

+THE STATE OF SOUTH CAROLINA
In The Court of Appeals

APPEAL FROM GREENVILLE COUNTY
Administrative Law Court

Shirley C. Robinson, Administrative Law Judge

Case No. 15-ALJ-07-0148-CC

South Carolina Department of
Health and Environmental
Control,

Respondent,

v.

Blessed Births, Inc. d/b/a
Blessed Births Family
Wellness and Birth Center,

Appellant.

SUPPLEMENT TO RECORD ON APPEAL

Randall S. Hiller
850 Wade Hampton Blvd.
Greenville, SC 29609
864-232-0026
Attorney for Appellant

Other Counsel of Record:
Vito M. Wicevic
2600 Bull St.
Columbia, SC 29201
803-898-3353
Attorney for Respondent

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SC Court of Appeals

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W. Marshall Taylor Jr., Acting Director

Promoting and protecting the health of the public and the environment

February 13, 2015

Amy Leland
Blessed Births, Inc.
Blessed Births Family Wellness and Birth Center
23 Mills Avenue
Greenville, S.C. 29605-4015

CERTIFIED MAIL
ELECTRONIC RECEIPT REQUESTED
91 7199 9991 7033 6614 1324

Dear Ms. Leland:

Please find enclosed the Department's Administrative Order, executed February 12, 2015. This Administrative Order represents a final staff determination regarding the Department's enforcement action against Blessed Births Family Wellness and Birth Center.

Also, enclosed are instructions regarding the process should you elect to submit a Request for Final Review (RFR) to the S.C. Board of Health and Environmental Control.

Should you have questions, please contact me at (803) 545-4370.

Sincerely,


Gwen C. Thompson, Chief
Bureau of Health Facilities Licensing

GCT:sme

Enclosures: Administrative Order, executed February 12, 2015
Guide to Board Review

CC: Lauren A. Shuster, DHEC
Terry English, DHEC
Michell Hatcher, DHEC

Rupinderjit Grewal, Esquire, DHEC
Vito Wicevic, Esquire, DHEC
✓ Randall S. Hiller, Esq.



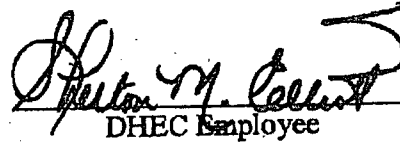
CERTIFICATE OF SERVICE

The undersigned for the South Carolina Department of Health and Environmental Control (DHEC) states that he/she has on February 13, 2015, served upon the necessary parties the letter(s) (91 7199 9991 7033 6614 1324) dated February 13, 2015, concerning DHEC's enforcement action against the facility listed below by depositing copies of same in the U.S. Mail, return address clearly stated with sufficient postage affixed thereto, addressed as follows:

Amy Leland
Blessed Births, Inc.
Blessed Births Family Wellness and Birth Center
23 Mills Avenue
Greenville, S.C. 29605-4015

(If applicable) Additional copies of this letter were sent to the facility's legal representative(s) at the following address:

Randall S. Hiller, Esquire
Attorneys at Law
850-B Wade Hampton Blvd.
Greenville, S.C. 29609


DHEC Employee

Columbia, South Carolina

February 13, 2015
Date

Sworn to before me this 13
Day of February, 2015
Katrina S Davis
Katrina S Davis
NOTARY PUBLIC for S.C.
My Commission Expires: 3/23/19

Embossed Hereon is My
State of South Carolina Notary Public Seal
My Commission Expires March 23, 2019
Katrina S Davis

South Carolina Board of Health and Environmental Control

Guide to Board Review

Pursuant to S.C. Code Ann. § 44-1-60

The decision of the South Carolina Department of Health and Environmental Control (Department) becomes the final agency decision fifteen (15) calendar days after notice of the decision has been mailed to the applicant, permittee, licensee and affected persons who have requested in writing to be notified, unless a written request for final review accompanied by a filing fee in the amount of \$100 is filed with Department by the applicant, permittee, licensee or affected person.

Applicants, permittees, licensees, and affected parties are encouraged to engage in mediation or settlement discussions during the final review process.

If the Board declines in writing to schedule a final review conference, the Department's decision becomes the final agency decision and an applicant, permittee, licensee, or affected person may request a contested case hearing before the Administrative Law Court within thirty (30) calendar days after notice is mailed that the Board declined to hold a final review conference. In matters pertaining to decisions under the South Carolina Mining Act, appeals should be made to the South Carolina Mining Council.

I. Filing of Request for Final Review

1. A written Request for Final Review (RFR) and the required filing fee of one hundred dollars (\$100) must be received by Clerk of the Board within fifteen (15) calendar days after notice of the staff decision has been mailed to the applicant, permittee, licensee, or affected persons. If the 15th day occurs on a weekend or State holiday, the RFR must be received by the Clerk on the next working day. RFRs will not be accepted after 5:00 p.m.
2. RFRs shall be in writing and should include, at a minimum, the following information:
 - The grounds for amending, modifying, or rescinding the staff decision;
 - a statement of any significant issues or factors the Board should consider in deciding how to handle the matter;
 - the relief requested;
 - a copy of the decision for which review is requested; and
 - mailing address, email address, if applicable, and phone number(s) at which the requestor can be contacted.
3. RFRs should be filed in person or by mail at the following address:
South Carolina Board of Health and Environmental Control
Attention: Clerk of the Board
2600 Bull Street
Columbia, South Carolina 29201
Alternatively, RFR's may be filed with the Clerk by facsimile (803-898-3393) or by electronic mail (boardclerk@dhec.sc.gov).
4. The filing fee may be paid by cash, check or credit card and must be received by the 15th day.
5. If there is any perceived discrepancy in compliance with this RFR filing procedure, the Clerk should consult with the Chairman or, if the Chairman is unavailable, the Vice-Chairman. The Chairman or the Vice-Chairman will determine whether the RFR is timely and properly filed and direct the Clerk to (1) process the RFR for consideration by the Board or (2) return the RFR and filing fee to the requestor with a cover letter explaining why the RFR was not timely or properly filed. Processing an RFR for consideration by the Board shall not be interpreted as a waiver of any claim or defense by the agency in subsequent proceedings concerning the RFR.
6. If the RFR will be processed for Board consideration, the Clerk will send an Acknowledgement of RFR to the Requestor and the applicant, permittee, or licensee, if other than the Requestor. All personal and financial identifying information will be redacted from the RFR and accompanying documentation before the RFR is released to the Board, Department staff or the public.
7. If an RFR pertains to an emergency order, the Clerk will, upon receipt, immediately provide a copy of the RFR to all Board members. The Chairman, or in his or her absence, the Vice-Chairman shall based on the circumstances, decide whether to refer the RFR to the RFR Committee for expedited review or to decline in writing to schedule a Final Review Conference. If the Chairman or Vice-Chairman determines review by the RFR Committee is appropriate, the Clerk will forward a copy of the RFR to Department staff and Office of General Counsel. A Department response and RFR Committee review will be provided on an expedited schedule defined by the Chairman or Vice-Chairman.
8. The Clerk will email the RFR to staff and Office of General Counsel and request a Department Response within eight (8) working days. Upon receipt of the Department Response, the Clerk will forward the RFR and Department Response to all Board members for review, and all Board members will confirm receipt of the RFR to the Clerk by email. If a Board member does not confirm receipt of the RFR within a twenty-four (24) hour period, the Clerk will contact the Board member and confirm receipt. If a Board member believes the RFR should be considered by the RFR Committee, he or she will

respond to the Clerk's email within forty-eight (48) hours and will request further review. If no Board member requests further review of the RFR within the forty-eight (48) hour period, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Final Review Conference. Contested case guidance will be included within the letter.

NOTE: If the time periods described above end on a weekend or State holiday, the time is automatically extended to 5:00 p.m. on the next business day.

9. If the RFR is to be considered by the RFR Committee, the Clerk will notify the Presiding Member of the RFR Committee and the Chairman that further review is requested by the Board. RFR Committee meetings are open to the public and will be public noticed at least 24 hours in advance.
10. Following RFR Committee or Board consideration of the RFR, if it is determined no Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Conference. Contested case guidance will be included within the letter.

II. Final Review Conference Scheduling

1. If a Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, informing the Requestor of the determination.
2. The Clerk will request Department staff provide the Administrative Record.
3. The Clerk will send Notice of Final Review Conference to the parties at least ten (10) days before the Conference. The Conference will be publically noticed and should:
 - include the place, date and time of the Conference;
 - state the presentation times allowed in the Conference;
 - state evidence may be presented at the Conference;
 - if the conference will be held by committee, include a copy of the Chairman's order appointing the committee; and
 - inform the Requestor of his or her right to request a transcript of the proceedings of the Conference prepared at Requestor's expense.
4. If a party requests a transcript of the proceedings of the Conference and agrees to pay all related costs in writing, including costs for the transcript, the Clerk will schedule a court reporter for the Conference.

III. Final Review Conference and Decision

1. The order of presentation in the Conference will, subject to the presiding officer's discretion, be as follows:
 - Department staff will provide an overview of the staff decision and the applicable law to include [10 minutes]:
 - Type of decision (permit, enforcement, etc.) and description of the program.
 - Parties
 - Description of facility/site
 - Applicable statutes and regulations
 - Decision and materials relied upon in the administrative record to support the staff decision.
 - Requestor(s) will state the reasons for protesting the staff decision and may provide evidence to support amending, modifying, or rescinding the staff decision. [15 minutes] *NOTE: The burden of proof is on the Requestor(s).*
 - Rebuttal by Department staff [15 minutes]
 - Rebuttal by Requestor(s) [10 minutes]

Note: Times noted in brackets are for information only and are superseded by times stated in the Notice of Final Review Conference or by the presiding officer.
2. Parties may present evidence during the conference; however, the rules of evidence do not apply.
3. At any time during the conference, the officers conducting the Conference may request additional information and may question the Requestor, the staff, and anyone else providing information at the Conference.
4. The presiding officer, in his or her sole discretion, may allow additional time for presentations and may impose time limits on the Conference.
5. All Conferences are open to the public.
6. The officers may deliberate in closed session.
7. The officers may announce the decision at the conclusion of the Conference or it may be reserved for consideration.
8. The Clerk will mail the written final agency decision (FAD) to parties within 30 days after the Conference. The written decision must explain the basis for the decision and inform the parties of their right to request a contested case hearing before the Administrative Law Court or in matters pertaining to decisions under the South Carolina Mining Act, to request a hearing before the South Carolina Mining Council. The FAD will be sent by certified mail, return receipt requested.
9. Communications may also be sent by electronic mail, in addition to the forms stated herein, when electronic mail addresses are provided to the Clerk.

