

Summary and Background of DHSR's Review of Baby+Co – Cary Facility

Background

Following a number of infant deaths at the Baby+Co's birthing center in Cary, North Carolina and at the request of a legislator, the NC Department of Health and Human Services (DHHS) conducted a review of Baby+Co's clinical standards and operations.

Scope of Review

Licensed healthcare facilities are subject to a variety of laws and regulations regarding care, quality and staffing. DHHS, through its Division of Health Service Regulation (DHSR), is tasked with assessing compliance with those standards in addition to investigating complaints made about those facilities.

Because DHSR does not regulate birthing centers, they had to secure permission from Baby+Co to come on-site to perform this review as well as negotiate the standards that would be applied in this review.

- DHSR staff reviewed the Cary location based on accepted practices of care and the criteria adopted by Baby+Co's accrediting body, the Commission for the Accreditation of Birth Centers (CABC).
- DHSR's review was not intended to determine the cause of death for any of the infants that died at or following their birth at the Cary location. Rather, the review identified certain concerns related to Baby+Co's performance on the negotiated standards and criteria.
- DHSR staff interviewed Baby+Co employees, their Medical Director, the physician that supervised the Certified Nurse Midwives, as well as patients and family members that received their antepartum (before birth) and intrapartum (labor & delivery) care at the Cary site.
- DHSR staff also reviewed Baby+Co's policies and procedures, individual patient medical records, EMS call logs, hospital records and personnel records. They also toured the Cary location.
- A total of 10 patient records were reviewed, five chosen by DHSR and another five by Baby+Co. DHSR's selection included the three recent deaths reported in the media, a fourth death that occurred in 2015 and one other case.
- Baby+Co heavily redacted its medical records to mask the identity of patients and staff. It also redacted the minutes of its Governing Board. This made it difficult to determine when/why policies were revised – some of which were modified because of our review. DHSR was not given direct access to any medical records.
- DHSR staff were on-site from April 23 – 26, 2018, and May 1, 2018. They visited again on May 21, 2018, for an exit conference to share their observations and concerns.

Concerns Identified During Review

DHSR identified numerous, significant concerns during the review. Those concerns included medical oversight and physician supervision of Certified Nurse Midwives (CNM), the criteria used to admit and discharge patients, after-hours staffing, laboratory operations, and staff orientation and training. A fuller list of concerns is identified below:

- Oversight by contracted Medical Director
- Physician supervision of CNMs
- Admission and discharge criteria
- Quality improvement processes
- Adequacy of informed consent
- Consistency in orientation and training
- Staffing of CNMs related to laboring mothers after normal business hours
- Screening of CNMs under a locum tenens contract
- CNM scope of practice
- Transfer of newborns
- Cleaning and disinfectant policies

- Oversight of laboratory director and supervision of laboratory services
- Presence of laboratory policies
- Documentation of microscopy testing and training
- Bi-annual verification of laboratory analytes and enrollment in proficiency testing
- Documentation of competency assessment of testing personnel

Structure of DHSR's 36-page Report

Following the summary, some introductory paragraphs and pertinent licensure and accreditation information, the balance then identifies DHSR's concerns by patient (chart #), staff (CNM #) and review criteria (standard #). Those concerns are collectively grouped under the applicable CABC standard. Where a concern did not exist specific to a patient, staff or accrediting standard, the report is silent. In other words, we only noted those charts, staff and standards for which we had a concern. A detailed summary of five of the 10 cases can be found near the end of the report along with a summary of patient and family interviews.

Clinician Licensure & Supervision

Baby+Co's Cary location contracts for its medical director who is a physician licensed and regulated by the NC Medical Board (NCMB). DHSR's review indicated that different physicians have recently served in this role, including one residing in Greensboro and another from Charlotte.

Baby+Co's Cary location has 14 Certified Nurse Midwives on staff. The Midwifery Joint Committee, a subcommittee of the NCMB and the NC Board of Nursing (NCBON), is responsible for the regulation of CNMs, and CNMs are required to be supervised by a physician who is actively engaged in the practice of obstetrics. DHSR's review indicated that one physician supervised all CNMs on staff.

Baby+Co's Cary location also has two Registered Nurses on staff who are licensed and regulated by the NCBON.

Accreditation

Baby+Co's Cary location is accredited by the Commission for the Accreditation of Birth Centers (CABC). This means that CABC has determined that the Cary location meets a minimum set of expectations for each of nine broad categories of standards. The CABC website indicates that this location was initially accredited in February 2015 and remains fully accredited to-date.

About Baby+Co

Baby+Co's website indicates they have six locations operational in three states (Wheat Ridge, CO; Nashville and Knoxville, TN; and Cary, Charlotte and Winston-Salem, NC). However, a newspaper article and a post on Baby+Co's Facebook page state that their locations at Wheat Ridge, CO, and Knoxville, TN, have recently closed.

Baby+Co's Cary location voluntarily suspended deliveries for a period of time. They resumed deliveries around Memorial Day.

Baby+Co's Cary location is one of seven birthing centers located in NC. According to provisional data at the State Center for Health Statistics, 330 births occurred at this location in 2017. Those births represent 28% of the 1,193 births which occurred at all NC birthing centers.

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION'S REPORT REGARDING ITS REVIEW OF
BABY+COMPANY – CARY FACILITY
JUNE 11, 2018

OBJECTIVE AND APPROACH

Following news reports regarding a number of infant deaths at Baby+Company, in Cary, North Carolina (Baby+Co) and a request by a state legislator, the NC Department of Health and Human Services (DHHS) conducted a review of Baby+Co's clinical standards and operations.

Licensed healthcare facilities are subject to a variety of laws and regulations regarding care, quality and staffing. DHHS, through its Division of Health Service Regulation (DHSR), is tasked with assessing compliance with those standards in addition to investigating complaints made about those facilities. Because birthing centers are not licensed in this state and their clinical care and operations are not subject to state oversight, DHSR had to secure permission from Baby+Co to come on-site to perform this review as well as negotiate the standards that would be applied in this review.

In correspondence dated April 17, 2018, Baby+Co and DHHS agreed to the conditions and standards that would be applied in the review.¹ Specifically, DHHS' review would, *“evaluate the Cary center against the standards / criteria adopted by the Commission for the Accreditation of Birth Centers (CABC), any applicable North Carolina licensure standards, and other widely accepted practice of care (e.g., CDC guidelines on infection control). In those instances for which there is no guidance, we will defer to the criteria adopted by Baby+Co and measure performance against that criteria.”*

AGENCIES / ORGANIZATIONS CURRENTLY RESPONSIBLE FOR OVERSIGHT / MONITORING OF BABY+CO AND/OR REGULATION OF ITS PROFESSIONAL STAFF

Baby+Co, and other birthing centers like Baby+Co, operate in North Carolina without a requirement that they be licensed. Unlike other licensed health care facilities, this means that birthing centers in North Carolina legally operate without the oversight and monitoring of DHHS' Division of Health Service Regulation (DHSR) and without governmental regulations that dictate and measure their birthing center operations.²

Baby+Co has chosen to be accredited by the Commission for the Accreditation of Birth Centers (CABC). This means that CABC has determined that Baby+Co meets CABC's accrediting standards. According to CABC, it uses the American Association of Birth Centers (AABC) standards as the basis for its accreditation process. The CABC survey process consists of nine broad categories of standards. Each standard then has a number of attributes. The CABC sets out CABC Indicators of compliance with each standard or attribute.³ While DHSR may have identified concerns with a number of Baby+Co's policies or practices during this

¹ A copy of that correspondence is attached.

² Baby+Co, in addition to its birthing services, also provides certain clinical laboratory services. These laboratory services are regulated by the Centers for Medicare & Medicaid Services (CMS) through Clinical Laboratory Improvement Amendments (CLIA). DHSR, as the state survey agency for CMS, does have authority to inspect Baby+Co's CLIA laboratory services and has recently performed such an inspection. The results of that inspection are being finalized and will be reviewed by CMS.

³ DHSR used the CABC Indicators R.Ed. V.1.1 (effective June15, 2016) as it reviewed Baby+Co.

review, it is important to note that, based on the information provided to DHSR, at the time, the accrediting body, CABC, had found such a policy to meet its accrediting standards.

CABC accreditation does not regulate the licensing of professional staff. Baby+Co has a number of Certified Nurse Midwives (CNM). CNMs are regulated by the Midwifery Joint Committee, a joint subcommittee of the North Carolina Medical Board (NCMB) and the North Carolina Board of Nursing (BON). CNMs are required to be supervised by a physician who is actively engaged in the practice of obstetrics. Physicians are licensed and regulated by the NCMB.

Baby+Co is located at 226 Ashville Avenue, Cary, North Carolina in close proximity to a local hospital that is part owner of Baby+Co. According to Baby+Co's website, it operates as a provider of "family-centered, out of hospital maternity care for low-risk pregnancies during delivery and immediately after delivery for generally less than twenty-four (24) hours."

At the time of this review, Baby+Co contracted with a specialty OB-GYN practice for the provision of its Medical Director.⁴ This specialty practice is advertised as being owned by this local hospital. At the time of the review, the Medical Director of Baby+Co served as the Supervising Physician for Certified Nurse Midwives. The Medical Director / Supervising Physician in an interview July 21, 2016, with Amy Romano, CNM on "Delivering Full-Spectrum Maternity Care to Families" posted on Baby+Co's website, stated: *"Our collaboration with Baby+Company is a natural evolution. Obviously, Baby+Company stratifies inherently low risk patients, while our group extends to high risk. We (...) are simply an extension of the Baby+Company team. ... If you seek care at Baby+Company and those plans fall through; my group is part of the team and will continue your care toward a happy, healthy baby. ... There are many reasons, when transfers to the hospital occur whether before or during labor, where midwives can still attend the birth. This includes pain control, need for augmentation of labor, fever, meconium stained fluid, etc."*

Baby+Co reported greater than 577 births and 625 transfers during calendar years 2016 through 2018. (This number does not include in-hospital deliveries occurring after the Baby+Co began diversion of cases on March 6, 2018.)

DHSR'S SCOPE OF REVIEW

An onsite review was conducted at Baby+Co. April 23, 2018 through April 26, 2018, and May 1, 2018, to determine systems in place for the provisions of quality and safe care provided to laboring mothers in an unlicensed birthing center. The official exit conference was held on May 21, 2018. At the invitation of Baby+Co, a subsequent visit was made on May 24, 2018.

The onsite review included a tour of the birthing center, interviews of staff, review of documents, (e.g., *redacted* client records, *redacted* committee minutes, *redacted* quality outcome data, ambulance call reports, hospital records, facility policies and procedures, facility provider / employee files, preventative maintenance files, contracts). A sample of ten medical records were reviewed. Of these ten records, five were selected by Baby+Co staff and five were selected by DHSR. Accordingly, this was a limited sample and DHSR did not attempt to conduct a full survey of all accreditation standards but instead, limited its review to these records.

Consistent with the scope of the review set forth in the April 17, 2018 letter, the review period was from May 2017 – May 2018, and the records DHSR reviewed were from this time period except for one record Baby+Co provided in the sample that was outside of this time period. Since DHSR did not review every accreditation standard and attribute to determine Baby+Co's compliance, this report only discusses those

⁴ DHSR has subsequently learned this contract no longer exists.

instances where DHSR, based on the information it reviewed/received, identified concerns. Following in this report DHSR identifies those standards/attributes together with DHSR's findings and concerns.

Documents provided to DHSR reviewers by Baby+Co were stamped "for review". Baby+Co did not allow DHSR staff to remove copies of Baby+Co documents from the facility. While DHSR understood that HIPAA would require redaction of protected health information from the medical records it reviewed, the heavily redacted documents were extremely difficult to review. The redactions also created difficulty in summarizing the data obtained through reviews of medical records, minutes, policies and procedures. In addition to the redactions in the medical records, there were also redactions from Baby+Co's Board minutes. Access to electronic records or non-redacted medical records was not granted for review by DHSR staff. The findings in this report are based on the information available and provided for review by Baby+Co. plus information DHSR learned from other interviews and other record reviews.

As a part of this review, DHSR interviewed approximately 20 Baby+Co staff, a number of families who utilized the services of Baby+Co, as well as several individuals who were present at some of the births at Baby+Co and the Medical Director of Baby+Co.⁵

CONCERNS IDENTIFIED DURING REVIEW BY DHSR STAFF

Based on findings during the onsite review together with interviews of a number of individuals, the following areas of concerns were identified:

- oversight by the contracted Medical Director / CNM Supervising Physician
- physician supervision of certified nurse midwives
- screening of CNM locum tenens
- consistency in orientation and training
- oversight of laboratory director and supervision of laboratory services
- presence of lab policies
- documentation of testing personnel training for PPMP testing
- documentation of competency assessment of testing personnel
- bi-annual verification of laboratory analytes or enrollment in proficiency testing
- transfers of newborns
- admission and discharge criteria
- staffing of certified nurse midwives related to presentation of laboring mothers after hours
- quality improvement processes
- adequacy of cleaning and disinfectant policies
- certified nurse midwife scope practices
- adequacy of informed consent

DHSR'S REVIEW AND FINDINGS

Following is a discussion regarding DHSR's review of Baby+Co documents and medical records and application of a number of applicable standards that were identified during DHSR's review. These standards that are set out are noted as the following: a CABC standard; a BON standard, regulation or position statement; a joint subcommittee of the NCMB and the BON standard, regulation or position statement; a NCMB standard, regulation or position statement or language from a Baby+Co contract, policy or bylaws of its Governing Body.

