baby+co.

June 11, 2018

NC Department of Health and Human Services
Division of Health Service Regulation

RE: Voluntary On-Site Review

I am writing in response to the report that you recently sent dated June 11, 2018, detailing your findings from the on-site review that the North Carolina Department of Health and Human Services conducted at our Cary Center.

Thank you, and please share our thanks with your colleagues for taking the time to conduct the evaluation. Our top priority, as we know it is yours, is the health and safety of the moms and families in our care.

We appreciate the unique political pressure your agency was under to conduct this review on short notice without state birth center standards or a formal process for review. However, the lack of familiarity with birth centers was evident in the report, resulting in significantly flawed findings.

The report in its current form leaves the public with a distorted impression of the quality of our safety systems and professionalism of our care providers. The findings do a disservice to families and practitioners of a model of care that has a tremendous overall track record of success.

Overall, the report reflects the opinions of the reviewers about a model of care with which they have no experience and about which they demonstrated little prior knowledge or understanding. Just as it was unfair to expect the reviewers to develop, in one month, the level of expertise, knowledge and understanding required to legitimately perform such a review, it is equally unfair to Baby+Co., nurse-midwives, our physician and hospital partners at WakeMed, other birth centers in North Carolina, and women who choose the birth center model of care, to subject that model to such a haphazard review.

We have three primary concerns, which are detailed in this letter:

1. **The report includes factual inaccuracies that result in misguidedconcerns**.

2. **The report bases conclusions on clinical judgments that are not backed by evidence and reflect a lack of expertise in obstetrics; midwifery or birth centercare.**

3. **The report misinterprets the Commission for the Accreditation of Birth Centers (CABC) standards it bases the evaluations on and wrongly infers that we are not in compliance with them.**

Certified Nurse-Midwives are highly-trained, masters prepared, Advanced-Practice Registered Nurses, that practice independently in all but six states in the United States. In North Carolina, Certified Nurse-Midwives are required to obtain a signed supervisory agreement from a physician to practice. This agreement does not require the physician be present during treatment or sign-off on care. The report implies that the outcomes in these cases are somehow related to the lack of physician participation labor and birth, which is simply unfounded.

The low-intervention model of care that we utilize across our centers delivers better outcomes for women with low-risk pregnancies than hospital-based care, with lower mortality and morbidity rates and significantly lower c-section, pre-term birth and NICU admission rates. We have operated in good standing in states that have birth center regulations in place and remain fully accredited by the CABC by the same standards used in the DHHS report.

As you know, we have taken the recent events in our Cary center very seriously. After each event we conducted two separate case reviews together with our accrediting body and with our partners at WakeMed and EMS. We voluntarily suspended birth center deliveries as we conducted a series of cross-case reviews. Reviews were conducted by our internal system-wide clinical leadership team and two outside groups with significant experience and expertise in the birth center model: The Institute for Perinatal Quality Improvement and the Commission for the Accreditation of Birth Centers (CABC). These external reviews included several day site visits.

The CABC has reviewed all these cases; interviewed staff and our colleagues at WakeMed and EMS; reviewed records and conducted an off-cycle, site visit this spring. That site visit was led by their most senior review team. The review team has decades of obstetric experience working in birth centers and hospitals and has undergone extensive training in the CABC indicators and data standards. The review findings went before the CABC's 23-member interdisciplinary Board of Commissioners, which includes obstetricians, a neonatologist, midwives, nurses, administrators, researchers and consumers. The Board of Commissioners reviews the inspectors' report from the site visit as well as all supporting documentation; Baby+Co. policies and procedures; risk and eligibility criteria; notes from interviews with staff and any other relevant materials.

We agreed to the opportunity for further review by the Department of Health and Human Services as a further effort to assess our systems of care.

While we respect the professionalism of the evaluation team, our experience was that the review team—which included four RNs —lacked clinical expertise in obstetrics, midwifery and birth center care and that some of the information that we provided during the interview was therefore misunderstood, misinterpreted and/or not recorded appropriately. Multi-disciplinary groups of perinatal experts have not drawn the same conclusions.