The above information is provided as a courtesy; parties are responsible for complying with all applicable legal requirements.

STATE OF SOUTH CAROLINA
THE DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

IN RE:
Blessed Births, Inc.
Blessed Births Family Wellness and Birth Center
23 Mills Street
Greenville, S.C. 29605-4015

ADMINISTRATIVE ORDER

The South Carolina Department of Health and Environmental Control ("DHEC" or "the Department") is the agency of the State of South Carolina responsible for administering the *Birthing Center Licensure Act* ("the Act"), S.C. Code Ann. §§ 44-89-10, *et seq.* (2002), and *Standards for Licensing Birthing Centers For Deliveries By Midwives* ("the Regulation"), 8 S.C. Code Ann. Regs. 61-102 (2012). Blessed Births Family Wellness and Birth Center ("Blessed Births" or "the Facility") is a birthing center licensed by the Department and is located in Greenville, South Carolina. As a result of a routine inspection and complaint investigation conducted on July 16, 2014, the Department determined that Blessed Births is in violation of the Act and Regulation. After careful consideration, the Department determined it appropriate to issue this Administrative Order imposing a monetary penalty.

FINDINGS OF FACT:

1. Blessed Births, Inc. is the licensee of Blessed Births, a birthing center with two birthing rooms located at 23 Mills Street, Greenville, South Carolina, 29605-4015.

2. Based upon documentation obtained and observations made during a July 16, 2014 visit to Blessed Births for complaint investigations and a routine inspection, a Department representative cited the Facility for the following violations of the Regulation:

	Section	Description of Violation
1.	C.(3)	The Facility did not have an individual named to act in the absence of the administrator.
2.	D.(3)(b)	The Facility's policy and procedure did not address the receiving, transcribing, and implementing of orders for the administration of drugs.
3.	D.(3)(c)	Written prescriptions or orders signed by a practitioner legally authorized to prescribe medications in South Carolina were not

		available in a mother's medical record for the following drugs documented in the record as administered to a mother: 3 mL Pitocin IM; 500 ML NaCl IV. While the Facility had a prescription for 2 mL Pitocine IM, it did not have a prescription or order for the third mL, which according to the medical record was administered. The Facility did not provide a prescription or order for 500 ML NaCl IV.
4.	D.(3)(f)	Medications on a table in the "Hall Birthing Room" were unsecured and accessible to unauthorized individuals (e.g., family members of the patient laboring at the birthing center). The medications included three unopened vials of Pitocin 10 units/ml, one opened tube of Erythromycin ointment 0.5%, and one unopened 500 ml bag of HeSpan.
5.	D.(6)(d)	According to a review of a medical record for a delivery on 6/7/2014, there was only one staff member present during the delivery. Based upon observations made during the visit to the Facility, two members of the Facility's clinical staff or one member of the clinical staff and a registered nurse were not present in the Facility during a mother's delivery. A licensed midwife staff member of the Facility was the only staff member present at the time of delivery.
6.	F.5(a)	The Facility's "Hall Bathroom" had a putrid odor. On top of a cabinet, there were five white Styrofoam cups containing urine samples that were labeled with patient names and times. Inside the bathroom cabinet, there were two additional white Styrofoam cups containing urine samples that were also labeled with patient names and times.

3. The Department representative mailed by certified U.S. mail and emailed copies of the Licensing Standards Compliance Reports ("report of visit" or "ROV") to Blessed Births on July 25, 2014.

4. By letter dated August 6, 2013, the Department notified Blessed Births that it was considering an enforcement action against the Facility, and requested that Blessed Births attend a scheduled meeting to discuss the violations cited as a result of the July 16, 2014 inspections.

5. On August 18, 2014, the Department received a letter from Blessed Births' attorney disputing the Department's citations and declining to attend the scheduled meeting.

6. By letter, dated September 26, 2014, the Department explained the process of its scheduled meeting with Blessed Births, replied to the responses of Blessed Births' attorney regarding the cited violations, and again requested that Blessed Birth attend a scheduled meeting.

7. Blessed Births did not attend the scheduled meeting.
8. On October 16, 2014, the Department received a partial response from Blessed Births' attorney in reply to the Department's September 26, 2014 letter.
9. Based upon Blessed Births' violations of the Regulation, the Department issues this Administrative Order imposing a monetary penalty.

CONCLUSIONS OF LAW:

1. The Department is the agency of the State of South Carolina responsible for administering the *Birthing Center Licensure Act*, S.C. Code Ann. §§ 44-89-10, *et seq.* (2002), and *Standards for Licensing Birthing Centers For Deliveries By Midwives*, 8 S.C. Code Ann. Regs. 61-102 (2012).

2. No person may establish, conduct, or maintain a birthing center without being licensed by the Department. S.C. Code Ann. § 44-89-40 (2002) and 8 S.C. Code Ann. Regs. 61-102 § A.(2)(a) (2012).

3. The Department may deny, suspend, or revoke licenses or assess a monetary penalty for violations of provisions of law or departmental regulations. S.C. Code Ann. § 44-89-80(A)(3) (2002) and 8 S.C. Code Ann. Regs. 61-102 § A.(3)(e) (2012).

4. If a decision is made to assess monetary penalties, the schedule in Regulation 61-102 will be used as a guide to determine the dollar amount. 8 S.C. Code Ann. Regs. 61-102 § A.(3)(f) (2012).

5. The governing authority of a birthing center shall select an administrator who will be responsible for the management of the facility. *Id.* § C.(3) (2012). An individual shall be appointed to act in the absence of the birthing facility's administrator. *Id.*

6. A birthing facility shall have policies and procedures addressing the receiving, transcribing, and implementing of orders for administration of drugs. *Id.* § D.(3)(b).

7. A birthing facility shall have written prescriptions or orders signed by the practitioner legally authorized to prescribe drugs in South Carolina for all drugs administered to mothers and infants. *Id.* § D.(3)(c).

8. Drugs, medications, and chemicals shall be stored and secured in specifically designated cabinets, closets, drawers, or storerooms and made accessible only to authorized persons. *Id.* § D.(3)(f).

9. Two members of the clinical staff or one member of the clinical staff and a registered nurse shall be present during a mother's delivery. *Id.* § D.(6)(d).

10. The birthing facility shall be kept neat, clean, and free from odors. *Id.* § F.(5)(a). Bath and toilet facilities must be maintained in a clean and sanitary condition at all times. *Id.*

11. Based upon the foregoing facts, the Department finds the Facility in violation of the Regulation as follows:

a. Blessed Births violated Section C.(3) by failing to have an individual appointed to act in the absence of the Facility's administrator. Violation of Section C.(3) is a Class II violation and carries a penalty range of \$100-500 for a first occurrence.

b. Blessed Births violated Section D.(3)(b) by failing to ensure its policy and procedure addressed the receiving, transcribing, and implementing of orders for the administration of drugs. Violation of Section D.(3)(b) is a Class I violation and carries a penalty range of \$200-1,000 for a first occurrence.

c. Blessed Births violated Section D.(3)(c) by not having written prescriptions or orders signed by a practitioner legally authorized to prescribe in South Carolina for medications documented as administered to a mother and infant. Violation of Section D.(3)(c) is a Class I violation and carries a penalty range of \$200-1,000 for a first occurrence.

d. Blessed Births violated Section D.(3)(f) by failing to ensure that drugs and medications were stored and secured in specifically designated cabinets, drawers, or storerooms and accessible only to authorized persons. Violation of Section D.(3)(f) is a Class I violation and carries a penalty range of \$200-1,000 for a first occurrence.

e. Blessed Births violated Section D.(6)(d) by failing to ensure that two members of the clinical staff member or one member of the clinical staff and a registered nurse were present during a mother's delivery. Violation of Section D.(6)(d) is a Class I violation and carries a penalty range of \$200-1,000 for a first occurrence.

f. Blessed Births violated Section F.(5)(a) by failing to ensure that the Facility was free from odors and by failing to ensure that the bathroom was clean and sanitary at all times. Violation of Section F.(5)(a) is a Class II violation and carries a penalty range of \$100-500 for a first occurrence.

12. In considering enforcement against Blessed Births, the Department considered the specific conditions and their impact or potential impact on the mothers and newborns that Blessed Births serves. See 8 S.C. Code Ann. Regs. 61-102 § A.(3)(e) (2012). The failure to ensure that two members of the birthing center's clinical staff or one member of the clinical staff and a registered nurse are present during a mother's delivery, and the failure to ensure that prescriptions or orders signed for by a practitioner authorized to prescribe are obtained for all drugs administered in the birthing center present a threat to the safety and welfare of the clients of the birthing center.

13. Based upon the foregoing findings of fact and conclusions of law, the Department determined it appropriate to issue this Administrative Order imposing a monetary penalty against Blessed Births.

ORDER

NOW, THEREFORE IT IS ORDERED, pursuant to S.C. Code Ann. § 44-89-80(A)(3) (2002) and 8 S.C. Code Ann. Regs 61-102 § A.(3)(e) (2012), the Department assesses a \$2,200 monetary penalty against Blessed Birth Family Wellness and Birth Center. Payment of the assessed monetary penalty shall be remitted to the Department within 30 days of the date of execution of this Administrative Order. The payment shall be made by certified check or money order made payable to South Carolina Department of Health and Environmental Control, and shall be sent to the following address:

Attention: Gwen C. Thompson, Chief
Bureau of Health Facilities Licensing
S.C. Department of Health and Environmental Control
2600 Bull Street
Columbia, S.C. 29201

Instructions regarding the appeals process are enclosed.