⁵ Since DHSR's interview, there have been two successor Medical Directors named as Baby+Co's Medical Director.

DHSR's review, as noted previously, involved 10 patient charts. The findings discussed below only include those charts where DHSR identified concerns in the charts reviewed.

Baby+Co: Governing Body Bylaws

Bylaws of the Governing Body approved December 31, 2015, state the organized clinical staff is "restricted to physicians and certified nurse-midwives." "Clinical staff are credentialed and appointed by the Governing Body based on recommendation of the clinical staff, as applicable."

Staff interviews conducted April 25, 2018 at 1350, defined "full scope care" as "taking care of the mom, baby and fetus. Care of women from menses to menopause, ante-partum (before birth), intra-partum (labor), post-partum (after birth) and newborns up to 28 days. Continued interview revealed the center typically only cared for newborns up to 48 hours after birth or until seen by their pediatrician. Additional care provided by the CNM included birth control and care of men and women with STDs (sexually transmitted diseases)."

CABC Standard 2- Organization

Standard 2.1: 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.

Required evidence that the birth center has:control over birth center specific policies and procedures, ability to supervise, evaluate, discipline, and control access to clinical privileges of individuals practicing within the birth center,

CABC Standard 4- Facility, Equipment and Supplies

Standard 4.2: Complies with applicable local, state and federal codes, regulations, including current OSHA and ADA regulations and ordinances for construction, fire prevention and public safety and access.

NCMB Position Statement:

The NC Medical Board's November 2015 position statement on "Physician supervision of other licensed health care practitioners" states: *"The physician who provided medical supervision of other licensed healthcare practitioners is expected to provide adequate oversight. The physician must maintain the ultimate responsibility, to assure that high quality care is provided to every patient. In discharging that responsibility, the physician should exercise the appropriate amount of supervision over a licensed healthcare practitioner which will ensure the maintenance of quality medical care and patient safety in accord with existing state and federal law and the rules and regulations of the North Carolina Medical Board. What constitutes an 'appropriate amount of supervision' will depend on a variety of factors. Those factors may include, but are not limited to: number of supervisees under a physician's supervision, ... experience of the supervisee, frequency, quality, and type of ongoing education of the supervisee, ... the quality of written collaborative practice agreement, supervisory arrangement, protocol or other written guidelines intended for the guidance of the supervisee. ..."*

The North Carolina Medical Board's June 4, 2012, position statement on "NCMB and physician supervision of certified nurse midwives: the facts", states in part: *"To practice lawfully, CNMs must be supervised by a licensed physician in accordance with criteria set out in Article 10A of the NC General Statutes. Proper supervision includes having detailed written guidelines that describe the clinical role of the CNM and the supervising physician, written guidelines that describe how and under what*

circumstances the CNM and the supervising physician will communicate, and a formal process for periodically reviewing care, among other things”

Midwifery Joint Committee Requirement:

The Midwifery Joint Committee State of North Carolina’s Application for Annual Renewal As A Nurse-Midwife under Material To Keep On File At Each CNM Practice Site states:

- “1. General Statutes (G.S. 90-178.1) and Administrative Rules 21 NCAC 33.0001-.0006.*
- 2. Photocopy of completed annual renewal application and letter of approval.*
- 3. Written clinical practice guidelines for each clinical practice, which define the individual and shared responsibilities of the midwife and the supervising physician(s). Guidelines must include a list of those drugs and devices that you may prescribe or order and ongoing communication with the supervising physician(s) that provide for and define appropriate consultation. Guidelines must be signed by you and all supervising physicians.*
- 4. Process for periodic and joint evaluation of services rendered, e.g. chart review, case review, patient evaluation, and review of outcome statistics by CNM and supervising physician(s).*
- 5. Process for periodic and joint review and updating of the written guidelines by CNM and supervising physician(s).*
- 6. Other pertinent correspondence with the Midwifery Joint Committee.”*

North Carolina Regulation Regarding Physician Supervision of CNMs:

“The applicant shall furnish the committee evidence, satisfactory to the committee, that the applicant will perform the acts authorized by the Midwifery Practice Act under the supervision of a physician who is actively engaged in the practice of obstetrics in North Carolina. Such evidence required by the committee shall include a description of the nature and extent of such supervision and a delineation of the procedures to be adopted and followed by each applicant and the supervising physician responsible for the acts of said applicant for the rendering of health care services at the sites at which such services will be provided. Evidence to be provided to the committee shall include:

- (1) mutually agreed upon written clinical practice guidelines which define the individual and shared responsibilities of the midwife and the supervising physician(s) in the delivery of health care services;*
- (2) mutually agreed upon written clinical practice guidelines for ongoing communication which provide for and define appropriate consultation between the supervising physician(s) and the midwife;*
- (3) periodic and joint evaluation of services rendered, e.g. chart review, case review, patient evaluation, and review of outcome statistics; and*
- (4) periodic and joint review and updating of the written medical clinical practice guidelines.”*

(21 NCAC 33 .0104)

Baby+Co Medical Director Service Agreement

At the time of the DHSR review, Baby+Co derived services of a Medical Director through a Medical Director Services Agreement dated March 16, 2016 with a local OB-GYN physician practice.⁶ The Medical Director qualifications included a requirement that the Medical Director be an active member on the medical staff of a particular local hospital. The agreement did not identify the name of the

⁶ DHSR has learned that the Medical Director Service Agreement it reviewed has been terminated, and Baby+Co first contracted with another Medical Director in Greensboro. Subsequently DHSR has learned that another Medical Director has been named for Baby+Co, a physician from Charlotte. The newest Medical Director is not on the medical staff of the local hospital where Baby+Co had a transfer agreement at the time of the review.

physician who would fulfill the responsibilities of Medical Director. Exhibit A of the agreement listed examples of Medical Director and Consultative Duties and Services which in pertinent part included:

“b) Agree to and execute necessary documents as agreements with each Center midwife and provide clinical supervision for the Center midwives, all as may be requested by Center and is consistent with and as may be required by licensure requirements and laws applicable to the Center’s midwives and Center’s operations.

c) Be available 24/7 to provide consultative and case review support to Center midwives, as needed under applicable State law and as requested by the Center from time to time.

d) Participate in regular phone calls / conferences on an agreed

e) Participate in monthly chart reviews as requested by Center

f) Participate, at least quarterly, in meetings with Center’s Quality Management Committee to assist in reviews of outcome data, transfers, and clinical and quality measures.

g) Coordinate the provision of backup clinical support for Center, as needed and requested from time to time, including the provision of ultra-sound and other ancillary services.

i) Assist, as requested by the Center,

j) Assist, as requested by Center in coordinating and facilitating patient transfer to hospital and / or other providers, as may be needed from time to time based on clinical risk or patient needs.”

Additional Support Services:

“ Contractor shall provide general administrative support to Center in conjunction with its Medical Director Services, as may be reasonably requested by Center from time to time.

Make available to Center patients, as requested by the Center, ultrasounds and other ancillary services offered by Contractor.”

DHSR Concern

Based on review of the information available during the onsite visit, Baby+Co’s clinical areas were staffed by fourteen practicing Certified Nurse Midwives (CNM), two Registered Nurses (RN) and one Medical Assistant (MA). Although the Medical Director Services Agreement provided that a physician would serve as the supervising physician for all Baby+Co CNMs, neither Baby+Co nor its CNMs could provide DHSR reviewers with the details of the supervision. For instance, there were no written agreements or written protocols or guidelines that described the scope of supervision provided each CNM in accordance with state regulations or that set out the parameters or circumstances in which the CNM would be required to contact their supervising physician for direction. When interviewed, the supervising physician for the CNMs at Baby+Co noted that CNMs may perform low risk, normal vaginal deliveries, largely independently.⁷ The supervising physician (who also acted as the Medical Director) noted he was not contacted by Baby+Co staff prior to or during the deliveries of the reviewed records that resulted in infant deaths during his tenure. For the three deaths that occurred during his tenure as Medical Director he was contacted days after the deaths occurred.

⁷ DHSR has learned that Baby+Co CNMs currently have a different supervising physician than at the time of the DHSR review.

As to the consultative services of the Medical Director, in the interview, the Medical Director indicated the CNMs called him for complications or questions on patients throughout his tenure as Medical Director. However, there were not written protocols or guidelines that dictated when he should be contacted.

According to staff interview on April 24, 2018, at 1035 and April 26, 2018, at 1212, the Medical Director / Supervising Physician did not orient staff, but the facility stayed in “close contact” with him regarding “what happened” and “how it is going”. She stated the Medical Director was not “hands on” and that the facility utilized the Medical Director as a consultant, a referring physician and to oversee hospital births. The Medical Director was “not on the ground working next to us”. According to interview, the Medical Director did not attend monthly Baby+Co staff meetings, but, attended scheduled quarterly collaborative quality meetings at the local hospital. However, the Medical Director / Supervising Physician had not attended any births at Baby+Co Birthing Center. The Medical Director / Supervising Physician did attend births at a local hospital with CNMs credentialed to provide care in the hospital setting. Neither Baby+Co nor the Medical Director / Supervising Physician provided any data to validate physician supervision of Baby+Co’s CNMs.

CABC Standard 6- Staffing and Personnel

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

Standard 6.1: “Professional staff and consulting specialists provide evidence of knowledge and skills required to provide services offered by the birth center. Required evidence of written job descriptions, job definition, lines of authority, ... orientation mechanism, ... policies and procedures.”

Standard 6.6: “. . . at each birth there shall be two staff currently trained in”

Discussion

Onboarding and Job Description Review

Review of the “Onboarding” policy and the job descriptions for Lead CNM, CNM, CNM Fellow, Registered Nurse and Medical Assistant was performed on April 23, 2018.

According to interview April 24, 2018 1035 and 1320 all new hires were screened initially by reviewing candidates’ curriculum vitae (CV). Baby+Co provided that all CNM candidates’ CVs should have an indication they were experienced with “Full Scope” practice. “Full Scope” meant caring for a woman throughout her life span prenatal, labor, birth, postpartum, well-woman, menopausal and contraception. The second step was a telephone interview by both regional directors. Interview revealed if the CNM passed the phone interview, the candidate was brought in for a face-to-face interview with the leadership and selected team members. Subsequently, the candidates were selected and received a job offer.

The Baby+Co Certified Nurse Midwife Position description last modified February 8, 2018 at 1751 stated:

“The certified midwife provides care to low risk women, and their newborns, seeking Baby+Co’s innovative model of care emphasizing personalized care planning, intensive education, and family-centered care. The CNM will be responsible for the management of the low risk woman and fetus throughout the labor and delivery process and for woman’s primary gynecological health including family planning, well woman visits, gynecological problem visits, and appropriate screening and health education. The CNM is expected

to fill clinical and educational roles including Clinic 1, Clinical 2, Call 1, Call 2, and Educator, based on center needs and individual competencies. ...”

The Baby+Co Certified Nurse Midwife Fellow Position Description last modified February 8, 2018 at 1752 stated:

“Baby+Co offers a Fellowship opportunity for new graduate CNMs interested in strengthening their skills in birth center care and exploring long-term employment in a Baby+Co Center. ... CNM Fellows will be placed in existing Baby+Co Centers, where they will function primarily in the Call 2 – LBRP and Clinic 2 roles, as described below.

Call 2 – Labor, Birth, Recovery, Postpartum (“LDRP”): in this role, the CNM Fellow is the answering service contact and has primary triage responsibilities for intrapartum care and after-hours / weekend calls. Under the supervision of an experienced CNM mentor, the CNM Fellow provides the necessary care, support, and management from admission to the birth center through discharge or transfer.

Clinic 2 – Has primary responsibility for postpartum / newborn (home / hospital) and same-day / walk-in encounters, as general clinical operations. ...

Based on performance and experience, and with approval by the Director of Clinical Operations, Fellows may assume the Call 1 and Clinic 1 roles during the Fellowship Year.”

Fellow requirements included:

- *Graduated within the previous 6 months from an accredited nurse midwife program*
- *Passionate about Baby+Co mission, vision, values, and care model*
- *Eligible for licensure in state where center is located*
- *Current neonatal resuscitation program certification*
- *Willingness to relocate after fellowship strongly preferred*
- *Prior birth center or home birth experience preferred (including exposure during midwifery education*
- *Prior group prenatal care experience preferred (including exposure/training during midwifery education.”*

Supervision, Competency Assessments and Annual Review

Credential and Personnel file reviews revealed three versions of a clinical competency assessment form utilized for new hires. One was titled “Clinical Staff Orientation Checklist” [Version #1], another was titled “CNM Clinical Staff Orientation Checklist” [Version #2] and the third version was titled “Clinical Staff Orientation Checklist” [Version #3]. The three-versions of the clinical staff orientation checklist covered the following clinical skills/topics: “Priority Orientation Topics”, “General Clinic Operations”, “Antepartum” (before birth), “Intrapartum” (labor and delivery) and “Other”.

