies the patients. Our experience with transfers from [Birth Center C] has not always been so collaborative."

"... greatly prolonged labors and when patients finally get here, they expect to be able to get an epidural and sleep, rather than be actively managed after their egregiously prolonged labors (that probably should have result in section many hours beforehand)." (parenthetical original)

In the interest of patient safety and ensuring high-quality care, MHA suggests that MDH recommend that the Legislature amend Minn. Stat. sec. 144.615, subd. 6 (b). Currently, this provision requires birth centers to "have procedures in place specifying criteria by which risk status will be established and applied to each woman at admission and during labor." MHA respectfully suggests that state law go further to require birth centers to (a) establish those procedures, as well as transfer and communication protocols, in conjunction with the hospital expected to receive the patient when complications arise, and (b) have similar procedures and protocols in place for establishing risk status for each born or unborn child.

In addition, MHA encourages MDH to revise its licensing standards or propose legislation requiring birth centers to inform patients about the criteria that it will use to establish risk status and determine when a patient needs to be transferred to a hospital, and to have a written and signed form from each patient designating the hospital to which she prefers to be transferred and the hospital to which she prefers her child to be transferred unless the particular complications or risks that arise necessitate a transfer to a different facility in the judgment of her caregivers.

Sincerely,

Matthew L. Anderson, JD

Vice President, Regulatory/Strategic Affairs

Tania Daniels, PT, MBA Vice President, Patient Safety

Anna Danvels