We understand the challenge of reviewing our facility without clear regulations or familiarity with our care model and the standards put in place. We also appreciate the team's worthwhile feedback on laboratory management and their advice on how to strengthen our documentation in a range of areas.

Unfortunately, the report is the work product of a "crash course" by the reviewers regarding obstetrical care in general, and the birth center model specifically. Our patients deserve better. The community deserves better. And, frankly, Baby+Co. and our physician partners deserve better.

We respectfully ask you to address the following issues:

I. Medical Oversight + Physician Supervision

The report incorrectly alleges that we do not have a clear collaborating agreement with our Medical Director that specifies when clinical consultation and/or transfer are required.

DHSR Report Claim: On page 1 the report says "DHSR identified numerous, significant concerns during the review. These concerns included medical oversight and physician supervision of Certified Nurses Midwives (CNMs)".

Page 8 continues "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".

On page 9 "However, there were not written protocols or guidelines that dictated when he should be contacted".

The facts: The Center's Medical Director serves as the collaborating physician for each of the midwives working at the Center. The collaborating agreement and communication parameters are reflected in a signed contract outlining the Medical Director's responsibilities and in a ***detailed document that outlines clinical criteria.*** This document that was developed with our midwives in collaboration with our Medical Director sets clear thresholds for when to transfer; when to consult and when to continue care in the center. These thresholds are based on recognized clinical evidence, with policies reviewed and updated as evidence evolves, and provide specific guidance on potential patient conditions. These guidelines have been reviewed by the Commission for the Accreditation of Birth Centers; and a multi-disciplinary team of experts at WakeMed and have not been called into question by any of them. They also comply with regulations set forth by the North Carolina Board of Nursing, the regulatory body with the authority to assess the practice of nurse-midwifery in the state, as detailed below.

The report raises concern over the fact that our Medical Director is not more involved in the day to day course of care and states several times throughout the report that he should have been called sooner in these cases. It seems to imply that the physician supervisor did not meet the requirements under state law for supervision.

On page 9, the DHSR report says "… the Medical Director / Supervising Physician did not orient staff... was not 'hands-on'...had not attended any births at Baby+Co... etc."

On page 28, DHSR says (in reference to Chart E) **"**While this may not have been outside of policy, the concern is that no consultation with the supervising physician occurred"

The facts: The American College of Obstetricians and Gynecologists recently reaffirmed and strengthened its position on independent nurse-midwifery practice in a joint policy statement with the American College of Nurse-Midwives that defines the relationships as collaborative, not supervisory, and indicates:

"OB/GYNs and CNMs/CMs are experts in their respective fields of practice and are educated, trained, and licensed independent clinicians who collaborate depending on the needs of their patients".

While NC is one of 6 states that requires physician supervision, it leaves the specific parameters of when collaboration and consultation is required up to the licensed physician and midwifery pair and does not require any set of supervisory activities or communication. NC law does not require the physician to be on site during labor and deliveries, to be involved in orienting or training a certified nurse midwife or to conduct any type of periodic performance review.

What it is required by state statute is summarized below and Baby+Co. and its supervising physician meet those requirements:

1. **Written clinical practice guidelines for each clinical practice that define individual and shared responsibilities of the CNM and the physician**. Baby+Co. has these guidelines in place. They were developed together with our supervising physician and were reviewed by our supervising physician and CNMs

2. **A process for periodic and joint evaluation of services rendered** – Baby+Co. CNMs and their supervising physician speak weekly, if not daily, to review cases and align on ongoing operational and policy developments. Those meetings may not have all been well documented, but all the parties involved can and did validate that they happened. We also have a more formal quarterly review, that is well documented, in which the Medical Director reviews outcome data; any policy changes; chart review outputs and conducts a case review.