Version #1 of the clinical staff orientation checklist (no date of revision or implementation date) did not include a microscopy (use of the microscope for wet prep screenings) check-off. Version #1 was found in the credential file for CNM #4 hired in April, 2017 and for several of the CNM records reviews for CNMs hired prior to April 2017.

“CNM Clinical Staff Orientation Checklist” [Version #2] (no date of revision or implementation date) included a microscopy check off under the topic “General Clinic Operations”. Version #2 was found in the credential’s file of CNM #11 (hired 07/24/2017) and those hired after that date.

“Clinical Staff Orientation Checklist” [Version #3] (revision date 4/18/2018) was provided for review by CNM #17 on April 26, 2018, but, was not in any of the credential files reviewed.

DHSR’s review found no 30 day, 60 day, 90 day or annual competency assessments for review in any of the CNM credential files or the RN and MA files.

DHSR’s review found no individual contracts between fourteen of fourteen CNMs and their respective supervising physician in the credential files. Request for a detailed list of responsibilities with each CNM of the supervising physician was requested, but was not available.

According to interview May 1, 2018 at 1420 “there was no formal annual competency check list, the drills were considered the annual competency. The facility expected the CNMs to maintain licensing requirements, to follow the CABC standards and to complete three modules in five years as recommended by AMCB (American Midwifery Certification Board)”.

April 24, 2018 at 1320 staff interview indicated the orientation process for new CNMs had been “informal”. There was no formal sign-off or documented communication and “periodic evaluations are not documented in writing.” Growth opportunities had been identified during a recent accreditation survey related to supervisory sign off / validation records of competency documentation. The staff at the front desk knew “who can do what.” CNM progress and performance in the “Birth Space” was discussed at clinical meetings where experienced CNMs, CNM fellows and new hires all attended. Interview revealed, it was up to the mentor to share what she (fellow / orientee) needed practice with and it was up to the orientee or fellow to be “proactive” and request assistance / support from more experienced CNMs with the skill or process. All staff followed a [name] board (computer) that has check lists and check points. (TRELLO or computer checklist was not available for review team due to limited access to files.) Further interview on April 24, 2018 at 0900 staff stated they considered the annual review and the drills to meet the CNMs’ annual competency assessments.

Credential File Review

Five of fourteen CNM s (#1, #5, #6, #7 and #8) were listed as credentialed to provide care and practice at the local hospital.

Baby+ Co “Locums Tenens Agreement dated August 3, 2017 for supplemental staffing included the following Client (Baby+Co) responsibilities:

“Represent the practice accurately, and provide suitable staff, work schedule, medical equipment and supplies. ...

Process and approve chosen Provider’s (CNM) credentials, granting appropriate privileges, in accordance with Client’s statement of work. Client is responsible for assessing competency of Provider in accordance with Client’s requirements.

Assume cost associated and applying for hospital privileges.”

- Review on April 24, 2018 of the Credential file for CNM #2 revealed a hire date of January 3, 2018 as Locum Tenens. According to the file review, CNM #2 graduated with a MSN of Midwifery in

2004 and received her initial certification by the state of NC on August 19, 2016. Continued review referenced CNM #2 had 14 years of Labor and Delivery experience as a RN prior to completing her MSN. The credential file revealed a signed job description for a CNM. Review revealed no delineation of privileges the CNM would be allowed to provide. Continued review revealed no completed competency checklist, no comments or feedback, and no quantified number of observations of care/tasks requirement for validation of competency. Continued review revealed CNM licensure with the Medical Director listed as supervising physician. There was no contract between CNM #2 and Medical Director / Supervising Physician defining the scope of supervision to be provided by the physician. Review revealed no list of facility emergency drills that CNM #2 was a participant. CNM#2 was terminated in February 2018 with no additional information available.

Interview on April 24, 2018 at 1035 with Baby+Co staff stated “CNM #2 was credentialed by an outside agency.” Interview revealed Baby+Co believed CNM #2 “lied” on a background check resulting in her termination from the facility. Continued interview indicated the outside agency was not aware of the issue and future Locum Tenens employees would have an additional background check performed by the facility prior to work assignments.

Based on the “Locums Tenens Agreement,” referenced above, Baby+Co held the responsibility to: *“Process and approve chosen Provider’s (CNM) credentials, granting appropriate privileges, in accordance with Client’s statement of work. Client is responsible for assessing competency of Provider in accordance with Client’s requirements.”* In summary, there was no evidence available to determine that Baby+Co conducted or validated criminal background checks, references, or skills, prior to scheduling CNM #2 to work.

- Review on April 25, 2018 of the Credential file for CNM #15 revealed a hire date of March 19, 2018 as a fellow. The file referenced CNM #15 graduated with a DNP of Midwifery in August 2016 and received her initial certification by the State of NC on March 3, 2018. Continued review referenced CNM #15 had one and a half years of Labor and Delivery experience as a RN prior to completing her DNP. The credential file revealed a signed job description for a CNM. Review revealed no delineation of privileges the CNM would be allowed to provide. Continued review revealed no competency checklist available for review. Review revealed no comments or feedback, and no quantified number of observations of care/tasks requirement for validation of competency. Continued review revealed CNM licensure with the Medical Director listed as supervising physician. There was no contract between CNM #15 and Medical Director / Supervising Physician defining the scope of supervision to be provided by the physician. Review referenced no list of facility emergency drills that CNM #15 participated in. Review included no 30-day review of skills/progress available.
- Review on April 25, 2018 of the Credential file for CNM #16 revealed a hire date of March 18, 2018 as a fellow. Review referenced CNM #16 graduated with a MSN of Midwifery in December, 2017 and received her initial certification by the State of NC on March 6, 2018. Continued review revealed CNM #16 had five years of Labor and Delivery experience as a RN prior to completing her MSN. The credential file revealed a signed job description for a CNM. Review revealed no delineation of privileges the CNM would be allowed to provide. Continued review revealed incomplete competency checklist for microscopy. Review revealed no comments or feedback, and no quantified number of observations of care/tasks requirement for validation of competency. Continued review included CNM licensure with the Medical Director listed as

supervising physician. There was no contract between CNM #16 and Medical Director / Supervising Physician defining the scope of supervision to be provided by the physician. Review revealed no list of facility emergency drills that CNM #16 participated in. Review included no 30-day review of skills/progress available.

- Review on April 25, 2018 of the Credential file for CNM #14 revealed a hire date of February 5, 2018. Review referenced CNM #14 graduated with a MSN of Midwifery in October, 2012 and received her initial certification by the State of NC on March 6, 2018. Continued review revealed CNM #14 had five years of Labor and Delivery experience as a RN prior to completing her MSN. The credential file revealed a signed job description for a CNM. Review revealed no delineation of privileges the CNM would be allowed to provide. Continued review revealed no competency checklist available for review. Review revealed no comments or feedback, and no quantified number of observations of care/tasks requirement for validation of competency. Continued review included CNM licensure with the Medical Director listed as supervising physician. Further review revealed no contract between CNM #14 and the Medical Director / Supervising Physician defining the scope of supervision to be provided by the physician. Review revealed no list of facility emergency drills that CNM #14 participated in. Review included no 30 or 60-day review of skills/progress available.
- Review on April 24, 2018 of the Credential file for CNM #3 revealed a hire date of September 7, 2017. Review referenced CNM #3 graduated with a MSN (Master Degree in Nursing) of Midwifery in August 2014 and received her initial certification by the State of NC on October 15, 2017. Continued review revealed CNM #3 had three years of Labor and Delivery experience as a RN prior to completing her MSN. The credential file revealed a signed job description for a CNM. Review revealed no delineation of privileges the CNM would be allowed to provide. Continued review referenced a completed competency checklist including microscopy that was dated and initialed. Review revealed no comments or feedback, and no quantified number of observations of care/tasks requirement for validation of competency. Continued review included CNM licensure with the Medical Director listed as supervising physician. Further review revealed no contract between CNM #3 and the Medical Director / Supervising Physician defining the scope of supervision to be provided by the physician. Review revealed a list of facility emergency drills that CNM participated in and an annual evaluation. Review included no annual competency assessment available for review.
- Review on April 24, 2018 of the Credential file for CNM #9 revealed a hire date of August 31, 2017 as a fellow. Review revealed CNM #9 graduated with a MSN of Midwifery in May, 2017 and received her initial certification by the State of NC on October 17, 2017. Continued review revealed CNM #9 had two years of Labor and Delivery experience as a RN prior to completing her MSN. The credential file revealed a signed job description for a CNM. Review revealed no delineation of privileges the CNM would be allowed to provide. Continued review revealed a completed competency checklist with microscopy that was dated and initialed. Review revealed no comments or feedback, and no quantified number of observations of care/tasks requirement for validation of competency. Continued review included CNM licensure with the Medical Director listed as supervising physician (MD #10). Further review revealed no contract between CNM #9 and the Medical Director / Supervising Physician defining the scope of supervision to be provided by the physician. Review revealed a list of facility emergency drills that CNM #9 participated in. Review included no 30, 60 or 90-day review of skills/progress available.

- Review on April 24, 2018 of the Credential file for CNM #11 revealed a hire date of July 24, 2017 as a fellow. Review revealed CNM #11 graduated with a MSN of Midwifery in March, 2017 and received her initial certification by the State of NC on June 28, 2017. Continued review revealed CNM #11 had three years of Labor and Delivery experience as a RN prior to completing her MSN. The credential file revealed a signed job description for a CNM. Review revealed no delineation of privileges the CNM would be allowed to provide. Continued review revealed a completed competency checklist with microscopy that was dated and initialed. Review revealed no comments or feedback, and no quantified number of observations of care/tasks requirement for validation of competency. Continued review included CNM licensure with the Medical Director listed as supervising physician. Further review revealed no contract between CNM #11 and the Medical Director / Supervising Physician defining the scope of supervision to be provided by the physician. Review revealed a list of facility emergency drills that CNM #11 participated in. Review included no 30, 60 or 90-day review of skills/progress available.
- Review on April 24, 2018 of the Credential file for CNM #4 revealed a hire date of April 24, 2017 into the Fellowship Program. Review referenced CNM #4 graduated with a MSN of Midwifery in August 2016 and received her initial certification by the State of NC on October 25, 2017. Continued review revealed CNM #4 had two years of Labor and Delivery experience as a Doula (birth assistant) prior to completing her MSN. The credential file revealed a signed job description for a CNM Fellowship Program. Review revealed no delineation of privileges the CNM would be allowed to provide. Continued review revealed a completed competency checklist without microscopy that was dated and initialed. Review revealed no comments or feedback, and no quantified number of observations of care/tasks requirement for validation of competency. Continued review included CNM #4 licensure with the Medical Director listed as supervising physician. Further review revealed no contract between CNM #4 and the Medical Director / Supervising Physician defining the scope of supervision to be provided by the physician. Review revealed a list of facility emergency drills that CNM participated in and an annual evaluation. Review referenced no 30, 60 or 90-day review of skills/progress available. Review revealed no annual competency assessment available for review.
- Review on April 24, 2018 of the Credential file for CNM #8 revealed a hire date of September 23, 2016. Review referenced CNM #8 graduated with a MSN of Midwifery in May, 2015 and received her initial certification by the State of NC on July 23, 2015. Continued review revealed CNM #8 had two years of Labor and Delivery experience as a RN prior to completing her MSN. The credential file revealed a signed job description for a CNM. Review revealed no delineation of privileges the CNM would be allowed to provide. Continued review revealed a completed competency checklist without microscopy that was dated and initialed. Review revealed no comments or feedback, and no quantified number of observations of care/tasks requirement for validation of competency. Continued review included CNM licensure with the Medical Director listed as supervising physician. Further review revealed no contract between CNM #8 and the Medical Director / Supervising Physician defining the scope of supervision to be provided by the physician. Review revealed a list of facility emergency drills that CNM #8 participated in and an annual evaluation. Review included no annual competency to review.
- Review on April 24, 2018 of the Credential file for CNM #1 revealed a hire date of April 19, 2016. Review referenced CNM #1 graduated with a MSN (Master Degree in Nursing) of Midwifery in September 2015 and received her initial certification by the State of NC on May 12, 2016.

Continued review revealed CNM #1 had two years of Labor and Delivery experience as a RN prior to completing her MSN. The credential file revealed a signed job description for a CNM. Review referenced no delineation of privileges granted for CNM #1 to provide at the Center. Continued review revealed a completed competency checklist without microscopy that was dated and initialed. Review revealed no comments or feedback, and no quantified number of observations of care/tasks requirement for validation of competency. Continued review included CNM #1's NC CNM licensure with the Medical Director as supervising physician. Further review revealed no contract between CNM #1 and the Medical Director / Supervising Physician defining the scope of supervision to be provided by the physician. Review revealed a list of facility emergency drills that CNM participated in and an annual evaluation. Review included no annual competency assessment available for review.