**FOR THE SOUTH CAROLINA DEPARTMENT OF HEALTH AND
ENVIRONMENTAL CONTROL BY:**



Lauren A. Shuster
Director of Public Health

Date: 2/12/2015

Gwen C. Thompson
Gwen C. Thompson, Chief
Bureau of Health Facilities Licensing

Date: 2/11/15

Reviewed by:

Vito Wicevic
Vito Wicevic, Esquire
Assistant Counsel for Health Regulation

Date: 2015-02-06



Catherine B. Templeton, Director

Promoting and protecting the health of the public and the environment

July 25, 2014

Amy Leland, LMW
Blessed Births, Inc.
Blessed Births Family Wellness and Birth Center
23 Mills Avenue
Greenville, S.C. 29605-4015

CERTIFIED MAIL
ELECTRONIC RECEIPT REQUESTED
91 7108 2133 3933 6662 3376

Dear Ms. Leland;

Please find enclosed the Reports of Visit ("ROVs") for inspections/investigations conducted at Blessed Births Family Wellness and Birth Center on July 11, 2014 and July 16, 2014. The Plans of Correction ("POCs") are due on August 9, 2014. These ROVs were also emailed to babycatcher@blessedbirths.com on July 25, 2014.

If you have any questions, you may contact me at 803-545-4968, hatcheml@dhec.sc.gov or Terry English at 803-545-4458, englistl@dhec.sc.gov.

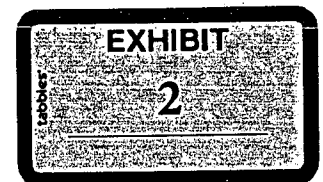
Sincerely,

Michell Hatcher, RN, BSN
Perinatal Nurse Administrator
DHEC Health Facilities Licensing

MH:mh

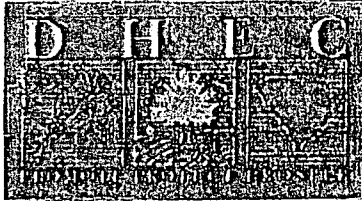
Enclosures:

Blessed Births ROV for Routine Visit dated 7/11/2014
Blessed Births ROV for Routine Visit dated 7/16/2014
Blessed Births ROV for Investigation Cx M07007-14 dated 7/16/2014
Amy Leland ROV for Investigation Cx M07008-14 dated 7/16/2014
Blessed Births ROV for Investigation Cx M07009-14 dated 7/16/2014
Amy Leland ROV for Investigation Cx M07010-14 dated 7/16/2014



CC: Stefanie Corbett, DHEC
Gwen C. Thompson, DHEC
Terry English, DHEC

Vito Wicevic, Esquire, DHEC
Rupinderjit Grewal, Esquire, DHEC
Randall S. Hiller, Esquire



Facility Information	Audit Information
Permit Number: BC-0003	Audit: Birthing Center ROV 20140627
Permit Type: HL- Birthing Center	Type: L01 Routine
Location Name: BLESSED BIRTHS FAMILY WELLNESS AND BIRTH CENTER	Date: 07/16/2014
Address: 23 MILLS AVE	Stop Date: 07/16/2014
City/State/Zip: GREENVILLE, SC, 29605-4015, Greenville	Auditor: Michell Hatcher
Phone: 864-233-5513	Contact Name: SUSANNAH BALDWIN
E-Mail: BABYCATCHER@BLESSEDBIRTHS.COM	Contact Email:

Bureau of Health Facilities Licensing 2600 Bull St Columbia SC 29201-1708 REPORT NOTICE: If applicable, this Report of Visit includes a detailed description of the conditions, conduct or practices that were found to be in violation of requirements. This inspection or investigation is not to be construed as a check of every condition that may exist, nor does it relieve the licensee (owner) from the need to meet all applicable standards, regulations and laws. The South Carolina Code of Laws requires this Department to establish and enforce basic standards for the licensure (permitting), maintenance, and operation of health facilities and services to ensure the safe and adequate treatment of persons served in this State. It also empowers the Department to require reports and make inspections and investigations as considered necessary. Furthermore, the Code authorizes the Department to deny, suspend, or revoke licenses (permits) or to assess a monetary penalty against a person or facility for (among other reasons), violating a provision of law or departmental regulations or conduct or practices detrimental to the health or safety of patients, residents, clients, or employees of a facility or service. If applicable to the type of report being made, the signature of the activity representative indicates that all of the items cited were reviewed during the exit discussion. If this Report of Visit is required by regulation to be made available in a conspicuous place in a public area within the facility, redaction of the names of those individuals in the report is required as provided by Sections 44-7-310 and 44-7-315 of the S.C. Code of Laws, 1976, as amended.	Report Notice
ADMINISTRATOR'S SIGNATURE - PLAN OF CORRECTION	
PLAN OF CORRECTION - Administrator's Certification: I certify that the attached plan of correction describes: (1) the actions taken to correct each cited deficiency, (2) the actions taken to prevent similar recurrences, and (3) the actual or expected completion dates of those actions. PRINT NAME: _____ TITLE: _____ SIGNATURE: _____ DATE: _____ Any violations cited in this report of visit were observed at the time of the inspection. Administrator returns a copy of this report (original signature required) with description of corrective actions to: SCDHEC, Bureau of Health Facilities Licensing, 2600 Bull St, Columbia, SC, 29201 Your response to this report must be received in our office by close of business (5:00 p.m.) no later than the date listed below: • Plan of correction due date to be determined	POC REQUIRED

INSPECTION INFORMATION

An unannounced visit was made to Blessed Births on July 16, 2014, for the purpose of conducting a general inspection and complaint investigations.

Two representatives from the Department (Michell Hatcher, RN and James Harmon, HFOD Field Manager) visited the birthing center on July 11, 2014 for the purpose of conducting an inspection/investigation(s), but the birth center was closed, and after talking with the Administrator via phone, the inspectors were not allowed access to the birthing

center.

Upon arrival to the birthing center today (July 16, 2014), the Department inspector, accompanied by another Department representative and a Greenville City Police officer, presented an affidavit and search warrant to Ms. Leland. Pursuant to the search warrant, a walk through of the facility was completed, and the policy and procedure manual was reviewed. Copies of pages (3-10) were made, and taken back to the office for review. Medical records were not reviewed as part of this general inspection, due to medical record reviews completed for several complaints at the same visit. Medical records were copied and taken back to the office for review as noted on the Blessed Births Report of Visit Memo, dated July 11, 2014, and left with the facility on the same date (see attached). Medical record review Reports of Visit for the complaint investigations, will be reported separately.

Inspection Includes Licensing:	YES
Inspection Includes Fire & Life Safety:	NO
Is this an On-Site Visit?	YES
Select the Type of Inspection to be Performed:	Birthing Center Inspection (Licensing and/or FLS)
What Date Did the Auditor Arrive at the Facility?	7/16/2014
What Time Did the Auditor Arrive at the Facility?	11:40:00 AM
Licensed Capacity:	2
Current Census:	1
Facility Administrator:	Amy Leland
Enter the name and title of the Facility/Activity Representative for this Report of Visit.	Amy Leland
Is the Current Facility/Activity Administrator the same as the Administrator of Record?	YES
Are there any other individuals accompanying the auditor for this visit? • James Harmon, Field Manager of HFOD, DHEC Health Facilities Licensing Officer Andrew Sturman, Greenville City Police Department	YES
BC REGULATION SECTIONS A-G 61-102	
C.(3) Administrator: The chief administrative officer shall be selected by the governing authority and shall have charge of and be responsible for the management and administration of the facility in all its branches and departments and shall see that the bylaws and amendments thereto are complied with. Any change in the position of the chief administrative officer shall be reported immediately by the governing authority to the Department in writing. An individual shall be appointed to act in the absence of the administrator. (Class II Violation) • The Department inspector did not observe an individual named to act in the absence of the administrator at the time of policy and procedure manual review.	OUT
D.(3)(f) Drugs, medications, and chemicals shall be stored and secured in specifically designated cabinets, closets, drawers, or storerooms and made accessible only to authorized persons. (Class I Violation) • The Department inspector observed the following medications on a table in the Hall birthing room. The medications were unsecured and accessible to unauthorized individuals (e.g. family members of the patient laboring at the birthing center): Pitocin 10 Units/ml (3) unopened vials, Erythromycin ointment 0.5%(1) opened tube, and HeSpan(1) unopened 500 ml bag.	OUT

D.(6)(d) At least one member of the clinical staff or a registered nurse shall be in the facility when a patient is present; and up to at least one hour after each mother's delivery. Two members of the clinical staff or one member of the clinical staff and a registered nurse shall be present during the mother's delivery. (Class I Violation) • A patient delivered at the birthing center during the time the Department was conducting the inspection. The Department inspector did not observe two (2) members of the center's clinical staff or one (1) member of the clinical staff and a registered nurse in the facility during the mother's delivery. Ms. Leland, a licensed midwife, was the only Blessed Births staff observed in the facility during the delivery. A registered nurse was not observed at the birthing center during the mother's delivery.	OUT
F.(5)(a) General: A facility shall be kept neat, clean and free from odors. Accumulated waste material must be removed daily or more often if necessary. There must be frequent cleaning of floors, walls, ceilings, woodwork, and windows. The premises must be kept free from rodent and insect infestation. Bath and toilet facilities must be maintained in a clean and sanitary condition at all times. (Class II Violation) • At the time of inspection, there was a putrid odor noticed in the Hall bathroom. Five (5) white styrofoam cups were observed sitting on top of the cabinet and were labeled as follows: ** Two (2) of the cups were labeled with individual patient names and dated 7/15/14, and had times noted ** Two (2) of the cups were labeled with patient names, dated 7/15/14, and had no time documented ** One (1) cup was labeled with a patient name and time. In addition, two (2) white styrofoam cups were observed in the bathroom cabinet and were labeled as follows: ** One (1) of the cups was labeled with a patient name and time. ** The other cup was labeled with a patient name and time. The cups contained yellow liquid, differing in color shades and amounts.	OUT
DHEC 0282 (05/2010) AUDIT - [Records Retention Schedule #SBH-F&S-17]	
PROTECTED INFORMATION	
Is this information CONFIDENTIAL? This section names or identifies certain individuals related to cited violations. If you identify by name any patient, client, resident, or participant, you must check 'YES' by CONFIDENTIAL. Otherwise, check 'NO.' (The names of facility/activity staff members are NOT considered CONFIDENTIAL. If required for the audit, list the names of staff members in the citation.) • F.5.- 1) Patient SB 2) Patient IM 3) Patient CH 4) Patient MT 5) Patient SC 6) Patient LT 7) Patient P	YES