3. ***Process for periodic and joint review and updating of the written guidelines*** – any guideline changes are reviewed formally at the quarterly quality meetings with periodic all staff review meetings between the medical director and all the CNMs under his supervision. Baby+Co. has newly implemented an online attestation form to document the participation of all its CNMs and their supervising physician.

These cases were carefully reviewed by our Medical Director; a multi-disciplinary team of perinatal experts at WakeMed and the Commission on the Accreditation of Birth Centers. None of these groups have raised the lack of physician consultation as a concern.

The report incorrectly states that the Medical Director was not informed about the losses reviewed for days after they occurred.

On page 8, the DHSR report says "For the three deaths that occurred during his tenure as Medical Director he was contacted days after the deaths occurred"

The facts: At the time of these cases, the Baby+Co supervising physician was on our daily team report that provides a de-identified update on any births, transfers or unusual events. He was also notified by phone immediately after each case in all the cases reviewed, except for one, during which he was on vacation. In that one case where he was on vacation the on-call OB/GYN at our Medical Director's practice was notified.

II. Criteria used to Admit/ Discharge Patients + Overall Intrapartum Management(as noted by DHSR in their medical record review)

You made a broad statement that you have serious concerns about our admission and discharge criteria and implied that the criteria and/or our application of them delayed the transfer of clients. We firmly disagree with your conclusion.

On page 1 of the DHSR report (and in your press statement) you say "DHSR identified numerous, significant concerns including …. The criteria used to admit and discharge patients."

The facts: As indicated above, we have a detailed set of transfer criteria that evidenced based and in-line with CABC guidelines. These criteria are reviewed and approved by our Medical Director and a multi-disciplinary team of experts from all the health systems that we collaborate with across markets. The CABC has reviewed these criteria on multiple occasions and never found that any of them are out-of-line with standard of care.

You cited broad and serious concerns but then failed to give concrete examples of criteria that you believe to be out-of-line with standard of care or with CABC guidelines or to provide the evidence base behind this claim.

You did offer a handful of examples of places where you believe that we should have interpreted our guidelines differently and/or should have transferred or called for consult despite the fact that the client did not meet our transfer or consult thresholds. We find these examples to be based on an inaccurate set of facts and/or out of line with best practice. These cases have been well reviewed by perinatal experts who did not draw these sameconclusions

II. A. Criteria used to Admit/ Discharge Patients: Weight Gain

The report improperly suggests that weight gain should have been a factor that led to transfer and/or clinical consult for Chart A and Chart E.

The facts: According to the Institute of Medicine, weight gain during pregnancy needs to be monitored because significant weight gain is associated with certain complications such as shoulder dystocia and macrosomia. However, the IOM makes clear that, while associated it is not predictive of shoulder dystocia or macrosomia (large neonates). For example, 99% of women with significant weight gain do not have shoulder dystocia and the majority of shoulder dystocia cases are not in women with significant weight gain.

That is why when we have a client with significant weight gain who does not reach our transfer threshold, our practice is to evaluate the full range of clinical facts: including glucose tolerance, pre-pregnancy body mass index (BMI) and nulliparity (mother's first birth) vs. multiparity (mother's subsequent births) to evaluate risk. Clinical indicators outside of weight gain were not suggestive of macrosomia or shoulder dystocia.

Macrosomia was not an issue in either of these two cases.

The report claimed that we should have called for clinical consult for Chart A because the client had already gained 60 lbs. 5 days before she went into labor

DHSR Report Claim: On page 18 “the DHSR concern is that here 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.

The facts: Our policy at the time of Chart A’s case, was to consult if a client had gained 60 lbs. by the time they were 37 weeks pregnant NOT by the time of labor. We followed policy in this case. This is in-line with CABC standards. CNMs use their clinical judgment to assess when weight gain after 37 weeks is concerning. The weight gain pattern at term often reflects normal physiologic fluid retention (swelling) and is not predictive of fetal size.