- Review on April 24, 2018 of the Credential file for CNM #17 revealed a hire date of April 20, 2015. Review referenced CNM #17 graduated with a MSN of Midwifery in August, 2010 and received her initial certification by the State of NC on December 28, 2016. Continued review referenced CNM #17 had one year of Labor and Delivery experience as a RN prior to completing her MSN. The credential file revealed a signed job description for a Lead CNM. Review revealed no delineation of privileges the CNM would be allowed to provide. Continued review revealed a completed competency checklist without microscopy that was dated and initialed. Review revealed no comments or feedback, and no quantified number of observations of care/tasks requirement for validation of competency. Continued review included CNM licensure with the Medical Director listed as supervising physician. Further review revealed no contract between CNM #17 and the Medical Director / Supervising Physician defining the scope of supervision to be provided by the physician. Review revealed a list of facility emergency drills that CNM #17 participated in and an annual evaluation. Review included no annual competency to review.
- Review on April 24, 2018 of the Credential file for CNM #5 revealed a hire date of April 6, 2015 for part-time employment. Review revealed CNM #5 graduated with a MSN of Midwifery in December, 2007 and received her initial certification by the State of NC on July 1, 2009. Continued review referenced CNM #5 had two years of Labor and Delivery experience as a RN prior to completing her MSN. The credential file included a signed job description for a CNM. Review revealed no delineation of privileges the CNM would be allowed to provide. Continued review revealed a completed competency checklist without microscopy and dates in that was initialed. Review revealed no comments or feedback, and no quantified number of observations of care/tasks requirement for validation of competency. Continued review included CNM licensure with the Medical Director listed as supervising physician. Further review revealed no contract between CNM #5 and the Medical Director / Supervising Physician defining the scope of supervision to be provided by the physician. Review revealed a list of facility emergency drills that CNM #5 participated in and an annual evaluation. Review included no annual competency assessment available for review.
- Review on April 24, 2018 of the Credential file for CNM #6 revealed a hire date of December 15, 2014. Review referenced CNM #6 graduated with a MSN (Master Degree in Nursing) of Midwifery with no graduation date available, but obtained her first midwifery job in 2008. CNM #6 received her initial certification by the State of NC on November 1, 2011. Continued review referenced CNM #6 had nine years of Labor and Delivery experience as a RN prior to completing her MSN. The credential file revealed a signed job description for a CNM and CNM Lead. Review revealed

no delineation of privileges the CNM would be allowed to provide. Continued review revealed a completed competency checklist without microscopy that was dated and initialed. Review revealed no comments or feedback, and no quantified number of observations of care/tasks requirement for validation of competency. Review revealed a letter verifying re appointment and delineating detailed privileges at a local hospital. Continued review included CNM licensure with the Medical Director listed as supervising physician. Further review revealed no contract between CNM #6 and the Medical Director / Supervising Physician defining the scope of supervision to be provided by the physician. Review revealed a list of facility emergency drills that CNM #6 participated in and an annual evaluation. Review included no annual competency assessment available for review.

- Review on April 24, 2018 of the Credential file for CNM #7 revealed a hire date of December 9, 2014 as a nurse and then, a new graduate CNM. Review referenced CNM #7 graduated with a DNP (Doctorate Degree in Nursing) of Midwifery in May, 2015 and received her initial certification by the State of NC on July 23, 2015. Continued review revealed CNM #7 had two years of Labor and Delivery experience as a RN prior to completing her DNP. The credential file included a signed job description for a CNM. Review revealed no delineation of privileges the CNM would be allowed to provide. Continued review revealed a completed competency checklist without microscopy that was dated and initialed. Review revealed no comments or feedback, and no quantified number of observations of care/tasks requirement for validation of competency. Continued review included CNM licensure with the Medical Director listed as supervising physician. Further review referenced no contract between CNM #7 and the Medical Director / Supervising Physician defining the scope of supervision to be provided by the physician. Review revealed a list of facility emergency drills that CNM #7 participated in and an annual evaluation. Review included no annual competency to review.

Other Staff

- Review on April 24, 2018 of the personnel file for RN #13 revealed a hire date of May 1, 2015. RN #13 completed her BSN (Bachelors in Nursing) in 1996. Review referenced RN #13 had 20 years of labor and delivery experience. Review revealed a competed and dated competency checklist. Review revealed no autoclave competency in the personnel file for review. Review included no comments or feedback, and no quantified number of observations of care/tasks requirement for validation of competency. Review referenced no annual competency to review.

Interview on 04/24/2018 at 1530 with RN #13 indicated she was responsible for inventory, checking for expiry dates and provided birth assistance. Interview referenced RN #13 worked in the clinic most frequently and that she performed some of the home visits.

- Review on April 25, 2018 of the Personnel file for MA #12 revealed a hire date of February 6, 2017. Review referenced MA #12 had one-year prior experience as a MA. Review referenced no autoclave (sterilization) competency in the personnel file for review. Review included no comments or feedback, and no quantified number of observations of care/tasks requirement for validation of competency. No annual competency was provided to review.

Interview on April 24, 2018 at 1530 with RN #13 revealed the MA performed spore testing and autoclave maintenance. Continued interview revealed “we had a nurse” that did the autoclave spore testing, training and maintenance, but she was no longer there.

DHSR Concern

In summary, Baby+Co did not have a consistent and formal orientation process to validate the skills of its CNMs. Based on file reviews, there were no documented comments or feedback, and no quantified number of observations of care/tasks requirement for validation of competencies. CNM records did not include delineation of privileges the CNM would be allowed to provide. There was no evidence to validate the training of CNM to perform microscopy. There was no documented training on how to perform the procedures, competency assessments at six (6) months after initial training, and again after 12 months; and, yearly thereafter to ensure these test procedures are performed accurately. Facility staff failed to conduct 30, 60 or 90-day review of skills/progress available. Review revealed no annual competency assessment available for review. Further, there were no protocols / agreements regarding what circumstances would trigger a requirement for Baby+Co's CNMs to contact their respective supervising physician.

Medical Record Reviews

CABC Standard 3- Administration

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.

Standard 3.10: "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:...*3.10.B. Transport Services....REQUIRED....Evidence of:....Smooth transfers without delay in arrival to or departure from the birth center. ..." (Charts A, B, D)

CABC Standard 5 – Quality of Services

Standard 5.1.C: "Be informed of the benefits, risks and eligibility requirements of an out of hospital labor and birth....REQUIRED...Evidence of...A plan to assure an informed consent process is in place regarding the birth center with every client and pregnancy (Charts A,B, D, E)

Standard 5.2.I: "Intrapartum Care....Evidence of...P&Ps include guidelines for management of prolonged first and second stage labor that are consistent with best-available advice. ..." (Chart E)

Standard 5.2.L: states "*Referrals to meet the needs of each client outside the scope of birth center practice....REQUIRED....Evidence of...Referrals to meet the needs of each mother and/or newborn that falls outside the scope of birth center resources and risk criteria at any point during the course of care.... UNACCEPTABLE....Failure to refer or transfer mother or newborn who develops a problem that makes them inappropriate for....birth center care according to....birth center's own risk criteria.*" (Charts D, E)

Standard 5.4:"*...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.*" (Chart B)

CABC Standard 6 – Staffing and Personnel

Standard 6.2: "Professional staff and consulting specialists are *licensed to practice their profession* in the jurisdiction of the birth center. ..." (Chart E)

Standard 6.4: "There are *adequate numbers of professional and support staff* on duty and on call to meet the 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*....REQUIRED....Evidence of....Adequate personnel available to manage unexpected emergencies. ..." (Charts C, E)

CABC Standard 7 - Health Record

Standard 7.2.F: "Continuous periodic prenatal examination and evaluation of risk factors....The risk status must be documentedat least at the following intervals....each trimester....admission in labor. ..." (Charts A, E)

Standard 7.2.I: "Monitoring of Progress in labor and on-going assessment of maternal and fetal reaction to the process of labor in accordance with accepted professional standards. Evidence ofP&P's (policies and procedures) require documentation of fetal heart tones (FHT's) consistent with the following at a minimum....Active labor – every 30 minutes....Second stage with pushing – every 5-15 minutes....increased frequency of vital signs in the presence of risk factors....such as....decelerations. ..." (Chart B)

Standard 7.2.J:"Consultation, referral and transfer for maternal or neonatal problems that elevate risk status....UNACCEPTABLE....Evidence of failure to transfer according to risk criteria as per birth center's P&Ps. ..." (Chart D)

Summary of Chart A

Record review of Chart A showed the client arrived to the Birth Center at 0640, 7 centimeters (cm) dilated and at 41.0 week gestation. Fetal heart tones (FHTs) were noted as 135-145 with accelerations, no decelerations. The maternal/fetal risk status was documented as zero (0) (appropriate for Birth Center). Documentation noted a pregnancy weight gain of 60 pounds on the last prenatal visit, and showed a pre-pregnancy weight of 111. The document indicated an estimated fetal weight of 8.5-9.0 pounds. Per the record membranes ruptured at 1141 with clear fluid noted, the patient was completely dilated at 1440, and started spontaneously pushing at 1415. The Birth Note stated there was reassuring fetal status throughout the 2nd stage of labor. Documentation stated FHTs were taken approximately every 5 minutes during the 2nd stage and did not show any notations that decelerations were noted. The last FHTs noted were at 1630 (10 minutes before delivery) and ranged from 128-140. The baby's head was documented as delivered at 1638 and then delivery was noted to slow down. Maternal position changes were made, suprapubic pressure was applied, and an episiotomy cut, after which the infant was born at 1640 (2 minutes after the head delivered, and 2 hours, 25 minutes after the start of spontaneous pushing). Apgar scores were noted as 5 at one minute and 5 at five minutes of age. Record review of the Transfer Note noted EMS was called due to "shoulder dystocia" and minimal respiratory effort by the infant at birth. EMS, per review, arrived at 1644-1645 (4-5 minutes after birth) with care of the infant transitioned to them upon arrival. Further record review indicated some confusion/ discussion related to the hospital of transfer. Review noted the baby was transferred to Hospital at 1703 (23 minutes after birth) and revealed a note that the infant was not taken to the Special Care Nursery but was instead transported to the ED where resuscitation was continued.

Interview with Certified Nurse Midwife (CNM) K was conducted on 04/24/2018 at 1445. The CNM stated she took care of the patient in Chart A and was a Fellow at the time (in her first year as a CNM), but was not new and had managed other deliveries independently. CNM K stated a Senior Midwife had been present during the labor since 1415 and she turned care over to the Senior Midwife prior to birth, who did the episiotomy and swept the arm. She also stated some concerns related to the transfer and stated she offered to place a LMA because she saw the baby's progress was changing.

Interview with CMN H noted she delivered the baby after she was asked to step in. She stated the patient was repositioned, suprapubic pressure was applied, and she cut an episiotomy and the baby delivered. It did not take long, the CNM stated. In further interview, she stated that once chest compressions were started EMS decided to transfer to Hospital B. After reaching a supervisor, she indicated, they were able to get agreement to transfer to Hospital A. She stated it was important to transfer to Hospital A because of the proximity across the street vs. a 15-20 minute ambulance ride, the infant's condition, and that it had been agreed, based on past transfers, that Hospital A would be used.

Review of Chart A showed documentation that stated the baby's head was delivered at 1638 but then slow delivery of the rest of the baby and color change of the fetal scalp was noted. The record stated there were maternal position changes and suprapubic pressure was applied. Per review, a CNM cut an episiotomy, freed the fetal arm and the infant was born at 1640 (2 minutes after the head delivered). Documentation showed 911 was called at 1639 (one minute after the head delivered and one minute before birth). The Transfer Note stated EMS (Emergency Medical Services) was called due to shoulder dystocia and newborn's minimal respiratory effort at birth. Review of the record stated no spontaneous respiratory effort was made by the infant at birth and positive pressure ventilation (PPV) was begun at 1640. According to the Baby+Co records, EMS was noted to arrive to the center at 1644-1645 with care of the newborn transferred by 1646 and a note the infant was stable. EMS, the record stated, used their own equipment and was noted to readjust the infant mask several times. Per the Baby+Co record, EMS was asked on three different occasions for a CNM to place a LMA (laryngeal mask airway – another type mask to deliver respirations) but EMS declined. The Baby+Co record also stated its staff asked EMS staff to transfer the newborn to the nearby hospital (Hospital A), but EMS stated the baby needed to be transferred to a different hospital which although farther away, had a neonatal intensive care unit. (According to information obtained by DHSR staff, EMS has certain protocols regarding transfers and follow those in the absence of an order overriding the protocol. EMS personnel are not allowed to take orders from a CNM.) Documentation stated several calls were made by EMS staff and Baby+Co staff to reach agreement on the transfer location. Per the record, agreement to transfer to Hospital A was reached at 1702 and the newborn was transferred out to the hospital at 1703 (23 minutes after birth and 18-19 minutes after EMS arrival). The record further stated the newborn was transported by EMS to the Emergency Department rather than the Special Care Nursery. Baby+Co documentation at 1729 stated "...I update....on infant status and significant lapse in care upon EMS arrival."