Auditor Signature: Michell Hatcher	Account Signature: Amy Leland
<i>Michell Hatcher BSN</i>	<i>Report to be emailed and sent out via mail today</i>



Promoting and protecting the health of the public and the environment

July 25, 2014

Amy Leland, LMW
Blessed Births, Inc.
Blessed Births Family Wellness and Birth Center
23 Mills Avenue
Greenville, S.C. 29605-4015

CERTIFIED MAIL
ELECTRONIC RECEIPT REQUESTED
91 7108 2133 3933 6662 3376

Dear Ms. Leland;

Please find enclosed the Reports of Visit ("ROVs") for inspections/investigations conducted at Blessed Births Family Wellness and Birth Center on July 11, 2014 and July 16, 2014. The Plans of Correction ("POCs") are due on August 9, 2014. These ROVs were also emailed to babycatcher@blessedbirths.com on July 25, 2014.

If you have any questions, you may contact me at 803-545-4968, hatcheml@dhec.sc.gov or Terry English at 803-545-4458, englistl@dhec.sc.gov.

Sincerely,

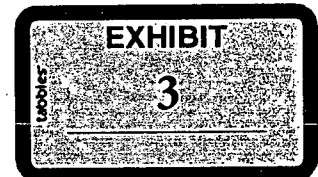
Michell Hatcher RN, BSN

Michell Hatcher, RN, BSN
Perinatal Nurse Administrator
DHEC Health Facilities Licensing

MH:mh

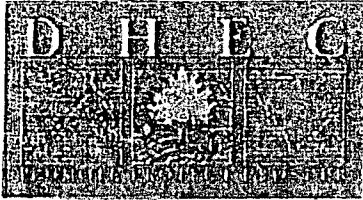
Enclosures:

Blessed Births ROV for Routine Visit dated 7/11/2014
Blessed Births ROV for Routine Visit dated 7/16/2014
Blessed Births ROV for Investigation Cx M07007-14 dated 7/16/2014
Amy Leland ROV for Investigation Cx M07008-14 dated 7/16/2014
Blessed Births ROV for Investigation Cx M07009-14 dated 7/16/2014
Amy Leland ROV for Investigation Cx M07010-14 dated 7/16/2014



CC: Stefanie Corbett, DHEC
Gwen C. Thompson, DHEC
Terry English, DHEC

Vito Wicevic, Esquire, DHEC
Rupinderjit Grewal, Esquire, DHEC
Randall S. Hiller, Esquire



Facility Information	Audit Information
Permit Number: BC-0003	Audit: Birthing Center ROV 20140627
Permit Type: HL- Birthing Center	Type: L07 Investigation
Location Name: BLESSED BIRTHS FAMILY WELLNESS AND BIRTH CENTER	Date: 07/16/2014
Address: 23 MILLS AVE	Stop Date: 07/16/2014
City/State/Zip: GREENVILLE, SC, 29605-4015, Greenville	Auditor: Michell Hatcher
Phone: 864-233-5513	Contact Name: SUSANNAH BALDWIN
E-Mail: BABYCATCHER@BLESSEDBIRTHS.COM	Contact Email:

Bureau of Health Facilities Licensing
2600 Bull St
Columbia SC 29201-1708

REPORT NOTICE: If applicable, this Report of Visit includes a detailed description of the conditions, conduct or practices that were found to be in violation of requirements. This inspection or investigation is not to be construed as a check of every condition that may exist, nor does it relieve the licensee (owner) from the need to meet all applicable standards, regulations and laws. The South Carolina Code of Laws requires this Department to establish and enforce basic standards for the licensure (permitting), maintenance, and operation of health facilities and services to ensure the safe and adequate treatment of persons served in this State. It also empowers the Department to require reports and make inspections and investigations as considered necessary. Furthermore, the Code authorizes the Department to deny, suspend, or revoke licenses (permits) or to assess a monetary penalty against a person or facility for (among other reasons), violating a provision of law or departmental regulations or conduct or practices detrimental to the health or safety of patients, residents, clients, or employees of a facility or service. If applicable to the type of report being made, the signature of the activity representative indicates that all of the items cited were reviewed during the exit discussion. If this Report of Visit is required by regulation to be made available in a conspicuous place in a public area within the facility, redaction of the names of those individuals in the report is required as provided by Sections 44-7-310 and 44-7-315 of the S.C. Code of Laws, 1976, as amended.

Report
Notice

ADMINISTRATOR'S SIGNATURE - PLAN OF CORRECTION

PLAN OF CORRECTION - Administrator's Certification: I certify that the attached plan of correction describes:

- (1) the actions taken to correct each cited deficiency,
- (2) the actions taken to prevent similar recurrences, and
- (3) the actual or expected completion dates of those actions.

PRINT NAME: _____

TITLE: _____

SIGNATURE: _____

DATE: _____

Any violations cited in this report of visit were observed at the time of the inspection.

Administrator returns a copy of this report (original signature required) with description of corrective actions to:

SCDHEC, Bureau of Health Facilities Licensing, 2600 Bull St, Columbia, SC, 29201

Your response to this report must be received in our office by close of business (5:00 p.m.) no later than the date listed below:

- Date Plan of Correction is due is to be determined

POC
REQUIRED

INSPECTION INFORMATION

An unannounced visit was made to Blessed Births on July 16, 2014, for the purpose of a complaint investigation against Blessed Births for Cx # M07007-14.

Two representatives from the Department (Michell Hatcher, RN and James Harmon, HFOD Field Manager) visited the birthing center on July 11, 2014 for the purpose of conducting an inspection/investigation(s), but the birthing center was closed, and after talking with the Administrator via the phone, the inspector was denied access to the

birthing center.

Upon arrival to the birthing center today (July 16, 2014), the Department inspector, accompanied by another Department representative and a Greenville City Police officer, presented an affidavit and search warrant, dated July 16, 2014 and signed by Judge James E. Hudson, to Ms. Leland. Pursuant to the search warrant, a walk through of the facility and review of medical records was completed by the Department inspector. Officer Andrew Sturman, with Greenville City Police Department and James Harmon, Field Manager for HFOD, with DHEC Health Facilities Licensing accompanied the Department inspector for the visit. The medical record was requested per myself, and provided by Ms. Leland. The medical record was reviewed, and copies of the following documents were made and taken back to the office for further review:

- 1) Blessed Births Medical History
- 2) Blessed Births Patient Registration
- 3) Blessed Births signed Informed Consent
- 4) Blessed Births Acknowledgement of Receipt of Notice of Privacy Practices
- 5) Blessed Births Prenatal Visits and Supplemental Prenatal Visits
- 6) Handwritten note to Dr. Stojord updating him on ultrasound results performed on 5/7/2014
- 7) Cornerstone Family Medicine History and Physical
- 8) Kelly Ultrasound Center Reports with reported Dates of Service on 1/6/2014 and 2/17/2014
- 9) Blessed Births Prescription Request/ Upstate Medical Pharmacy- no physician signature
- 10) Handwritten note to have Dr. Stojord sign prescription request to Upstate Pharmacy
- 11) Kelly Ultrasound Center Report with reported Date of Service 5/7/2014
- 12) Regional Maternal-Fetal Medicine Obstetrical Ultrasound Report with reported Study Date of 3/26/2014
- 13) Blessed Births Vitamin K and Cephalic Erythromycin Choices
- 14) Blessed Births Birthing Record with Date of Birth 6/07/2014
- 15) Blessed Births Labor and Delivery Notes - with no date
- 16) Blessed Births Admission and identification dated 06/07/2014
- 17) Blessed Births Labor and Transport Summary with Labor onset date reported as 6/6/14
- 18) Maternity Superbill

Inspection Includes Licensing:	YES
Inspection Includes Fire & Life Safety:	NO
Is this an On-Site Visit?	YES
Select the Type of Inspection to be Performed:	Birthing Center Complaint Investigation
Section Team Log Number: • M07007-14	Section Team Log Number
Complaint Allegation(s): • 1) Amy Leland spoke with our supervising physician who recommended immediate transfer to the hospital. Despite this specific recommendation, Amy Leland kept the patient at the birth center for more than six (6) hours and delivered there. 2) Transfer was further delayed until the patient was hemodynamically unstable with life-threatening hemorrhage and anemia.	Complaint Allegation(s)
What is the Source of the Complaint:	Consumer Complaint
Date Agency (DHEC) Notified of Complaint: • July 8, 2014	Date Agency (DHEC) Notified of Complaint
Detailed Results of this Investigation:	Detailed