The report incorrectly states that client E gained 64 lbs. and that because she gained 64 lbs, Baby+Co. should have transferred her or called for physician consult

DHSR Report Claim: On page 28. “The concern is that, per the record, the patient had gained 64 pounds at 37.6 weeks, and arrived at 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”

The facts: The report fails to recognize that the client self-corrected her pre-pregnancy weight with a note in the medical record and that her total weight gain, using this corrected pre-pregnancy weight, was actually 56.4 lbs. at 37.6 weeks and 47.4 lbs. at her 36-week assessment. Furthermore, Baby+Co.’s policy at the time of this case was to call for consult if the client gained 60 lbs. or more lbs. by 37 weeks.

II.B. Criteria used to Admit/ Discharge Patients: Protracted Labor

The report inaccurately says that the client in Chart E pushed for 4 hours in violation of our protracted labor policy. This is not accurate. The client actually pushed for 2 hours and 54 minutes.

DHSR Report says, on page 27 “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.”

The Facts: You indicated that the client in Chart E began pushing at 1651. In fact the client began pushing at 1827 and, therefore, pushed for 2:54 hours, NOT 4 hours. We follow ACOG guidelines on the appropriate pushing interval. Those guidelines suggest 3 hours for a primp (first birth) and 2 hours for a multiple (prior births) once effective pushing is established.

II.C. Criteria used to Admit/ Discharge Patients: Protocol Adherence

The report claims that the CNM managing the case in Chart D failed to follow the Baby+Co. transfer protocol and implies that the outcome might have been different if she had.

The facts: The meconium protocol cited was not relevant to the outcomes associated with this case. Furthermore, the CNM managing the case believed that birth was imminent and that it was

safer to deliver the baby at the birth center than it was to transfer the client to the hospital and risk a delivery en route.

II.D. Criteria used to Admit/ Discharge Patients: Fetal Monitoring

The report inappropriately claims that in Chart B we should have transferred the client because of an isolated deceleration in fetal heart rate was noted during the 2nd stage of labor.

On page 21, the DHSR report states "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"

The facts: Baby+Co.'s policy, which is in-line with CABC guidelines and best evidence, is to transfer a client if repetitive decelerations are noted or recovery to the normal range does not occur. In this case, heart tones recovered to the normal range after an initial deceleration at 1053 and interventions to resolve the issue, including position changes and oxygen administration. Decelerations did not repeat after these measures were taken.

II.E. Criteria used to Admit/ Discharge Patients: Ruptured Membranes

The report raises concern over Baby+Co.'s policy to offer families in early labor the option to go home without being admitted to the birth center, even after rupture of membranes.

On page 23, DHSR said **"**Another area of concern is regarding not checking fetal heart tones prior to a vaginal exam and sending patients home with ruptured membranes".

The facts: A complete assessment includes a vaginal exam and auscultation of fetal heart tones, but, unless there is concern for fetal wellbeing, it is appropriate to perform the vaginal exam before the heart rate assessment. In accordance with American College of Nurse-Midwives guidelines, Baby+Co. offers expectant management until active labor for up to 24 hours after discussion of risks, benefits, and alternatives including the option to induce labor, which requires hospital admission. Clients frequently stay at the birth center for a period of time with ruptured membranes but often prefer to be home or walking to encourage labor progression. Before going home, the CNM and client discuss warning signs and plan for further assessment and monitoring.

II.F. Overall Intrapartum Management: Manual Rotation

The report raises concern over whether a CNM in Chart E's case attempted to turn the infant during labor.

On page 27, DHSR says **"**There is also a concern about whether one of the CNMs may have turned the infant without charting this as attempted/done… Also, according to the Medical Director / supervising physician, this action would be outside the scope of practice for a CNM"

The facts: The review references **internal version (**turning a fetus from a breech or transverse position to head-down) and incorrectly implies that one of our CNMs attempted an internal

version. This is out of scope for midwives and none of the CNMs in this case attempted internal or external version. DHSR staff did not interview this midwife concerning this case or ask the staff involved in this client's labor and delivery about this point. One of the CNMs did gently attempt with fingers open **manual rotation**, a technique used to optimally tilt a baby's head towards its chest during pushing**,** which is in scope for a CNM.