The Medical Director, in interview on 05/09/2018 at 1600, stated the Baby+Co eligibility/ risk admission criteria that was in effect at the time of the Chart A case was in place when he became Medical Director in 2016. He noted that it had been reviewed and adjusted over time. The 60 pound pregnancy weight gain limit, the Medical Director noted, was not new. The decision on whether delivery could occur at Baby+Co, he stated, was an individual one that depended on the circumstances, but in general a woman would risk out of being able to deliver at Baby+Co at a pregnancy weight gain above 60 pounds. He stated he did not receive any calls on this patient.

DHSR Concerns with Chart A

Despite the requirement of CABC Standard 3.10, regarding agreements/protocols/procedures with outside agencies to assure smooth transfers without delay, it appears there was not a clear understanding between Baby+Co staff and EMS staff related to neonatal resuscitation and the transport location. A smooth transfer did not occur. Based on the record and interviews there were questions and concerns about resuscitation equipment, clinical care, and the transfer location. A Baby+Co staff member stated documentation of a transfer agreement with Hospital A (EMS was not a party to this agreement) was shown to EMS while at the center, however, there was still confusion and concerns.

Baby+Co shared with DHSR reviewers that it has taken a number of actions since this event which include: a clarifying document was formulated in regards to the transfer agreement; CNMs and EMS have worked together, and per interview with a CNM ongoing communication and education has occurred and understanding of roles between the two groups. Now, the CNM stated, there is clarity on the transport hospital and the nurse midwife rides in the ambulance with EMS. The CNM stated a neonatal / maternal transport bag was developed with medications and supplies so the transporting CNM can continue to provide hands on care during transport.

With respect to the Baby+Co risk assessment in Chart A, CABC Standard 7.2F requires that Baby+Co perform “Continuous periodic prenatal examination and evaluation of risk factors....The risk status must be documentedat least at the following intervals....each trimester....admission in labor. ...” Baby+Co presented DHSR with its Risk Assessment criteria, dated October 2017, which indicated a consult or referral should be made to a physician if a patient’s pregnancy weight gain was over 60 pounds. Record review of Chart A showed a pre-pregnancy weight of 111 pounds. Per the record, at 40.2 weeks the patient had already gained 60 pounds. She arrived in labor at 41.0 weeks (5 days later). No weight was documented as taken on arrival. Per CNM interview patients are not weighed when they arrive to the Birth Center in active labor. A CNM stated the pre-pregnancy weight or the size of the mother did not change the total weight gain allowed, it was 60 pounds regardless. In this case, DHSR’s concern is that there was not further consideration of weight after the last prenatal visit nor consultation with the supervising physician for a 60 pound weight gain (maximum weight gain allowed to still meet Baby+Co admission criteria) that was noted 5 days before arrival to Baby+Co for delivery in labor, in a patient with a pre-pregnancy weight of 111 pounds.

Summary of Chart B

Chart B documented the Client arrived to the Birth Center at 0700, was 8 cm. dilated and 37.6 weeks pregnant on arrival. Review of FHTs on arrival documented a range of 136-149, with no decelerations. At 1049 notes indicated the Client was fully dilated and at 1050 spontaneous rupture of membranes with clear fluid was noted. The first noted decrease in FHTs was at 1053, when FHTs were documented as 80-90. It was noted that the patient was pushing well and there was good fetal descent. Oxygen at 10L was applied, per review, at 1055 and the patient was out of the tub and turned on her left side at 1100. At 1100 FHTs were noted as 90-100 with accelerations and at 1105 90-100 with decelerations and “head visible”. At 1110 FHTs were noted as 110-115, at 1122 were 125-138, and at 1126 were 110-115. At 1135, the last noted FHTs were 124-139, with a “crown” documented, and scalp pink noted. The infant was delivered at 1145. Review of the Birth Note noted documentation the patient delivered OA (Occiput anterior – head down and body facing toward the mother’s back), compound presentation of the right posterior hand. The record indicated the infant did not have respiratory effort at birth and positive pressure ventilation was begun. Apgar was 2 at one minute and 1 at 5 minutes. 911 was called at 1148 and Paramedics were noted to arrive at 1153 (8 minutes after birth). Apgar was noted as 5 at 10 minutes. The infant was transferred to Hospital A at 1208 (23 minutes after birth and 15 minutes after EMS arrival).

Staff interviewed indicated this was an appropriate delivery at the Birth Center, stating compound presentations can happen anywhere and that one cannot always tell a hand is presenting prior to birth. The staff stated there was some question of transferring the baby to Hospital B, but after discussion, the baby was transferred to Hospital A.

In interview with the Medical Director, on 05/09/2018 at 1600, he stated the CNMs called him for complications or questions on patients throughout his tenure as Medical Director although he did not receive a call regarding the patient in Chart B.

DHSR Concerns with Chart B

DHSR reviewers note the same concerns regarding CABC Standard 3.10 as was noted in the Chart A discussion. Chart B documentation stated the infant was born at 1145, EMS was called at 1148, paramedics arrived at 1153, and the infant was transferred out at 1208 (23 minutes after birth, 15 minutes after EMS arrival). In review of Chart B, there was no documentation noted that related to questions or concerns about the transfer hospital, however on interview a CNM stated EMS wanted to transfer the newborn to a different hospital than Hospital A, which was typically the transfer hospital. The CNM stated she had not transferred an infant in this type of situation before and did not know about the policy. In interview, the CNM stated another midwife was there, knew the agreement and was able to get the infant transferred to Hospital A.

In interview with another Baby+Co CNM, she stated action was initially taken after the birth and transfer of Baby B. A document was created, she stated, clarifying Hospital A as the transfer hospital. After the birth of Baby in Chart A (see above), which the CNM stated occurred later, additional action was taken as described above and a new clarifying document was created. The CNM stated they have worked closely with EMS with ongoing communication and education between the two groups and stated there has been improvement and understanding of roles. Now, she said, there is clarity on the transport hospital, and the nurse midwife rides to the hospital in the ambulance with EMS. The CNM stated a neonatal / maternal transport bag was developed with medications and supplies so the transporting CNM could continue to provide hands on care during transport.

CABC Standard 5.4 states “...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. ...”

CABC Standard 7.2.1 states “Monitoring of Progress in labor and on-going assessment of maternal and fetal reaction to the process of laborP&P’s (policies and procedures) require documentation of fetal heart tones (FHT’s) consistent with the following at a minimum....Active labor – every 30 minutes....Second stage with pushing – every 5-15 minutes....increased frequency of vital signs in the presence of risk factors....such as....decelerations. ...”

Review of Birth Center documents showed policies that related to monitoring of FHTs according to these standards, and staff interview noted that electronic fetal heart monitoring was not acceptable in labor.

In review of Chart B, a document was noted that stated at some point in labor the portable Doppler (used to hear FHTs) had a hard time finding FHTs. Labor record review showed FHTs were documented every 30 minutes up to 1030. At 1030 FHTs were documented as 137-160 with accelerations. At 1049 a note was made the patient was 10 cm dilated and pushing. At 1050 spontaneous rupture of membranes was noted. At 1053, FHTs were noted as decreased to 80-90 with a statement the patient was pushing well and had good fetal descent. The patient was placed on oxygen, per the record at 1055. FHTs were documented again at 1100 and noted as 90-100, with a statement the patient was on her left side. At 1105 (5 minutes later), fetal heart tones were documented as 90-100 with the head visible and decelerations. At 1110 (5 minutes later), fetal heart tones were documented as 110-115 and at 1122 (12 minutes later), they were documented as 125-138 and accelerations were noted. At 1126 (4 minutes later), FHTs were documented as 110-115 with a note of small crowning. At 1135 (10 minutes before delivery) FHTs were documented as 124-139. Birth was recorded as 1145 (52 minutes after the first fetal heart rate drop at 1053).

The concern of DHSR staff was whether there were decreased fetal heart tones that might have needed electronic fetal monitoring, consultation with the medical director or possibly transfer to the hospital,

especially if there was difficulty hearing fetal heart tones with known decelerations. In reviewing policies related to the frequency of fetal heart tones, the Birth Center policy stated every 5-15 minutes. Action taken by Baby+Co since this event include a policy update that provides for FHTs during second stage of pushing every 5-10 minutes and discusses pulse oximetry on the mother if there is difficulty differentiating fetal and maternal heart rates.

Summary of Chart C

Chart C was reviewed and documentation noted the patient presented to Baby+Co (date redacted) after spontaneous rupture of membranes at 0730. The temperature was documented as 98.4, she was 3 cm dilated, 50% effaced, and -1 (minus 1) station. FHTs were noted as 130-140s with no decelerations. The patient was noted to be sent home to await labor with instructions to notify a CNM if fever, decreased fetal movement, or labor. Per review she returned to Baby+Co at 0130 (date redacted), and was 7 cm dilated. The note stated FHR was documented as 58 (low), the patient was positioned on her side, a vaginal exam done and a coiled cord was palpated (prolapsed cord). According to record review, the patient was then placed in a knee chest position, her husband called 911, and the CNM notified another individual (name redacted) to call the hospital and come to Baby+Co.. At 0133, 10 liters of oxygen were noted to be on the patient. The CNM, documentation indicated, listened for a FHR, and heard a rate of 110 but could not be certain if it was the heart rate of mom or fetus. Once EMS arrived the patient, with CNM, was placed on a stretcher and transferred directly to the OR at Hospital A. The note stated the CNM kept her hand on the cord the entire time to protect the cord, removing it only after the infant delivered.

In interview with CNM F she stated the patient was seen in the afternoon because her membranes were ruptured. The patient was not in labor, the head was “well appointed”, and FHTs were okay, the CNM stated, so the patient went home to wait for labor. She came back in at 0130. Per interview, a vaginal exam was done, the patient had progressed and she was excited and stood up. She laid back down, the CNM said, to check FHTs, and the reading was low (58). The CNM stated the patient was vaginally checked again and she felt a “handful of cord” which was not there the first time she checked the patient. She stated the patient’s husband called 911 and she used her other hand to call another CNM. After she felt the cord, the CNM stated, she never removed her hand, kept it inside the vagina “protecting the cord”. CNM F stated it was patient’s choice whether to stay if there were ruptured membranes and no active labor. There was not a requirement to stay, she said and most patients did not want to stay if they were not in labor. On further interview CNM F stated she met the patient at Baby+Co, there were no other patients or staff there. The CNM stated it was the patient, husband, and herself. She stated it was normal to check a patient and evaluate the situation, then call the 2nd person when in active labor.

In interview with the Medical Director, on 05/09/2018 at 1600, he revealed the eligibility/ risk criteria for the Birth Center was in place when he became Medical Director in 2016. The Medical Director stated his preference was that a woman remain in the facility after membranes were ruptured.

DHSR Concerns with Chart C

Although CABC Standard 6.4 states “There are *adequate numbers of professional and support staff* on duty and on call to meet the 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....REQUIRED....Evidence of....Adequate personnel available to manage unexpected emergencies*, the chart review in this case indicated that the patient arrived at Baby+Co at night and there was only one staff person there (the Certified Nurse Midwife who met them) on arrival and did the initial evaluation. On interview, the CNM stated that it was not unusual for a CNM to meet the

patient and family member/support person at the Birth Center alone to evaluate the patient and then to call in another clinical person when needed, generally when the patient was in active labor. DHSR's concern is that in this case, a true emergency occurred very quickly and while the CNM was alone in the Birth Center with only the patient and her family member. The CNM had to keep one hand on the umbilical cord, and there was no other staff person available to help her either call for assistance or provide additional assessment or care.

Another area of concern is regarding not checking fetal heart tones prior to a vaginal exam and sending patients home with ruptured membranes. As this report will document, DHSR reviewers heard in subsequent interviews that some patients may have been unaware of the risks of a ruptured membrane and of the options that were available.

Summary of Chart D

Review of Chart D noted the patient arrived to the Birth Center at 1115 at 40.2 weeks gestation and 6 cm dilated. Documentation noted a reassuring fetal status and a risk status of 0, appropriate for delivery at the Birth Center. At 1145 FHTs were 124-147. At 1341, FHTs were 131-149, with accelerations. The record noted FHTs were intermittently assessed, with no FHR noted below 120 prior to rupture of membranes. At 1907, spontaneous rupture of membranes with thin meconium was noted and at 1915 the start of pushing was charted. At 1941 a FHT of 110-110 was documented, at 1944 mom's heart rate was noted as 118, and at 1945 FHTs of 90-100 were documented, with decelerations. At 1946 FHTs were 130-130 and at 1950 FHTs were noted as difficult to auscultate due to maternal position. At 1951 FHR was noted as 155-155, category 1. At 2000 (53 minutes after meconium noted when membranes ruptured), documentation stated the patient was evaluated for transfer to the hospital due to possible meconium and at 2005 review revealed that a decision was made to stay at the Birth Center based on the overall picture at that time. At 2026 a small crown was noted with FHTs of 155-155. At 2031 and 2033 notes were made of attempts to auscultate FHTs but difficulty in auscultation due to position and pushing. At 2035.22 FHTs were noted to decrease to 70-80 with difficulty in auscultation and distinguishing maternal and fetal heart rates. At 2037 and 2040 FHTs were documented as 90-100 with decelerations. At 2042, review noted FHTs of 110-120 with a note that intermittent FHTs indicated fetal recovery and gradual return to baseline. At 2044, documentation stated a full crown with a significant portion of the baby's head still felt behind the perineum with tight perineal tissue. Review noted category II FHTs and stated preparing to cut an episiotomy. The infant was born at 2046. Per the record, EMS was called at 2046.50 as the infant was not breathing and had poor tone. Positive pressure ventilation was documented as initiated at 2047.20 and the one minute Apgar was noted as 3. Two attempts were made to place a LMA (Laryngeal mask airway) without success (2048 and 2052) and PPV with "Neotee" was resumed. The Fire Department was noted to arrive at 2049.50 with EMS on the way. At 2051, the five minute Apgar was 3. Records reflect that EMS, arrived at 2054. At 2056 the 10 minute Apgar was noted as 3. Baby+Co's records indicate a note at 2057 stating that EMS was encouraged to transport the baby immediately but EMS wanted to intubate prior to transport. The Baby+Co records state that intubation was attempted at 2058 without success and PPV was resumed. The infant was transported to Hospital A at 2106 (20 minutes after birth). Further record review noted the mom sustained a 4th degree laceration and was sent to the hospital for repair.