• Violations were cited as a result of the investigation.	Results
Is this an Unlicensed Facility/Activity Complaint?	NO
Has the Initial QI Review Been Completed?	YES
Name of Reviewer: • Terry English	Name of Reviewer
What Date Did the Auditor Arrive at the Facility?	7/16/2014
What Time Did the Auditor Arrive at the Facility?	11:40:00 AM
Licensed Capacity:	2
Current Census:	1
Facility Administrator:	Amy Leland
Enter the name and title of the Facility/Activity Representative for this Report of Visit.	Amy Leland
Is the Current Facility/Activity Administrator the same as the Administrator of Record? • Ms. Leland did not provide a date for the change of Administrator, when inspector inquired.	NO
Are there any other individuals accompanying the auditor for this visit? • James Harmon, Field Manager for HFOD, with DHEC Health Facilities Licensing and Officer Andrew Sturman, with Greenville City Police Department.	YES
BC REGULATION SECTIONS A-G 61-102	
D.(3)(b) There shall be policies and procedures addressing the receiving, transcribing, and implementing of orders for administration of drugs. (Class I Violation) • The Department inspector did not observe a policy/procedure addressing the receiving, transcribing, and implementing of orders for administration of drugs at Blessed Births during a review of the Blessed Births policy and procedure manual.	OUT
D.(3)(c) There shall be written prescriptions or orders signed by a practitioner legally authorized to prescribe in South Carolina for all drugs administered to mother and infant within the birthing center. (Class I Violation) • The Department inspector did not observe written prescriptions or orders signed by a practitioner legally authorized to prescribe in South Carolina, for the following drugs, documented in the medical record, as administered to the mother while at the birthing center: 9:35a 1mL Pitocin IM given to mom; 9:50 a 1 mL Pitocin IM given to Mom; 10:00a 1mL Methergine IM given to mom; 10:05a 500mL NaCl IV given to mom. 10:20a 1mL Pitocin IM given to Mom.	OUT
D.(3)(d) Drugs shall be administered by personnel or clinical staff currently licensed in South Carolina to administer drugs. (Class I Violation) • The Department inspector was unable to determine if the medications listed below were administered by personnel or clinical staff currently licensed to administered drugs. The Department inspector did not observe signatures or initials in the medical record, associated with the documented administration of the medications. 9:35a 1mL Pitocin IM given to mom; 9:50 a 1 mL Pitocin IM given to Mom; 10:00a 1mL Methergine IM given to mom; 10:05a 500mL NaCl IV given to mom; 10:20a 1mL Pitocin IM given to Mom.	OUT
D.(6)(d) At least one member of the clinical staff or a registered nurse shall be in the facility when a patient is present; and up to at least one hour after each mother's delivery. Two	

members of the clinical staff or one member of the clinical staff and a registered nurse shall be present during the mother's delivery. (Class I Violation) • The Department inspector did not observe documentation indicating that two (2) members of the clinical staff or one (1) member of the clinical staff and a registered nurse were present during the mother's delivery, which was documented as occurring at the birthing center.	OUT
DHEC 0282 (05/2010) AUDIT - [Records Retention Schedule #SBH-F&S-17]	Retention
PROTECTED INFORMATION	
Is this information CONFIDENTIAL? This section names or identifies certain individuals related to cited violations. If you identify by name any patient, client, resident, or participant, you must check 'YES' by CONFIDENTIAL. Otherwise, check 'NO.' (The names of facility/activity staff members are NOT considered CONFIDENTIAL. If required for the audit, list the names of staff members in the citation.) • Patient KD [REDACTED] EDD 5/28/14	YES

Auditor Signature: Michell Hatcher	Account Signature: Amy Leland
<i>Michell Hatcher RN, BSN</i>	<i>Report was emailed and mailed certified today</i>

A. Governing Authority and Management

1. General: Facility shall be organized, equipped, manned, and administered to provide adequate care for each person admitted.
2. Governing Authority: The governing authority Amy B. Leland, LMW, CPM shall be the supreme authority responsible for the management control of the facility and shall develop a written set of bylaws or other appropriate policies and procedures for operation of the facility. This list is included and addressed herein:
 - a. Purpose of the facility: The purpose of the facility is to provide delivery services to low risk women.
 - b. Name of person to whom responsibility for operating and maintenance of the facility is delegated to Amy B. Leland, LMW, CPM. Method established by the governing authority for holding such individual responsible shall be the provision of at least annual meetings of the governing authority and the Director of Midwifery, ~~Laura Gilbert~~, CNM, MS.
DARA CURTIS
 - c. Provision for this policies and procedures manual which is designed to ensure Professional and safe care for the patients is to include but is not limited to:
 - (1) Admission Criteria: Patients will be admitted for care if they are low risk and have a signed informed consent statement.
 - (2) Extent of Physician Participation in Services Offered: Physician participation shall include but not be limited to two visits made to consulting physician's office with one of these visits being in the last six weeks of pregnancy. The physician will provide a statement that patient is low risk to remain eligible for delivery at the center.
 - (3) Rights and Responsibilities of Patients:
 - ✓ The right to be treated with dignity and without prejudice.
 - ✓ The right to informed consent concerning her care, having relevant information upon which to base decisions.
 - ✓ The right to full disclosure of the costs of her care.
 - ✓ The right to know who will participate in her care and to obtain additional consultation of her choice.
 - ✓ The right to privacy except where this right is preempted by law inhibits the quality of care.
 - (4) Midwife Rights:
 - ✓ The right to refuse care to clients with whom no midwife/client relationship has been established.



- ✓ The right to discharge clients from her care, provided a referral to other care is extended.
- ✓ The right to receive, honest relevant information from clients upon which to base care.

(5) **Patients Grievance Procedures:** Patients will have the right to submit any grievances in writing to the person responsible for the operation and maintenance of the facility. There will also be a consumer feed back form provided to each patient at the completion of delivery that is self addressed to the Division of Health Licensing, S.C., Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201.

(6) **Infection Control Procedures:** See section D

(7) **Personnel Training Requirements:** See section A.5

(8) **Transfer of Mothers who During the Course of Pregnancy, Delivery or Recovery are Determined Ineligible for Care:** The primary goal in any birth is to have a healthy outcome regardless of the birth setting. Circumstances can occur where for either psychosocial or physiological reasons a transfer of care is deemed appropriate. If client care is transferred all pertinent prenatal and/or delivery records shall be given to the new provider to facilitate and promote continuous care. Termination of care can be made because of but not limited to the following list of reasons:

- Patient at any time in the course of care is no longer considered low risk.
- Patient is irresponsible and/or unwilling to change detrimental habits.
- Dishonesty, intentional breach of contract.
- Unstable or dangerous home environment.
- Immaturity or questionable emotional status.
- Refusal to submit to specified testing, emergency medical care or transport as determined necessary by midwife or physician.
- Unresolved conflicts or personality differences between client and midwife.
- Not honoring financial contract/commitment.

The midwife is not ethically, morally, or legally bound to keep a client if it is not in the best interest of both parties.

(9) **The Use of IV's, Foods, Fluids, Analgesia/Anesthesia, Antihemorrhagics, Antibiotics, Episiotomies, and Positions for Delivery.**

- IV's, antibiotics and antihemorrhagics shall be administered only when medically necessary by those certified to so.
- Food and fluids shall be permitted and encouraged throughout labor and delivery when seen to be of benefit.

- Analgesia/Anesthesia – A local anesthetic may be infiltrated to facilitate perineal repair.
 - Episiotomies will not be routinely performed and only utilized when medically necessary.
 - Delivery position choice by patient is permitted as long as it is assessed to be a healthy choice.
- (10) Provisions for the education of mother, family and others, as appropriate in birthing, newborn care and maternal postpartum care. It is impossible to write exhaustive plans of client education because an educational experience in which real learning occurs requires that each client be assessed individually for her educational needs. Tailoring education to client interests and needs follows the principals of personalized midwifery care. Educational topics shall include but not be limited to:
- Nutrition – prenatal and during lactation
 - Maternal changes and common experiences/discomforts
 - Fetal Development
 - Danger Signs
 - Drugs/smoking/alcohol/work place environmental hazard during pregnancy
 - Normal labor, birth and postpartum
 - Discuss complications
 - Essentials of newborn care
 - Preparations for giving birth in the selected birth site, including sibling preparation and comfort measures
 - Emergency plans
 - Sexuality during pregnancy and early postpartum
 - Family Planning
 - Family relationships
 - Breastfeeding
 - Exercise and activity
 - Prenatal visits
 - Routine and special prenatal testing
 - Child development
 - Circumcision → Ref: to MD care
- (11) Plans for follow up of mother and infant after discharge from center: Within 24 to 36 hours after delivery, the midwife shall communicate with the mother/infant; however if the midwife is present for the first 20 to 24 hours after delivery the consultation at 24 to 36 hours is not considered mandatory. A follow up visit shall be made ^{within 14 days} at which assessments of both mother and baby will be made and newborn screening offered.
- Plans for tests/treatments including, but not limited to; prenatal labs/cultures, newborn screen, bilirubin, blood type, Rh factor, ophthalmic prophylaxis, prophylaxis for hemmorrhagic newborn disease.

PKU: Neonates will be tested for PKU within 72 hours to 2 weeks post-birth unless the parents provide a written refusal.

Bilirubin: If need presents for testing, infant will be referred to a pediatrician if levels are found to be high.

Rh factor: Infants of Rh negative mothers will be blood typed at birth. If a positive blood type is found, a titer will be drawn on the mother and Rhogam administered within 72 hours of birth.

Ophthalmic Prophylaxis: Ophthalmic erythromycin shall be administered in neonate's eyes within one hour of birth.

Prophylaxis for neonatal hemorrhagic disease: Vitamin K shall be administered to the neonate via intramuscular injection or oral administration at the parent's request or if the midwife determines that it is necessary.