IV. After Hours Staffing

The report makes the broad statement that DHSR has 'serious concerns' about Baby+Co.'s afterhours staffing model

DHSR Report Claim: ON page 1 the report says "DHSR identified numerous, significant concerns including… after hours staffing'. On page 23 in reference to Chart C's case "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 facts: Births at Baby+Co. are attended by at two providers ---either 2 Certified Nurse Midwives or 1 Certified Nurse Midwife and 1 Registered Nurse. We have a 3rd provider on call who is called in if there are ever two births taking place at one time. This is standard birth center practice across the country and aligns with the guidelines set by the Commission on the Accreditation of Birth Centers.

The National Birth Center Study I and II, which documented the safety and benefits of birth center care, including mortality and morbidity rates that are lower than those seen in hospitals, collected data from 79 birth centers the vast majority of which utilize a similar staffing model.

The report inappropriately implies that we were not sufficiently staffed to provide individualized attention to each patient on the day of Chart E's birth because the primary CNM managing Chart E's birth delivered 5 babies during her shift

On page 27, DSHR said: "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 the patient's room during labor."

The facts: While there were 5 births during the 24-hour period in which Client E gave birth, only one other family was in labor at the same time as Client E. There were 3 providers, two CNMs and one RN, in the room at the time of Client E's birth and a CNM/RN pair stayed with the family after delivery. While it is true that the primary CNM had to leave the room immediately after the newborn's birth, there were not any safety issues because there were two other providers in the room.

The report raised concern over the number of providers when Client C arrived at the birth center.

On page 27, DSHR said (in reference to Client C's chart) "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 facts: It is common practice in most birth centers for the primary provider to meet a family to do an initial evaluation and to call a second provider when active labor begins. It is rare that emergencies occur so quickly after initial arrival at the birth center. When they do our second provider is prepped and ready to come in to provide support. In the case of Chart C, a second provider was contacted three minutes after the patient arrived, arrived within 5 minutes and assisted with the transfer. A third provider was contacted five minutes after the patient's arrival and got to the birth center shortly after the ambulance had left. As noted in the DHSR report, this was the fastest ambulance transfer of the cases reviewed and the patient left the birth center 12 minutes after EMS was initially notified.

IV. Laboratory Operations

The report raises concern over Baby+Co.'s management and administration of our laboratory.

The report raises several documentation concerns and appears to imply that these concerns are somehow linked to the outcomes in these cases and/or indicative of overall mismanagement of the laboratory.

On page 32, the DHSR report said, "No detailed Policy and Procedure Manual reviewed and signed by the lab director to ensure quality test results."

The facts: We outsource the vast majority of the laboratory tests that we offer at Baby+Co. to the laboratory at WakeMed and/or to Quest or LabCorp. We perform only two relevant tests: wet mount tests and FERN tests. Neither test was used in these cases and neither was relevant to the outcomes.

Our relevant lab policies are contained within our umbrella Policies and Procedures Manual, and specific policies regarding daily lab administration, infection control, and quality assurance were provided to the review team.

Regular quality assurance measures are in place to track the overall management and administration of the lab, laboratory procedures, and clinical and emergency supplies.

V. Staff Orientation and Training

The report incorrectly claims that we have inconsistent orientation + training standards

On page 17, DHSR Claims: "Baby+Co. did not have a consistent and formal orientation process to validate the skills of its CNMs."

The facts: Certified nurse-midwives have masters or doctorate degrees and must accumulate hundreds of hours of classroom and clinical training, demonstrate competency on core competencies for independent practice defined by the American College of Nurse-Midwives, and successfully complete a board certification exam. They must maintain current with continuing education programs and recertify every 5 years showing continued competency in antepartum, intrapartum, postpartum, well-woman, and newborn care.