Review of the EMS "Patient Care Report" indicated the midwives "...recommended getting a definitive airway in place prior to transport... ."

In interview with CNM D she stated the patient met criteria for a Baby+Co delivery when she arrived. Meconium, she stated, was noticed when the patient's membranes ruptured. The CNM stated the policy that was in effect at the time of this delivery was to transfer the mother to the hospital when meconium

was noted unless delivery was imminent. CNM D stated she was unclear about the definition of imminent at that time, and thought the baby was coming down well and anticipated delivery soon. She indicated she consulted with another midwife and they decided it would be safer to deliver at Baby+Co rather than a hospital since they thought delivery would be quick and there had been no further meconium noted since the membranes first ruptured. CNM D further stated she wanted the infant transferred by EMS immediately, but EMS wanted to intubate the newborn before the transfer.

In interview with the Medical Director, on 05/09/2018 at 1600, he stated this eligibility/ risk criteria was in place when he became Medical Director in 2016 but that it had been reviewed and adjusted over time. When asked about meconium in amniotic fluid, the Medical Director stated Baby+Co had made some changes in the criteria over time. The MD stated it was difficult when there was subjective criteria, such as descriptions of “thin” or “moderate” meconium used in a risk assessment. According to the Medical Director, currently, if there is any meconium seen, it is a risk out for delivery at Baby+Co and patients should be transferred. The Medical Director stated he did not receive any calls on the patient in this chart prior to delivery.

DHSR Concerns with Chart D

CABC Standard 5.2.L. states “*Referrals* to meet the needs of each client outside the scope of birth center practice....REQUIRED....Evidence of....Referrals to meet the needs of each mother and/or newborn that falls outside the scope of birth center resources and risk criteria at any point during the course of care.... UNACCEPTABLE....Failure to refer or transfer mother or newborn who develops a problem that makes them inappropriate for....birth center care according to....birth center’s own risk criteria. ...”

CABC Standard 7.2.J. states “Consultation, referral and transfer for maternal or neonatal problems that elevate risk status....UNACCEPTABLE....Evidence of failure to transfer according to risk criteria as per birth center’s P&Ps. ...”

The concern with these two standards related to Chart D is that based on staff interview and risk criteria presented by Baby+Co, at the time of this birth if any meconium was present in amniotic fluid it was indication for transfer to the hospital if birth was not imminent. According to the record the patient’s membranes ruptured at 1907 and thin meconium was noted. Pushing, it stated, started at 1915. At 1941 the FHT was stated as 110-110 with a note that pulse oximetry was on the mom. At 1945 FHTs were documented as 90-100, with decelerations noted. At 1946, FHTs were documented as 130-130 and at 1948 were 134-134. At 1950 there was a note that the FHTs could not be heard due to maternal position, however at 1951 FHT was noted as 155-155, at 1955 was documented as 153-153, and at 1957 was recorded as 152-152. At 2000 a note stated that someone (name redacted) was in the room to evaluate for transfer due to possible meconium (53 minutes after the note of ruptured membranes with thin meconium at 1907). The note indicated that light meconium was likely but had not been seen since the original rupture of membranes. It further stated that given the overall picture, which included a reassuring fetal status, good pushing efforts from the mom, a visible fetal head and good fetal descent with directed pushing, a decision was made to remain at the birth center at that time. Review of the Birth Record stated that during the second stage of labor (pushing), fetal heart decelerations to the 70s were noted with recovery to the 110s to 120s. According to the record, thin meconium was observed when the membranes ruptured at 1907 and the infant was not born until 2046 (1 hour 39 minutes later). In addition, a note was made about FHTs dropping to 90-100 with decelerations at 1945. Further note review indicated it was difficult to maintain audible heart sounds because of low fetal station and maternal pushing. In interview, the CNM stated she was confused about the policy and the meaning of “imminent birth”. She stated the mother was pushing well, and the baby was coming down so she thought delivery would happen quickly.

The concern is the patient was not transferred to the hospital and there was no documentation noted to indicate the supervising physician was consulted about the decision not to transfer. Moreover, staff did not understand the risk assessment policy regarding “imminent birth”. As in several of the prior chart reviews, review of this record also raised the question about whether there was a smooth transfer of this newborn in accordance with CABC Standard 3.10. According to the Baby+Co record, EMS arrived at 2054 (8 minutes after birth) and were instructed of the need to immediately transfer the newborn to Hospital A. The record indicated EMS prepared to intubate the newborn, and was encouraged by Baby+Co staff to transport immediately because the baby was stable and there had previously been two attempts for an alternative airway. According to Baby+Co’s records, EMS wanted to intubate prior to transfer, made an unsuccessful attempt at intubation, and then agreed to transport immediately. Baby+Co records indicate the newborn was transferred to Hospital A at 2106 (20 minutes after birth, 12 minutes after EMS arrival). In contrast to the Baby+Co records, a review of the EMS records, showed a note stating that “Midwives (sic) recommended getting a definitive airway in place prior to transport... .”

Summary of Chart E

Record review of Chart E revealed at 34.2 weeks Hydronephrosis of the fetus was noted with documentation for postnatal follow up with pediatric urology. At 37.6 weeks, the last noted prenatal visit, documentation noted a pregnancy weight gain of 64 pounds.

Review revealed the patient arrived to the center (unclear if 0130 or 0650). Review revealed the patient was 6 cm dilated and fetal weight was estimated at 8.5-9 pounds. FHTs were 135-145, with acceleration, and risk status was noted as 0. At 0727, review revealed spontaneous rupture of membranes with clear fluid. FHTs were noted approximately every 25-30 minutes from 1030-1600 with rates ranging from 117-160 with no decelerations documented. At 1600 the patient was noted to be in active labor and at 1640 was 10 cm dilated and feeling pressure. At 1651 spontaneous pushing was noted. At 1730 risk status was noted as 0 with FHTs 110-120. At 1810 FHTs were 137-152 and at 1827 documentation stated the start of pushing and noted guided active pushing with minimal descent. FHTs at 1829 were noted as 128-138. Record review revealed at 1841, there was no descent past +1 and an in and out catheterization was done. At 1845, FHTs were noted as 132-148 and at 1900 were noted as 124-140. Review revealed documentation at 1916 indicating thin meconium, a risk status of 1 with a note appropriate for Birth Center, and a notation that (redacted) was at the bedside to assist with pushing. Review revealed FHTs of 110-130, with oxygen applied and maternal position changed at 2005. At 2010 documentation stated there was good recovery with oxygen and noted FHTs 120-138 and accelerations. At 2055, review revealed oxygen was still applied and FHTs were 116-130, accelerations noted with stimulation, and the mother was moved to the birth stool. At 2110 review revealed FHTs were 120-130, with scalp pink. The infant was born at 2121 (2 hours 5 minutes after meconium noted at 1916, 4.5 hours after spontaneous pushing noted at 1651 and 2 hour 54 minutes after 1827 note that guided active pushing began). Review revealed a one minute Apgar of 2. Review revealed the infant was given warmth, stimulation and five rescue breaths. Review of a Resuscitation note, at 2123 revealed the infant’s heart rate was in the 60s and chest compressions begun with continuous PPV. 911 was called (no time noted) and EMS arrived at 2130 (9 minutes after birth). Resuscitation was continued, per review, until transfer at 2151 (30 minutes after birth).

Review of EMS form titled “Patient Care Report” revealed the initial time noted on the EMS record was 2127, the unit was dispatched at 2128, and was at the infant’s side at 2129. Review of a Narrative note revealed “... During ventilations, a thick ‘pea green’ colored fluid began coming from pt mouth and nose. Pt is suctioned, with approx. 3-4 mL of fluid suctioned. OPA (oral pharyngeal airway) did not fit, due to the size of the pt. Pt was bagging with good compliance and we were able to obtain a SaO2 in the upper 90s

-100%. Patient was transported to (Hospital A) Special Care Nursery while in arrest.... staff reports pt was born pulseless, apneic and flaccid at 2121 hours. Mom was reported having contractions for four days, and actively pushing for four hours today. ...”

CNM G interview revealed the 64 pound weight gain at delivery was not a risk out factor for delivery at Baby+Co. At that time, weight decisions were more based on weight gain at certain intervals. The CNM stated the policy is now clearer and not based on weight at varying points. Interview revealed any meconium in labor rules out delivery at Baby+Co now, but was not a rule out for birth center delivery when this patient delivered. Interview revealed the CNM did not feel there was a problem at the time. The pushing that started at 1650 was not effective, the CNM stated, noting some women need help with pushing. Interview revealed she asked another midwife to come in and help with pushing. Further interview revealed she had 5 deliveries that day, one shortly after this birth. Interview revealed she left the room to check on the other mom and thought she heard the baby cry. Another CNM was caring for the baby, she stated. She stated she checked on the other mom and ran back to this room where she saw the other midwife had started resuscitation. In a follow-up telephone interview on 04/26/2018 around 1600 CNM G said at the time the policy for FHTs during pushing was 5-15 minutes. Further, she stated, Hydronephrosis did not preclude delivery at the Birth Center.

Interview with the Medical Director, on 05/09/2018 at 1600, provided the same information set out in previous chart review discussions above regarding eligibility / risk assessments. With respect to labor/delivery, the Medical Director stated moms may be placed in different positions to try and get the baby to turn, and some manipulation is normal. In general, he said, babies turn on their own but there may be a need to manipulate a little “piece of cervix”. Further interview revealed that grasping the head or turning the fetus manually or with forceps is not within the scope of practice of a CNM. The Medical Director stated he did not receive any calls on the patient in this Chart.

DHSR Concerns with Chart E

CABC Standard 5.2.I. stated “Intrapartum Care....Evidence of....P&Ps include guidelines for management of prolonged first and second stage labor that are consistent with best-available advice. ...”

CABC Standard 5.2.L. “*Referrals* to meet the needs of each client outside the scope of birth center practice....UNACCEPTABLE....Failure to refer or transfer mother or newborn who develops a problem that makes them inappropriate for....birth center care... .”

Review of Appendix A, Eligibility for Birth Center Birth, dated 07/01/2017, stated it was Baby+Co’s policy to refer clients with certain health conditions, risk factors, and/or complications to a provider who could offer care in a hospital setting because they could increase the risk of complications and make birth in a hospital a safer choice. There was a section of the Appendix called Labor Birth that indicated referral for moderate or thick meconium in amniotic fluid unless birth was imminent. The section also included situations when the second stage was longer than two hours in a primipara (woman giving birth for the first time) if birth was not imminent and stated there should be consideration of transferring to the hospital if nonpharmacologic methods were not effective. In interview with Birth Center staff, it was noted that Appendix A was not an actual policy, it was an appendix attached to the consent form for client review of eligibility criteria.

A policy titled “Protracted or Arrested Labor”, last modified 2/20/2017 and presented for review on 05/21/2018, stated that arrest of labor in the second stage was no further fetal descent after 3 hours of effective pushing (if it was the first baby). In interview a CNM stated this is the actual policy for use to determine protracted or arrested labor, not Appendix A. The CNM noted the clinical team would utilize

this policy in determining whether there was a concern. In interview, it was stated that there had been prior delays with updating client information to match new policies, but action had been taken to change the process and this issue had been corrected now.

In record review of Chart E, the patient was noted to start spontaneous pushing at 1651. A note at 1827 stated active directed pushing started and noted minimal descent, stating the fetus moved down to +1, then back to 0 station. A note at 1855 stated progress was being made, and stated the patient was at +1 station. At 1916 thin meconium was noted in the amniotic fluid. The baby was born at 2121 (4.5 hours after spontaneous pushing, 2 hours 54 minutes after the notation of start of active directed pushing, and 1 hour 5 minutes after thin meconium was noted).

The concern is there was prolonged pushing from 1651-2121 (4.5 hours). With this, along with thin meconium noted at 1916, and with delivery not until 2121, there is concern that there was no noted consultation with the supervising physician in relation to the progress and to consider if transfer might be indicated for electronic fetal monitoring or further action.