- (12) Plans for circumcision: Infants will be referred to pediatrician for circumcision to be performed on the eighth day post-birth. *OR FR/MO*

~~THIS WILL BE PERFORMED AT BIRTH CENT BY KAREN ARDIS, MD~~ *NO LONGBER APPLIES*

- d. There will be annual reviews and evaluations of the facility's policies, procedures, management and operation.
- e. There will be a facility wide quality assurance program to evaluate the provision of patient care. The program shall be ongoing. The written plan of implementation is to provide patients with an in house feedback form that is to filed at their choosing with the center.
3. Administrator: The chief administrative officer shall be selected by the governing authority and shall have charge of and be responsible for the management and administration of the facility in all its branches and departments and shall see that the bylaws and amendments are reported immediately by the governing authority to the Department in writing. An alternate staff member shall be appointed to act in the absence of the administrator. The chief administrative officer is *ANN LELAND* LMW. CPM *IN THE ABSENCE OF CHIEF ADMINISTRATOR*
→ WILL ACT AS ADMINISTRATOR.
4. Administrative Records: The following essential documents and references shall be on file in the administrative office of the facility:
- Bylaws, policies and procedures of governing authority;
 - Minutes of the governing authority meetings if applicable;
 - Minutes of the facility's professional and administrative staff meetings;
 - A current copy of regulation 61-102 – Standards For Licensing Birthing Centers For Deliveries By Midwives;
 - Reports of inspections, reviews and corrective actions made related to licensure;
 - Contracts and agreements to which the facility is a party;
 - A record of each accident or incident occurring in the facility;
 - Appropriate documentation showing control and ownership.

5. Personnel: Qualified personnel shall be employed in sufficient numbers to carry out the functions of the facility. The licensee shall obtain written applications for employment from all employees. Such applications shall contain accurate information as to education, training, experience health, and personal background of each employee. All applications for licensed personnel shall contain the South Carolina license number and/or current renewal number if applicable. Personnel training requirements will be seen to by the chief administrator with personnel placements being determined when educational/training requirements are met.

a. All new employees who have contact with patients shall have a physical examination prior to employment, which shall include a tuberculin skin test, unless a previous positive reaction can be documented. The intradermal (Mantoux) method, using five tuberculin units of stabilized purified protein derivative (PPD) is recommended. Employees with positive reactions to the pre-employment tuberculin test shall follow and those who are documented with previously positive reactions shall be given a chest x-ray to determine whether tuberculin disease is present. If tuberculosis is diagnosed appropriate treatment shall be required prior to employment.

b. Personnel Records: A personnel record shall be maintained for each employee. The folder shall contain history and physicals, laboratory test results, resumes of training and experience, current job description that reflects the employee's responsibilities and work assignments, orientation and periodic evaluations.

6. Emergency:

a. All practicing and/or consulting physicians shall have admitting privileges at one or more hospitals with appropriate obstetrical services or other arrangements approved by the Department for the transfer of emergency cases when hospitalization becomes necessary.

b. Equipment and services shall be provided to render emergency resuscitative and life support procedures pending transfer to a hospital for both mother and infant.

c. The center shall enter into a signed agreement with an ambulance service licensed in this state to ensure the immediate transfer of mothers and/or newborns in emergencies, where appropriate.

Hospital to transport to Greenville Memorial

7. Clients Rights

a. The birthing center has this written policies and procedures to assure the individual client the right to privacy, dignity and safety.

b. This birthing center shall display in a conspicuous place on the premises, a copy of rights of patients.

B. Professional Care

1. Limitation of Services Offered by Birthing Center: in order to be delivered in this birthing center, the woman and/or infant shall exhibit no evidence of:

- Severe anemia;
- Diabetes mellitus;
- Symptomatic heart disease;
- Severe hypertension or preeclampsia;
- Renal disease;
- Thrombophlebitis;
- Multiple gestation that is considered high risk;
- Active herpes (within one week of delivery), syphilis, or HIV positive;
- Placental abnormalities;
- Premature labor;
- Intrauterine growth retardation;
- Fetal disease;
- Previous cesarean delivery with classical incision;
- Desire for transfer;
- Anticipated macrosomia;
- Breech birth;
- Six or more (non-miscarriage or non-abortion) pregnancies;
- Polyhydramnios or oligohydramnios, or chorioamnionitis;
- Malformed fetus;
- Any other high risk condition.

2. Birthing Center Policies and Procedures: This written policies and procedures shall include but not be limited to:

- a. Informed consent shall be obtained before onset of labor and shall include evidence of an explanation by personnel of the birthing service offered and potential risks. Documentation of the informed consent shall be filed in the patient's chart.
- b. Registration of birth and death certificates shall be filed within three days unless circumstances prohibit such and then it will be filed as soon as possible.
- c. Infection control committee duties and responsibilities shall include the development and implementation of specific patient care and administrative policies aimed at investigating, controlling and preventing infections within the facility.
- d. Arrangement shall be made for all mothers to be screened for blood typed and Rh factor (see section A.2.c.12).
- e. The physician or midwife shall, upon the birth of a child, instill or cause to be instilled in each eye of such newborn antibiotics of current efficacy in preventing development of ophthalmia neonatorum. A maximum delay of one hour shall be allowed between the time of birth and the administration of an approved prophylactic agent.

3. Pharmaceutical Services:

- All pharmaceuticals will be stored in a locked cabinet.
- Each item shall have a label containing name, strength and expiration date.
- Rhogam will be refrigerated in a medicinal refrigeration unit separate from foods. It will have a thermometer to insure maintenance of proper temperature.
- There shall be a written prescriptions or orders signed by a practitioner legally authorized to prescribe in South Carolina for all drugs administered to mother and infant with in the birthing center.
- Drugs shall be administered by personnel or clinical staff currently licensed in South Carolina to administer drugs.

4. Laboratory Services:

Lab to be used is the DHEC lab in Columbia, SC or other lab with whom arrangements are made.

5. Birth Center Equipment and Supplies: There shall be appropriate equipment and supplies maintained for the mother and newborn to include but not be limited to:

- A bed suitable for labor, delivery, birth and recovery;
- Oxygen flow with meters and masks or equivalent;
- Mechanical suction and bulb suction (immediately available);
- Resuscitation equipment to include resuscitation bags, endotracheal tubes and oral airways for mother and newborn;
- Firm surfaces suitable for resuscitation;
- Emergency medications, intravenous fluids, and related supplies and equipment for both mother and newborn;
- Fetal monitoring equipment;
- Means of monitoring and maintaining the optimal temperature of the newborn;
- A clock with a sweep second hand;
- Sterile suturing equipment and supplies;
- Adjustable examination light;
- Containers for soiled linen and waste materials which shall be closed;
- A refrigeration unit;
- Matching identification for the mother and baby;

6. Clinical Staff

- a. Clinical staff shall be organized and shall meet at least quarterly with minutes maintained of such meetings.

- (1) A physician will be on call and available to provide medical assistance via phone at the birthing center at all times it is serving the public.

- (2) A physician shall make a written determination that the planned birth is low risk.
 - (3) The center shall have a signed written agreement with an obstetrician(s) and a pediatrician(s) to ensure their availability to the staff via phone and mother at all times it is serving the public.
- b. The facility shall have an organized midwifery department under the supervision of a Director of Midwifery.
- (1) The Director of Midwifery shall be a certified nurse midwife and be responsible and accountable for all midwifery services to include:
 - A. Delivery of midwifery services to patients;
 - B. Development and maintenance of midwifery service objectives, standards of midwifery practice, midwifery policy and procedure manuals (reviewed annually), written job descriptions for each type of midwifery personnel;
 - C. Coordination of midwifery services with other patient services;
 - D. Establishment of a means of assessing the midwifery care needs of patients and staffing to meet those needs;
 - E. Staff development.
 - c. An adequate number of licensed and ancillary midwifery personnel shall be on duty to meet the total midwifery needs of patients. Midwifery personnel shall be assigned to duties consistent with their training and experience.
 - d. At least one member of the clinical staff or a registered nurse shall be in the facility when a patient is present; and up to at least one hour after each mother's delivery. Two members of the clinical staff or one member of the clinical staff and a registered nurse shall be present during the mother's delivery.
7. Medical Records:
- a. An accurate complete legible medical record shall be maintained in ink for each patient and shall include the following:
 - (1) Admitting identification data including patient history and physical examination;
 - (2) Signed consent;
 - (3) Orders of physician or certified practitioner;
 - (4) Laboratory tests;
 - (5) Prenatal care record containing at least prenatal blood serology, Rh factor determination, obstetrical history and physical examination;
 - (6) Labor and delivery record;
 - (7) Records of anesthesia/analgesia and medication given in the course of labor, delivery and postpartum;
 - (8) Recovery and other progress notes;
 - (9) Record of all medications ordered and administered;

(10) Condition and referral to community services on discharge.

b. Records of newborn infants shall include in addition to the requirements for medical records the following information:

- (1) Date and hour of birth, birth weight and length, period of gestation, gender, condition of the infant on delivery and APGAR scores;
- (2) ~~Mother's name and patient number, and/or similar identification;~~
- (3) Record of ophthalmic prophylaxis;
- (4) Record of administration of RH immune globulin if any;
- (5) Appropriate physical examination at birth and at discharge;
- (6) Test results and date specimen was collected for newborn screening test. (Except where parents object because of religious convictions; then file copy of executed "Statement of Religious Objection Form," DHEC #1804 with newborn record.)

c. Provisions have been made for the storage of medical records in an environment which shall prevent unauthorized access and deterioration. Records shall be treated as confidential and shall not be disposed of under 25 years. Records may be destroyed after 25 years provided that:

- (1) Records of minors have been retained until after the expiration of the period of election following the achievement of majority as prescribed by the statute.
- (2) This facility shall retain an index, register or summary cards providing such basic information as dates of admission and discharge, name of responsible clinical staff, and record of all diagnoses for all records so destroyed.

- d. In the event of change of ownership, all medical records shall be transferred to the new owners.
- e. Prior to the closing of the facility for any reason, this facility shall arrange for the preservation of records to insure compliance with regulations. This facility shall notify the Department, in writing, describing these arrangements.
- f. In order to provide information to other health care providers and contribute to the continuity of quality care a discharge summary sheet will be provided. This will be provided to health care providers to whom patients are discharged, transferred or referred.