Despite this extensive background, we have a consistent training and onboarding process that is continually improved over time, which is why DHSR noted three different training checklists. The DHSR review team looked at training checklists in individual personnel files for employees hired over a 4-year period. Training check-lists were consistently available in staff personnel files, except for employees hired more recently who completed their training checklists online with records stored in an online system called Trello. DHSR did not have time to review this online system but the checklist is in a similar format online as it is in hard copy.

Our orientation and training process includes:

1. Week 1: An on boarding with 15 hours of taped Webex trainings on topics from: our application of risk criteria, to documentation standards, to an overview of our care model with time to review our standard operating procedures and clinical policies documented in our online internal knowledge sharingsystem
2. Week 2-4: Shadowing a full-time clinician before joining the schedule, working through the training checklist as documented on the project management tool we use called Trello
3. Week 3-6: integration into the appropriate role
4. Ongoing-work through any remaining competency testing or other training with lead CNM or training mentor
5. An in-person 90-day review

We have recently implemented a new sign off system to document competency of certain critical skills prior to independently managing a labor.

We do not do annual competency reviews for clinical staff. This is not required by the CABC or the Board of Nursing and is not common practice in a physician or midwifery office or at the hospital.

We do annual reviews, which refer to observed clinical competencies and run regular drills to allow our CNMs to practice skills that are not used frequently. Those annual reviews are documented in staff personnel files. The DHSR noted a handful of instances in which they were missing, which is because we have clustered the reviews this year in June and July to get all current staff on the same review cycle. If any annual evaluations were determined missing, it is because the person had not yet been employed for a full year to have conducted a review.

It is worth noting that the new providers that had just been hired in February and March were still in the process of orienting, which is why the completed paper orientation checklist was no yet in the file. Additionally, because we were on diversion, they hadn't had a chance to review the full scope of skills as part of their orientation.

We have noted the need to tighten our documentation around that training and staff evaluation.

The report mischaracterized the screening process used when it hired a locum tenens CNM and takes a Baby+Co.'s staff members comment during an interview out of context

On page 12, DHSR Claims: "Baby+Co. held the responsibility to process and approve chosen providers (CNM) credentials, granting appropriate privileges, in accordance with clients' statement of work…. Interview on April 24, 2018 at 1035 with Baby+Co. staff stated "CN #2 was credentialed by an outside agency"

The facts: Baby+Co. has a robust process that we follow to vet all employees. The provider mentioned in the report was a contractor hired through a reputable agency that manages temporary hires (which Baby+Co. has only used one time in Cary). When Baby+Co. hires a contractor through this agency it reviews the providers resume and conducts an interview of the provider as it would a full-time staff member. The agency conducts a background and criminal check on Baby+Co.'s behalf. Baby+Co. sends any temporary employees through its standard orientation and competency assessment before placing them on the clinical schedule. This provider failed to disclose elements of her record to the agency or to Baby+Co. during the screening process, when we learned that the provider had not disclosed all of the details of her background, we demanded that the agency terminate the provider's service with our center immediately. The provider in question was not responsible for managing any of the cases under review and worked at Baby+Co. for less than 3 months.

The report incorrectly claimed that one of our staff members presented herself as a CNM when she was only licensed as an RN in North Carolina

On page 27, DSHR said "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."

The facts: This staff member, who is trained and certified as a CNM and was licensed in the state of Florida, was practicing as an RN while she waiting to receive her NC license and stayed in a support role during the birth.

VI. EMS Transport

The report implies that we did not have adequate transport protocols in place with EMS and that certain communications with the EMS during transport caused significant delay.

On page 19, the DHSR report says, "it appears there was not a clear understanding between Baby+Co. staff and EMS staff related to neonatal resuscitation and the transport location."

The facts: We have specific protocols in place with EMS that outline how transfers are to be handled at Baby+Co.; including the fact that all neonatal patients should be sent to WakeMed Cary. We run joint drills together with EMS against those protocols.

Emergent transfers are rare, but we have made 32 calls to EMS since we opened, and the vast majority of these transfers have gone smoothly.