There is also a concern about whether one of the CNMs may have turned the infant without charting this as attempted/done. Per interview with individuals present in the birth room, it was stated that one CNM suggested another CNM turn the fetus, asked the patient if that was okay, and then the second CNM came and was able to turn the fetus internally. There was no documentation noted by the CNM in the medical record to determine if this occurred, but a concern exists that it could have happened (note there is a statement in the CABC standards that external version in labor is unacceptable. No notation is noted on internal version.) Also, according to the Medical Director / supervising physician, this action would be outside the scope of practice for a CNM.

CABC Standard 6.2 states “Professional staff and consulting specialists are *licensed to practice their profession* in the jurisdiction of the birth center. ...”

Based on information provided in one of the interviews, a Baby+Co staff member was present in the room who may have presented herself as a CNM when she was not licensed as such in this state. According to interview with two individuals in the room during labor and delivery, a CNM licensed in another state was present in the room during labor. The individual was only licensed as a RN in this state, but was licensed as a CNM in another state. She introduced herself as a CNM, per interview, and the patient did not realize she was not licensed as such in NC until after the delivery was over. If this is accurate information, the concern is related to a patient’s right to know the qualifications of any person who is caring for her and another concern is whether this Nurse Midwife accurately identified herself.

CABC Standard 6.4 states “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.... REQUIRED....Evidence of.... Plan to ensure continuity of routine care for one client, or when more than one client needs care simultaneously....Adequate personnel available to manage unexpected emergencies... .”

The DHSR concern with respect to this standard is that, according to interview, the primary midwife was delivering all babies born during that period and, as such, was in and out of this patient’s room during labor. On interview she stated she left the birth room almost immediately after the newborn’s birth to check on another patient who was close to delivery. Per interview, she left so quickly she did not know the infant was in distress until she returned after quickly checking another patient. This CNM stated she thought she heard the infant cry prior to leaving. There was another midwife in the room at this time, so clinical staff was available to care for the infant. Still, the concern is whether the CNM delivering all the

babies was able to give the individualized attention each patient needed. Standard 7.2.F states “Continuous periodic prenatal examination and evaluation of risk factors....The risk status must be documentedat least at the following intervals....each trimester....admission in labor. ...”

The Birth Center staff showed the team Risk Assessment criteria, dated October 2017, (later stated as in place on 10/26/2017) which indicated a consult or referral should be made to a physician if a patient’s pregnancy weight gain was over 60 pounds.

Review of this patient’s weight in the Birth Center record indicated a pregnancy weight gain of 64 pounds at 37.6 weeks. Based upon the information the team reviewed a pregnancy weight gain over 60 pounds would indicate referral. In interview with Birth Center staff it was noted that the weight gain related to weight at “term”, which was defined on interview as 37.0 weeks. Per the interview and chart review on 05/21/2018, this mom had gained 55 pounds at 36.0 weeks, and did not return for another routine appointment until 37.6 weeks, at which point she had gained 64 pounds. Because she was over 37.0 weeks at the time, the staff member stated, the 36 week weight was taken as the term weight, which made the patient eligible for birth at the center. Any weight gained after the 37 week mark at that time, according to interview, was not considered in determining eligibility criteria. Now, she stated, a change had occurred and any weight gain over 60 pounds at any point in the pregnancy was a rule out for birth center delivery.

The concern is that, per the record, the patient had gained 64 pounds at 37.6 weeks, and arrived to the birth center in labor at 38.5 weeks. No further weights were taken and the 64 pound weight gain at 37.6 weeks did not preclude delivery at the center. While this may not have been outside of policy, the concern is that no consultation with the supervising physician occurred. It is noted that actions have since been taken to change the criteria and it now reads as greater than 60 pounds at any point in pregnancy.

Another concern with risk criteria related to meconium noted in the amniotic fluid. The risk criteria have been changed over time related to meconium, which according to interview with the CNMs was because evidence based guidelines changed. In this case, the criteria did not rule out thin meconium. Action has been taken since, and now any meconium in amniotic fluid is a rule out and requires transfer unless the baby is crowning.

DHSR Review of Informed Consent and Information Provided to Patients

CABC Standard 5.1.C. states “Be informed of the benefits, risks and eligibility requirements of an out of hospital labor and birth....REQUIRED...Evidence of...A plan to assure an informed consent process is in place regarding the birth center with every client and pregnancy.

An overall area of concern relates to informed consent. According to a client interview, consent information was sent electronically. The client did not recall personal face-to-face or detailed review related to it and the meaning of everything included. If there was not discussion and opportunities for questions prior to requesting an electronic signature, then there could be concerns with how informed clients were about what their consent entailed. A specific area of concern relates to the risk criteria attached to the consent form (Appendix A) and that it may not have always matched birth center policies. As discussed earlier, in interview staff stated the CNMs would use current policies to determine appropriateness of delivery. Appendix A, staff stated, was attached to the consent form and may not have been updated real time in which case prospective clients may possibly have given consent without full knowledge and understanding of policies.

Another concern was the amount of time it took to complete an actual transfer of a mom or newborn to the hospital. Per interview with one client, it was stated that the birth center discussed an 8 minute

transfer time. The concern is whether there was clarity with prospective clients/ patients on what the 8 minutes meant and whether they understood the real times that could be associated with transfer. On review of 4 EMS and 5 birth center transfer records, no transfer was completed within 8 minutes, neither from the time of birth nor from the time EMS was notified of the transfer. The undelivered patient in Chart C was transported out the most quickly, 12 minutes after EMS was initially notified. This patient arrived at the hospital 14 minutes after EMS initial notification.

Additionally, the emphasis Baby+Co and others placed on the “strong partnership” between the local hospital and Baby+Co may have given some the impression there was more of a medical connection between the two (more than the transfer agreement that existed) versus the fact that Baby+Co is a stand-alone, unlicensed birthing center.

Information Gathered From Other DHSR Interviews

Following is information obtained by DHSR reviewers as they spoke with individuals who were either family members who used the Baby+Co services, or individuals who were present in the delivery room during a birth at Baby+Co. The interviews below do not necessarily correlate to a Chart review summarized above.

Interview on 05/02/2018 at 1335 with two individuals who had knowledge of a birth at the center revealed the expectant clients had researched birth centers and chose Baby+Co for the upcoming birth. Interview revealed a tour occurred prior to the selection. During the tour, Baby+Co staff provided information that one positive of the using Baby+Co was the communication and “strong partnership” with the local hospital. Interview revealed it was stated that if any emergency happened, a patient could be transferred in eight (8) minutes, noting the staff said they could have the patient on an OR table before OB even got scrubbed in. Interview revealed a focus on proximity and safety. There was also discussion that the midwives had privileges at the hospital and if there were issues where a client “risked out”, care could be facilitated with a midwife from Baby+Co. Interview revealed the clients trusted the feedback, thinking they could have the best of both worlds, an out of hospital birth and a strong safety net. The interview indicated the clients had an ultrasound that showed the baby was in the right position, “OA’, in a good position for birth. The persons being interviewed stated midwives always checked the fetal heart tones and made the measurements. During the third trimester, they stated, an individual led the appointment being introduced as a nurse midwife. Later, interview revealed, these clients learned the individual was not licensed as a CNM in this state. The clients did not learn the individual was not licensed as a CNM in NC until after the birth. Interview revealed the clients checked in at the birth center several times in the days before birth, thinking the mom was in labor. Interview revealed the clients were not given an option to stay they were told they did not get to stay at Baby+Co until the mom was 6 cm. On one occasion, it was stated, the clients came in during the night, the building was dark and the only person there was the Nurse Midwife who let them in. The clients went back to the facility again around 0200 on the day of birth, and were instructed they could stay but needed to reach 6 cm in 2 hours. They were placed in a birthing room, however, no one came back to check on them for 4 hours, per interview. When a staff member came and checked the mom, she had reached 6 cm so they could stay. Further interview revealed the clients were surprised that the only fetal heart rate monitoring was via a Doppler, having heard on the tour there was access to additional monitoring if needed. Per interview, there were several midwives that came and went, and the primary Nurse Midwife was in and out of the room all day, was not continually by the clients’ side. Interview revealed it was not explained to the mom the reason oxygen was being placed, she did not understand the baby was having any difficulty. Further, it was stated, the client started actively pushing more than 4 hours before she delivered. A midwife, it was said, came to assist the client with pushing, stating the fetus was posterior. Interview revealed it was presented to the client as no big

deal, and there was no discussion of risk related to turning the baby. At that point, the interview revealed, the client went from pushing to pushing with a midwife's hand inside trying to turn the baby. During this time, per interview, someone in the room overheard a conversation between the midwives about meconium. Further interview revealed the client did not see a physician or have any awareness of one being contacted at any point in her labor, including related to the length of labor and pushing, turning the fetus, or the meconium that appeared. Interview revealed the resuscitation seemed very chaotic, as if people did not have a resuscitation plan and roles. The persons interviewed stated that the baby did not breathe after birth. Interview revealed the resuscitation seemed very chaotic. The infant was at the facility for 20-30 minutes after birth. The dad, it was stated, had gone to call family to come be with mom and then went straight to the hospital to be with the baby. Interview revealed the dad got to the hospital and the baby had not arrived, was still at the center.

Interview with another individual, on 05/02/2018 at 1315 and 1620, referenced knowledge of another birth at the center. Interview revealed the client was 41.5 weeks and had a prolonged labor (stated to be 70+ hours) with contractions starting days before birth. Interview revealed she finally stayed at the center when she was about 6 cm. Interview revealed the client was 10 cm just after midnight and pushed off and on throughout the night, resting for a couple of hours on two separate occasions. Interview revealed pushing started again around 0830 and the infant was born shortly after noon. At some point during the night, the individual stated, the client said she needed to go to the hospital and was told by Baby+Co staff that was not an option, it was too late and the baby was too far down. Further interview revealed the client did not see a physician during labor.

Interview with Regional Director #2, on 05/01/2018 at 1330, revealed they had discovered there was some confusion/ inconsistency in documenting fetal heart tones. Interview revealed staff should be documenting baseline and range of accelerations or decelerations. Some staff members had put baseline data (which should be a number, not a range) into the section that required a range. The inconsistency was in the documentation, not the assessment. That has now been standardized and training was done.

Notes Regarding DHSR Review of Certain Baby+Co Policies / Documents

Review of Risk Criteria, dated 6/2015 revealed a section titled "Intrapartum and Postpartum Transfer Factors". Review revealed, among others, the following were listed: meconium in amniotic fluid unless birth imminent, estimated fetal weight less than 2500 gm and over 4500 grams, and 2nd stage longer than 2 hours in primipara or longer than 1 hour in multipara. Review did not reveal specific notations related to rupture of membranes prior to labor.

Review of Appendix A, Eligibility for Birth Center Birth, dated 07/01/2017, revealed it was the Birth Center's policy to refer clients with certain health conditions, risk factors, and/or complications to a provider who could offer care in a hospital setting because they could increase the risk of complications and make birth in a hospital a safer choice. Review revealed a section for Labor Birth. That section, review revealed, included referral for moderate or thick meconium in amniotic fluid unless birth was imminent. The section also included situations when the second stage was longer than two hours in a primipara (woman giving birth for the first time) if birth was not imminent, or longer than 1 hour in a multipara, also if birth was not imminent.

Review of a Labor Admission Assessment & Plan document, dated 08/21/2017, revealed clients would be informed of choice to return home if in false labor or early latent phase.

Review of a document with Risk Assessment criteria, dated October 2017, revealed a notation to consult/refer to MD if weight gain was greater than 60 pounds. Further review revealed to offer hospital

birth with midwives when estimated fetal weight exceeded 4500 grams. Review revealed criteria related to Intrapartum care included Physician management if meconium was in the amniotic fluid unless the fetus was crowning.

Review of the most recent update of Risk Assessment and Eligibility Criteria, dated 03/11/2018 revealed macrosomia (large for gestational age) was defined as estimated fetal weight greater than 4500 grams (9 pounds 15 ounces) at term. Review revealed to refer the patient if prenatal weight gain was greater than 60 pounds. Further review of the document revealed a guideline to transfer clients with meconium stained amniotic fluid unless the fetus is crowning.

Review of Appendix A, Eligibility for Birth Center Birth, and modified 03/20/2018 revealed Antepartum/Prenatal referral for weight gain greater than 60 pounds. For Labor/Birth, document review revealed referral for significant fetal heart rate decelerations or bradycardia with intermittent auscultation and meconium in amniotic fluid unless baby is crowning (deleted the words moderate or thick from the 07/01/2017 document). Other referral criteria included arrest of first or second stage of labor, and ruptured membranes greater than 24 hours without active labor.