CONFIDENTIAL

BIRTHING RECORD

Day of Birth: ☐ M ☐ T ☐ W ☐ Th ☐ F ☐ S ☐ Su Date of Birth: 01/14/2014 Time: 4:20 ☐ AM ☐ PM EDD: 05/23/14

Parents Name: Patient SD & KD Baby's Name: Large Baby TMD Gender: ☐ M ☒ F

Midwife: ☒ Amy B. Leland ☐ Other _____ Delivery Site: ☐ Home ☒ Birth Center ☐ Hospital

Pregnancy 1 #Previous Births 0 #Miss 0 Vag. Delivery V-BAC C-Section Mother's Age: 24

BABY		MOTHER	
APGAR: 1 min <u>9</u> 5 min <u>10</u>		Length of labor Total: <u>11 h</u>	
Wks Gestation: <u>41.3</u> Weight: <u>7 lb 13.0 oz</u>		1 st Stage: <u>8:45 min</u> 2 nd Stage: <u>1h 20 min</u> 3 rd Stage: <u>55 min</u>	
Length: <u>20 1/2 in</u> Head: <u>13 in</u> Chest: <u>13 in</u>		Tear: <u>nick</u> 10 <u> </u> 20 <u> </u> 30 <u> </u> Sutures <u> </u>	
Presentation: <u>post. vert.</u>		Labial Skids: <u>0</u>	
Complications: <u>0</u>		Enema <u>0</u> Induction <u>✓</u> What Used <u>B.E.B., Pumping</u>	
Neuchal Cord: <u>0</u> Cord Cut: <u>9:25 am</u>		Rupture of Membranes: <u> </u>	
Amniotic Fluid Rupture: <u> </u>		Date <u>01/14/14</u> Time <u>10:45</u> Stage <u> </u> Art/Spont <u>Spont</u>	
Amount: <u> </u> Meconium <u> </u> Type: <u> </u>		Delivery Position: <u>on back on floor</u>	
FHT'S: Range: <u>130s - 150s</u> Decels: <u>0</u>		Placenta Time: <u>10:15 a</u> Condition <u>intact 3vc</u>	
# Cord Vessels: <u>3</u> Meds: <u> </u>		PP Hemorrhage: <u>Transferred to GHG</u> Blood loss: <u>7 2 cups</u> <u>Delayed placenta delivery</u>	
Erythromycin Time Administered: <u>9:30</u> ☐ AM ☐ PM		Meds: <u>1 ml Pitocin 1m @ 9:35a, 1 ml Pitocin 1m @ 9:50a, 1 ml Methergin 1m @ 10:20a</u>	
☐ Declined: Parent Signature _____		Notes: <u>From transported to hospital via Greenville County EMS for blood loss 7 2 cups @ 10:25</u>	
Notes: <u>Vit K LAT at 9:30 am</u>			

LABOR AND DELIVERY NOTES:

Date/Time	FHT'S	BP	Dil	Sta	Ctx	Push	Pt or MW Arrival Time:
12:30a							
01/07/14	140s						Arrived at birth center 12:26 am
1:00a	140s		5				on bed on L side
1:30a	140s						FHTs during CTX
1:45a	140s						laboring on toilet
2:15a	130s						in bed on L side
2:40a	130s						laboring on toilet
3:00a	130s						in bed on R side

EXHIBIT
5

Rh NEGATIVE

Blessed Births ~ 23 Mills Avenue, Greenville, S.C. 29605 ~ (864)233-5513

LABOR & DELIVERY NOTES

Patient Name Patient ID

CONFIDENTIAL

Date/Time	FHT'S	BP	Di	Sta	Cox	Push	
3:17a	1306						
3:25a	140s						In bath tub
4:00a	130s						
4:20a	140s						
4:35a	140s						
4:50a	140s						Out of bath tub, In bed on back
5:15a	140s						
5:30a	140s						Laboring on toilet
5:50a	140s						In bed on back
6:15a	140s						
6:30a	140s						laboring on toilet
6:50a	140s						In bed on back
7:20a	140s						
7:35a	140s						
7:50a	140s						
8:00a	140s		9			✓	
8:10a	140s						
8:20a	140s						
8:30a	140s						
8:40a	150s		10				In bed on L Side
8:45a	150s						
8:50a	150s						
8:55a	140s						In bed on all fours
9:00a	140s						
9:05a	140s						on floor on back
9:10a	140s						
9:15a	140s						
9:20a	140s						Birth
9:28a							Cord cut
9:30a							Baby Exam - erythromycin, Vit K1
9:35a							1 ml Pitocin IM given to mom
9:50a							1 ml Pitocin IM given to mom
9:52a							mom BP 98/70
10:00a							1 ml Methergine IM given to mom

21a
Pitocin
C-1 color
25a
Pitocin
10

Rh NEGATIVE

CONFIDENTIAL

Patient Name	Patient KD
--------------	------------

31

Blessed Births Family Wellness & Birth Center
23 Main Avenue, Greenville, SC 29605 (864) 233-5513

Prescription Request/ Update Medical Pharmacy Phone: 455-8910 / Fax: 455-8403

Date: _____ Patient Name: Patient KD _____ Date of Birth: _____
Address: _____ City / State: Simpsonville 29680
Phone: 864 _____ Allergies: NKDA
Insurance Type: BCBS (copy of card to follow)

Please dispense checked items:

- ☐ #2 Amps Pitocin - As needed for bleeding postpartum
☐ #2 Amps Methergine - As needed for bleeding postpartum
☐ #8 Methergine 2mg tablets - As needed for bleeding postpartum
☐ #20 Cytotec 100 mcg - As needed for bleeding postpartum
☐ #1 Ophthalmic Erythromycin - To be instilled within 1 hour of birth into baby's eyes.
☐ #4 Syringes 3cc, 21ga, 1in
☐ #2 Syringes 1cc, 27ga, 5/8in
☒ #1 Rhogam Full Dose (or equivalent) - For prenatal prophylaxis.
☐ #1 Rhogam Full Dose (or equivalent) - To be administered within 72 hours of delivery
☐ #20 Motrin 800mg - 1 PO q 6 hrs pm cramping.
☐ #1 Vitamin K (1mg/0.5ml neonatal dose) Disp 5 ml - for baby - Inject SQ/IM.
☐ #3 Penicillin 5million units - 5million units at start of labor, 2.5million units q 4hours until delivery.
☐ #3 Clindamycin 900mg - 900mg q 8hours until delivery
☐ #1 Epi Pen - Use as directed

Dispense as Written

Generic Permissible

Requested by: Dr. KEITH STAFFORD

Pharmacy Disregard This: O2 to be dispensed at 5 LPM as needed for mother or baby
Intra/postpartum.



CONFIDENTIAL

3/4/14

Please have Dr. S
sign + then fax to
Upstate Pharmacy

Pt is picking up her
Rx on 3/11

Thanks

Amy Leland

Blessed Births Family Wellness & Birth Center

23 Miller Avenue, Greenville, SC 29605 (864) 293-5513

Prescription Request/Update Medical Pharmacy Planned 252-1010 / Fax 453-3403

Date: 5-4-14 Patient Name: Patient KD Date of Birth: [REDACTED]
Address: [REDACTED] City / State: [REDACTED]
Phone: [REDACTED] Allergies: AKDA
Insurance Type: BSES (copy of card to follow)

Please dispense checked items:

- ☐ #2 Amps Pampin - As needed for bleeding postpartum.
- ☐ #2 Amps Methergine - As needed for bleeding postpartum.
- ☐ #3 Methergine 2mg tablets - As needed for bleeding postpartum.
- ☐ #20 Cytotec 100 mcg - As needed for bleeding postpartum.
- ☐ #1 Ophthalmic Erythromycin - To be instilled within 1 hour of birth into baby's eyes.
- ☐ #4 Syringe 3cc, 21ga, 1.5".
- ☐ #2 Syringe 1cc, 27ga, 5/8".
- ☒ #1 Rhogam Full Dose (or equivalent) - For postnatal prophylaxis.
- ☐ #1 Rhogam Full Dose (or equivalent) - To be administered within 72 hours of delivery.
- ☐ #20 Nubain 800mg - 1 PO q 6 hrs per cramping.
- ☐ #1 Vitamin K (1mg/0.5ml neonatal dose) Disp. 5 ml - for baby - Inject SQ/IM.
- ☐ #3 Penicillin G ampicillin units - 5million units at start of labor, 2.5million units q 6 hours until delivery.
- ☐ #3 Cefazolin 800mg - 800mg q 8 hours until delivery.
- ☐ #1 Epi Pen - Use as directed.

Dispensed on 5/4/14

K. S. [Signature]
Genetic Pharmacy

Requested by: Dr. Keith Stafford

Pharmacy Disregard This: O2 to be dispensed at 5 LPM as needed for mother or baby
intrapartum. A. KD



STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

South Carolina Department of Health
And Environmental Control,

Petitioner,

VS.

Blessed Births, Inc. d/b/a Blessed Births
Family Wellness and Birth Center,

Respondent.

Docket No. 15-ALJ-07-0148-CC

**RESPONSES TO REQUESTS
FOR PRODUCTION**

1. All documents, including but not limited to, reports, diagrams, maps, plats, test results, sketches, letters, correspondence, memoranda, e-mails, writings, and written communication of any type, whether electronically stored (including but not limited to in a computer hard drive, CD Rom, DVD, floppy disc, flash drive, PDA, or web based storage devise) or in hard copy, showing or establishing that the Department's decision to impose a monetary penalty against Blessed Births was arbitrary, capricious, an abuse of discretion, clearly erroneous, unsupported by the substantial evidence, in violation of constitutional or statutory provision, made upon unlawful procedure or affected by other error of law, is in violation of state and/or federal environmental laws and regulations, and/or is in violation of the law of nuisance.

RESPONSE: See attached.