In two specific cases (Chart A+ B) the EMT team that arrived on the scene was not aware of the protocol that we have in place for neonatal transfers and wanted to send the family involved to WakeMed Raleigh instead of to WakeMed Cary. We had documentation of the protocol, including in one case a letter from the EMS Director on Wake County letterhead outlining the protocol, which we shared with the EMTs on the scene cases and the particular EMTs team did not follow the letter's instruction. Since that time, we have done a lot of work with EMS to ensure that every single EMT is aware of transfer protocols. We have updated the scripts we use when we call for an EMS dispatch and the Baby+Co. transfer protocol is now distributed via the digital reader in the ambulance. This means that the protocol is not dependent on communication between Baby+Co. and EMS but is available, in advance, to all teams in the ambulance. We have run an incremental

set of drills that have been video-taped to be viewed by all EMTs and Baby+Co. staff. And a Baby+Co. CNM; WakeMed Neonatal Nurse Practitioner; and trainer from EMS co-led a continuing education series for all county EMTs to familiarize the team with the protocol for neonatal resuscitation and transport.

Wake County EMS has worked incredibly hard, alongside our team, to ensure that in an emergency we can consistently and quickly stabilize newborn clients and get them across the street to WakeMed Cary.

We are located across the street from WakeMed Cary, 0.4 miles away, and can get to L+D by car in 5 mins. We are confident that with these reinforcements EMS and our caregivers will be well prepared to undertake ambulance transport going forward.

We regularly conduct transfer drills with EMS and the hospital, and the most recent drill at the time transferred the "patient" to WakeMed L&D in eight minutes. It is made clear when discussing the transfer time with patients that the quoted eight-minute timeframe is an estimate, and that exact timing depends on several factors, including the clinical situation and the need to triage and/or stabilize before transporting, and no guarantees are made of an exact transfer time.

VII. Other

DHHS erroneously questioned whether our patients are truly informed when they sign an informed consent document.

On page 28 the DHSR report says "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"

The facts: Education is a core part of the Baby+Co. model of care and we spend time during our initial tour; during our first visit and on each subsequent visit providing age and stage appropriate information.

Our electronic medical record enables electronic consent, and a General Informed Consent document is sent to each new client prior to her initial prenatal visit. The system used enables clients to submit questions or comments with their signature, or to ask questions prior to signing. The consent form itself also includes language informing the client that she has a right to review the document with a provider before signing, or to revoke consent at any time. The standard initial visit includes a discussion of the care model, availability of consultation and referral, and emergency processes, and documentation of any questions and concerns the client expressed about eligibility, policies, or procedures. When policy changes impact eligibility or other content in the General Informed Consent, clients are notified if the policy change impacts an existing plan of care for that client.

Baby+Co. has recently updated our process for ensuring Appendix A is maintained up-to-date with every change to eligibility requirements and to notify clients proactively.

DHHS incorrectly claimed that between March 2, 2018 and March 6, 2018 we did not run the appropriate equipment checks on any of our emergency carts

On page 33 DHHS said “There was no further record to indicate emergency carts were checked after deliveries occurring between March 2, 2018 and March 6, 2018”

The facts: DHSR only reviewed the logs for birth rooms 2 and 3; not birth room 1. The cart and log check are specific to the birth room. The emergency carts are checked before and after each birth. There were no births in birth room 2 or birth room 3 during the date range noted.

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If left unaddressed or uncorrected, these findings will mislead the community about the safety of Baby+Co. As it stands, the review does a disservice to the entire birth center model of care that has proven to be a safe and important option for parents not only in the United States but around the world.

We are proud of our model and of our team of caregivers. Our top priority, as we know it is yours, is the health and safety of the moms and families that we serve.

We look forward to continuing to work with you and your team as we work to implement evidenced based licensing standards and appreciate the opportunity to demonstrate our commitment to our patients and our community.

Please contact me with any questions.

Sincerely,

Kate Condliffe
Chief Operating Officer, Baby+Co.