Review of a "Routine Intrapartum Care" policy, dated 04/06/2018, revealed a section on fetal heart rate. Review revealed fetal heart rate to be auscultated on admission, during early labor as indicated, during the active phase every 15-30 minutes, and during the second stage every 5 minutes and not to exceed 10 minutes. Review revealed a note to auscultate during the last portion of the contraction and immediately afterwards, to assess and document the fetal baseline and presence or absence of fetal heart rate accelerations or decelerations. The policy further stated to assess and document the maternal pulse hourly in the second stage and if there were fetal heart rate decelerations. A note stated that if the fetal heart rate could not be distinguished from the mother's pulse, then a pulse oximeter should be placed and remain until delivery or there was no longer any ambiguity. The policy further stated to document labor progress using category I or category II every two-three hours or as indicated. It stated that if category II then more frequent fetal heart assessment was indicated with a plan for intervention to resolve the findings, deliver the baby, or transfer.

Review of the Routine Intrapartum Care policy, modified 04/18/2017, revealed fetal heart tones by intermittent auscultation/ ultrasonic doppler would be assessed on admission, early labor as indicated, active phase very 15-30 minutes, and during second stage every 5-15 minutes. Review revealed to auscultate immediately after a contraction, assess and document the fetal heart rate baseline, using an average single number, not a range, and the presence or absence of accelerations or decelerations.

CABC Standard 4- Facility, Equipment and Supplies

The birthing center establishes and maintains a safe, homelike 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. Required Evidence that: ...

Standard 4.2: Complies with applicable local, state and federal codes, regulations, including current OSHA and ADA regulations and ordinances for construction, fire prevention and public safety and access.... Appropriate CLIA waiver or certificate for the level of testing performed at the birth center (e.g., dipstick urinalysis, Provider Performed Microscopy during the course of a client's visit, finger stick hematocrit or

glucose, urine pregnancy test). A limited list of microscopy procedures is included under this certificate type, including wet prep and ferning test.

Lab Services

Baby+Co. is CMS Medicare certified to operate as a Provider Performed Microscopy Procedures (PPMP) laboratory. According to information provided during the onsite review, there was no data provided to validate oversight of laboratory services by the lab director. The findings include:

- No detailed Policy and Procedure Manual (P/P) reviewed and signed by the lab director to ensure quality test results. There was no lab manual provided for review to include the following:
 1. Test procedures
 2. Specimen collection and handling procedures for the following test.
 - a. Amniotic fluid (to determine if the patient's water has broken and what stage of labor she may be in)
 - b. Vaginal fluid (to determine the health of the birth canal)
 3. Specimen labeling
 4. Ensure that the reagents, KOH (Potassium Hydroxide) and NaOH (Sodium Hydroxide) is in date.
 5. All testing personnel have documented training in their personnel file.
 6. Test procedures
 7. Documented competency assessments must be present in the testing personnel files at the 6-months, 12 month and yearly intervals for all personnel performing the test.
 8. Job description for all testing personnel that detailed the laboratory test performed
 9. A declaration for each testing personnel that they are authorized to perform specific test.
 10. Reporting test results and records retention
- No documented training on how to perform the procedures, competency assessments at six (6) months after initial training, and again after 12 months; and, yearly thereafter to ensure these test procedures are performed accurately.
- Baby+Co was not enrolled in an approved proficiency testing program and did not perform bi-yearly verification of accuracy to ensure the accuracy of the test performed.
- The test procedures performed under a PPMP certificate are performed by the providers; but, they a moderate complexity test. Thus, the facility must follow the CLIA regulations for moderately complexity testing, as if they had a Certificate of Compliance (COC).

Review of CLIA lab certificate 34D2104504 issued to "Baby and Company Cary, listed CNM # 6 as the Clinical Laboratory Director. Interview on April 25, 2018, staff indicated CNM # 6 had taken a new travel CNM position and was unaware she continued to be listed as Lab Director. Additional interview with staff, who "wears a lot of hats" to include clinical laboratory staff was unable to provide the name of the Lab Director until shown the certificate of PPMP posted on the designated lab area wall.

Additional interview on April 26, 2018 at 1600 with staff revealed she was a mentor for staff. Interview revealed the process for verifying microscopy (wet mount slides/microscope) competency was for the orientee to perform the test, have the orientee state the results and the mentor would then verify the correct interpretation. "CNMs were taught to review slides under the microscope in midwifery school." Interview revealed, if necessary, the technique was re-taught by using "google" to find slide images and then comparing the slide images to what was on the microscope. Continued interview revealed usually

five (5) slides were verified at the birth center in order for the orientee to get checked off. Interview revealed CNM #7 was not sure if all five slide validations were documented, but the skill was checked off in [training application name] in the computer.

DHSR Concern

Fourteen of fourteen CNM files reviewed failed to have evidence to validate training and competency in performance of PPMP testing, for examples, FERN testing, KOH prep, and wet prep, and urine microscopy procedures. During the onsite review, facility staff were unable to provide the exact date CNMs performed wet preps or microscopic exams. However, facility staff indicated approximately three to five wet preps are done monthly. Baby+Co had no laboratory policies and procedures for daily operations. There was no evidence of enrollment in proficiency testing or the in-house performance of bi-yearly verification of accuracy. There was no data available to validate supervision of laboratory services by the Lab Director. Therefore, Baby+Co was not in compliance with CLIA regulations.⁸

Additional DHSR Reviewer Concerns Based on Interviews with Baby+Co and Reviews of Its Policies

CABC Standard 4.15 states “A readily accessible emergency cart or tray for the mother is equipped to carry out the written emergency procedures of the birth center and securely placed written log of routine maintenance for readiness. ... Required ... Evidence of ... Cart , tray or other accessible storage is accessible for all birth rooms and readily available when there is a client in the birth center ... has a means to secure emergency supplies to ensure they are present when needed, after restocking ... Log is available and documents regular checks at intervals appropriate for volume of admissions ...”

According to staff interview April 23, 2018, the emergency cart was checked after each delivery to ensure all supplies and medications were available for the next use

Review of emergency cart logs had documentation the emergency cart was last checked on March 2, 2018. Review of one of the logs for the emergency cart (cart not identified) showed the emergency cart was checked on January 17, 2018; January 23, 2018; February 21, 2018 and March 2, 2018. Review of the other log for the second emergency cart showed the cart was checked on January 4, 2018; January 5, 2018; January 14, 2018; January 29, 2018 and February 3, 2018. Based on documentation, the last known delivery at the birthing center was March 6, 2018, prior to going on diversion to cease delivering babies at Baby+Co.

DHSR Concern

There was no further record to indicate emergency carts were checked after deliveries occurring between March 2, 2018 and March 6, 2018. Facility staff did not follow Baby+Co’s policy on emergency carts to ensure emergency equipment was available.

CABC Standard 4.10 states “Provides adequate housekeeping services to maintain a sanitary home-like environment. ... Required ... Evidence of ... Rooms and baths are cleaned between families. ... If birth center uses immersion in water during labor and/or attends water births, P &P’s are in place that address tub cleaning and maintenance P&P consistent with generally accepted national standards/guidelines/recommendations. ...”

⁸ Based on the information DHSR reviewers obtained during this portion of the review, CMS was notified and requested that DHSR, as the state survey agency, perform a survey of the CLIA certified services at Baby+Co. That survey occurred on May 24, 2018 and will be reported on separately. The report is being finalized and will be reviewed by CMS before it is disclosed. This report is not the state survey report for CMS.

Review of a “Terminal Cleaning Log” from January through March 2018 showed terminal cleaning of the birthing room, including the tub, was completed after each use of the birthing room.

During an interview a staff member disclosed that she trained staff on the process for cleaning the birthing tubs. The nurse explained the cleaning process and stated that the tub was cleaned and disinfected after use. The nurse stated all solid debris was removed using gloves and a biohazard bag. The tub was rinsed with hot water, then the tub was filled with hot water. Three cups of bleach was added to the hot water and it soaked for 30 minutes. The nurse stated she drained the water out of the tub and cleaned it with Peroxy II (Blue label). She stated she squirted the Peroxy II all over and allowed it to soak for two minutes contact time, then she used a cloth to wipe the tub. She explained that she then used NABC (red label) to squirt over all tub surfaces and allowed contact for 10 minutes. She stated then she used a wet cloth to wipe off the surface and rinsed with water. The nurse stated the use of the disinfecting wipes is a newly added procedure change since the clinic has been on diversion and that the training has not yet been done for this change.”

DHSR Concern

According to staff interviews inconsistent methods were used in cleaning the soaking tubs used by laboring mothers. The amounts of bleach varied from one-half cup to three cups of bleach for the initial cycle of terminal cleaning.

CABC Standard 4.17.D. states “Emergency Preparedness and Drills / Medical Equipment and Maintenance Policies ... Required ... Evidence of ... Fetoscope/doptone ... Appropriate functioning per use ...”

Review of the Doppler checks in the birthing rooms were included on the new Safety Checklist under the admission area. Staff interview and observation disclosed that batteries for the Doppler were kept in a room down the hall. The staff member explained that each Doppler had a low battery range that displayed on the Doppler when it was turned on and that part of the check on admission was to ensure adequate battery life was present for use during the delivery.

DHSR Concern

The batteries for the Doppler used to determine fetal heart rate were not readily accessible if needed in an emergency. Given the fact that at times, there was only one staff member present in the birthing center with a patient in labor, accessing replacement batteries could be problematic.

CABC Standard 4.17.C. states “Housekeeping and Infection Control / Medical Equipment and Maintenance Policies ... Required ... Evidence of ... Following the CDC or WHO guidelines for sterilization. ... A log of sterilization use which includes ... biological indicators results with monitoring that is appropriate for volume of center. ...”

Review of Autoclave Spore Testing results (biological indicator test) revealed results reported that indicated the test was passed (no growth, normal test outcome). Review showed 2 reported results for April 2018; 3 reported results for March 2018; 3 reported results for February 2018 and 3 reported results in January. The spore testing log recorded biological testing had been conducted weekly with 4 tests done in April 2018 (only 2 resulted, missing 2); 5 tests done in March (3 resulted, missing 2); 4 tests done in February 2018 (3 resulted, missing 1), and 4 tests done in January 2018 (3 resulted, missing 1).

Staff explained during interview that the spore test was completed weekly and sent to an outside company for reading and results are then faxed back to the clinic for review. The staff member stated she noticed in April that they were missing weekly results and she talked with the company representative

and did not get resolution. The staff member stated she had notified the center manager of the problem and there had been a decision to change vendors. There was no determined target date as to when the vendor change would occur.

DHSR Concern

Given the fact that the DHSR review was occurring in late April and May, it is concerning that there may have been weekly missing lab reports dating back to January and it was April before Baby+Co noticed the issue. It also calls into question Baby+Co's careful review and use of these reports.

Conclusion

DHSR reviewers learned from interviews with Baby+Co staff that Baby+Co conducted Root Cause Analysis (RCA) on the following dates: Monday, October 9, 2017, Friday, October 20, 2017, Friday, February 16, 2018, and Friday, March 16, 2018 to review the care of certain patients. Details of the RCAs were not disclosed to DHSR staff due to "peer review" information within the content. Information that was available to DHSR regarding patient charts was redacted. Given the fact that DHSR's review of Baby+Co was based on permissions granted by Baby+Co, versus DHSR legal authority to review, there were records that were unavailable – RCAs for instance.

Despite the limitations on the information available to DHSR, reviewers still had adequate information to piece together the circumstances regarding the infant deaths that had been reported as well as to review the operations of Baby+Co and learn about the accreditation standards of CABC, the accrediting organization for Baby+Co. In addition to some of the policy changes made by Baby+Co prior to DHSR's review, there have been several changes made since DHSR began its review. For instance, Baby+Co has implemented the following changes:

- May 11, 2018, signed a new Medical Director / Supervising Physician with a physician located outside Wake County. However, the Medical Director / Supervising Physician does not have admitting privileges at the local hospitals. CNMs are not delivering babies at the local hospital and are listed as leave of absence ("LOA") at the local hospital
- The new Medical Director / Supervising Physician Agreement includes formal expectations
- May 21, 2018 through May 22, 2018, each individual CNM signed an attestation co-signed by the Medical Director / Supervising Physician stating "I have reviewed Baby+Co Clinical Practice Guidelines, including Center Specific Guidelines and Eligibility Criteria and agree to work within their scope. I attest that my professional license is current and in good standing and in my personnel file."
- Policy changes were implemented in the "Risk Criteria" under endocrine and areas of life style – controlled gestational diabetes mellitus to provide standards in defining hospital delivery versus birth center delivery.

DHSR appreciates the cooperation of Baby+Co and its staff in connection with this review. DHSR especially appreciates the information shared with its reviewers by families who were patients of Baby+Co. Without exception these families were helpful and had relevant information to share with DHSR reviewers. DHSR did not include the interview information in this report from every family that it spoke with during this review process. DHSR intentionally has not provided the names of the families that spoke with the reviewers out of respect for their privacy and appreciating the fact that some of these families have experienced a devastating event in their lives. Several families expressed to DHSR their hope that providing information in this review process regarding their experiences could make a difference for another family.

Prior to the public release of this report, DHSR has provided a copy to the families who spoke with us and requested a copy. DHSR has also provided a copy of this report to Baby+Co. Upon the public release of this report, DHSR will also be providing a copy to the North Carolina Board of Nursing, the North Carolina Medical Board and the Midwifery Joint Committee.