2. All documents, including but not limited to, reports, diagrams, maps, plats, test results, sketches, letters, correspondence, memoranda, e-mails, writings, and written communication of any type, whether electronically stored (including but not limited to in a computer hard drive, CD Rom, DVD, floppy disc, flash drive, PDA, or web based storage devise) or in hard copy referenced, referred to or relied upon in answering the Department's First Set of Interrogatories to Blessed Births.

RESPONSE: See attached.

3. All physician or other authorized healthcare provider prescriptions or medication orders for Mother I.M. who delivered on July 16, 2014.

RESPONSE: See attached.

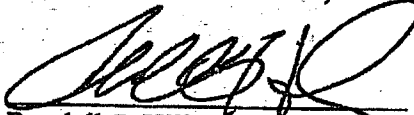
4. All physician or other authorized healthcare provider prescriptions or medication orders for the Mother K.D. who delivered at Blessed Births on June 7, 2014.

RESPONSE: See attached.

5. All documents, including but not limited to, policies, reports, diagrams, maps, plats, test results, sketches, letters, correspondence, memoranda, e-mails, writings, and written communication of any type, whether electronically stored (including but not limited to in a computer hard drive, CD Rom, DVD, floppy disc, flash drive, PDA, or web based storage devise) or in hard copy, relating to the appointing or employing of a person to act in the absence of Blessed Birth's administrator.

RESPONSE: See attached.

RANDALL S. HILLER, P.A.



Randall S. Hiller (SCB#2513)
850 Wade Hampton Blvd.
Greenville, SC 29609
864-232-0026
864-242-4692 Fax

July 8, 2015
Greenville, South Carolina

Blessed Birth's Family Wellness & Birth Center
Mills Avenue, Greenville, SC 29605 (404) 233-5513

Prescription Request/ Upstate Medical Pharmacy Phone# 455-8910 / Fax# 455-8403

Date: 06/17/2014 Patient Name: Patient IM Date of Birth: [REDACTED]
Address: [REDACTED] City / State: [REDACTED] SC
Phone: [REDACTED] Allergies: NIL DA
Insurance Type: SELF - PAY (copy of card to follow)

Please dispense checked items:

- ☒ #2 Amps Pitocin -- As needed for bleeding postpartum
- ☒ #2 Amps Methergine -- As needed for bleeding postpartum
- ☒ #8 Methergine 2mg tablets -- As needed for bleeding postpartum
- ☒ #20 Cytotec 100 mcg -- As needed for bleeding postpartum
- ☒ #1 Ophthalmic Erythromycin -- To be instilled within 1 hour of birth into baby's eyes.
- ☒ #4 Syringes 3cc, 21ga, 1in
- ☒ #2 Syringes 1cc, 27ga, 5/8in
- ☐ #1 Rhogam Full Dose (or equivalent) -- For prenatal prophylaxis.
- ☐ #1 Rhogam Full Dose (or equivalent) -- To be administered within 72 hours of delivery
- ☒ #20 Motrin 800mg -- 1 PO q 6 hrs pm cramping.
- ☒ #1 Vitamin K (1mg/0.5ml neonatal dose) Disp .5 ml -- for baby -- inject SQ/IM.
- ☐ #3 Penicillin 5million units -- 5million units at start of labor, 2.5million units q 4hours until delivery.
- ☐ #3 Clindamycin 900mg -- 900mg q 8hours until delivery
- ☐ #1 Epi Pen -- Use as directed

Dispense as Written

W. Keith Stafford, M.D.
Generic Permissible

Requested by: Dr. KEITH STAFFORD

Pharmacy Disregard This: O2 to be dispensed at 5 LPM as needed for mother or baby Intra/postpartum.



STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

South Carolina Department of Health
And Environmental Control,

Petitioner,

VS.

Blessed Births, Inc. d/b/a Blessed Births
Family Wellness and Birth Center,

Respondent.

Docket No. 15-ALJ-07-0148-CC

**RESPONSES TO REQUESTS
FOR PRODUCTION**

1. All documents, including but not limited to, reports, diagrams, maps, plats, test results, sketches, letters, correspondence, memoranda, e-mails, writings, and written communication of any type, whether electronically stored (including but not limited to in a computer hard drive, CD Rom, DVD, floppy disc, flash drive, PDA, or web based storage devise) or in hard copy, showing or establishing that the Department's decision to impose a monetary penalty against Blessed Births was arbitrary, capricious, an abuse of discretion, clearly erroneous, unsupported by the substantial evidence, in violation of constitutional or statutory provision, made upon unlawful procedure or affected by other error of law, is in violation of state and/or federal environmental laws and regulations, and/or is in violation of the law of nuisance.

RESPONSE: See attached.

2. All documents, including but not limited to, reports, diagrams, maps, plats, test results, sketches, letters, correspondence, memoranda, e-mails, writings, and written communication of any type, whether electronically stored (including but not limited to in a computer hard drive, CD Rom, DVD, floppy disc, flash drive, PDA, or web based storage devise) or in hard copy referenced, referred to or relied upon in answering the Department's First Set of Interrogatories to Blessed Births.

RESPONSE: See attached.

3. All physician or other authorized healthcare provider prescriptions or medication orders for Mother I.M. who delivered on July 16, 2014.

RESPONSE: See attached.

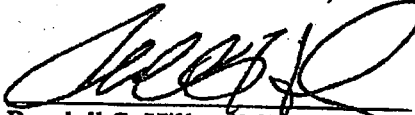
4. All physician or other authorized healthcare provider prescriptions or medication orders for the Mother K.D. who delivered at Blessed Births on June 7, 2014.

RESPONSE: See attached.

5. All documents, including but not limited to, policies, reports, diagrams, maps, plats, test results, sketches, letters, correspondence, memoranda, e-mails, writings, and written communication of any type, whether electronically stored (including but not limited to in a computer hard drive, CD Rom, DVD, floppy disc, flash drive, PDA, or web based storage devise) or in hard copy, relating to the appointing or employing of a person to act in the absence of Blessed Birth's administrator.

RESPONSE: See attached.

RANDALL S. HILLER, P.A.



Randall S. Hiller (SCB#2513)

850 Wade Hampton Blvd.

Greenville, SC 29609

864-232-0026

864-242-4692 Fax

July 8, 2015
Greenville, South Carolina



Catherine B. Templeton, Director

Promoting and protecting the health of the public and the environment

August 6, 2014

Amy Leland
Blessed Births, Inc.
23 Mills Avenue
Greenville, S.C. 29605-4015

CERTIFIED MAIL
ELECTRONIC RECEIPT REQUESTED
91 7108 2133 3933 6662 3277

Re: Blessed Births Family Wellness and Birth Center (License No.: BC-0003)
23 Mills Avenue, Greenville, SC 29605-4015

Dear Ms. Leland:

A representative of the Department visited Blessed Births Family Wellness and Birth Center to conduct a general inspection and complaint investigations on June 11, 2014 and June 16, 2014. As a result of the visits, we determined that the facility was in violation of Standards for Licensing Birthing Centers For Deliveries By Midwives, 8 S.C. Code Ann. Regs. 61-102 (2012). (see enclosed synopsis).

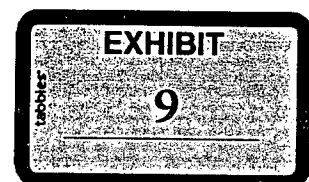
Based on the above, the Department, in accordance with S.C. Code Section 44-89-80(A)(3) (2002), is considering an enforcement action against Blessed Births Family Wellness and Birth Center.

However, before the Department renders a final decision, we would like to give you the opportunity to discuss this matter. A meeting will be held on Tuesday, August 26, 2014 at 1:30 p.m. in Room 3003 of the Columbia Mills Building, 301 Gervais Street, Columbia, S.C. 29201 (see attached map). Please call our office at (803) 545-4370 by no later than 5:00 p.m. Tuesday, August 19, 2014 to confirm your attendance at this meeting.

During this meeting, the Department will explain its role, authority, and responsibilities regarding licensing and enforcement of standards. You and/or your representative(s) (legal, technical, other) will then have the opportunity to discuss the Department's action as a result of our inspections.

We will attempt to establish a mutually agreeable resolution. If we are able to come to an agreement, we will place the terms of this agreement into the form of a Consent Order for appropriate parties to sign. However, if an agreement is not reached, the Department will issue a final decision regarding the penalty.

Should you have any questions, please contact me at (803) 545-4370.



Amy Leland
Blessed Births, Inc.
August 6, 2014
Page 2

Sincerely,

Gwen C. Thompson

Gwen C. Thompson, Bureau Chief
Bureau of Health Facilities Licensing

GCT:sme

Enclosures: Synopsis of Violations
Office Directions

CC: Stefanie Corbett, DHEC
Melinda W. Bradshaw, DHEC
Terry English, DHEC

Michell Hatcher, DHEC
Vito Wicevic, Esquire, DHEC
Rupinderjit Grewal, Esquire, DHEC

South Carolina Department of Health and Environmental Control
DIVISION OF HEALTH LICENSING
Summary of Violations (Basis for Imposing Penalties)

Exhibit A Page 1 of 3

42

(Facility)				
BLESSED BIRTHS FAMILY WELLNESS AND BIRTH CENTER			(Facility Type)	(License Units)
Date Cited	R.61-102 Section	Class	BF	2 BIRTHING ROOMS
Description of Violations				
7/16/14 Gen	C(3)	I	Administrator: The chief administrative officer shall be selected by the governing authority and shall have charge of and be responsible for the management and administration of the facility in all its branches and departments and shall see that the bylaws and amendments thereto are complied with. Any change in the position of the chief administrative officer shall be reported immediately by the governing authority to the Department in writing. An individual shall be appointed to act in the absence to the administrator. Comment The Department inspector did not observe an individual named to act in the absence of the administrator at the time of policy and procedure manual review.	
7/16/14 INV M07007-14	D(3)(b)	I	There shall be policies and procedures addressing the receiving, transcribing, and implementing of orders for administration of drugs. Comment The Department inspector did not observe a policy/procedure addressing the receiving, transcribing, and implementing of orders for administration of drugs at Blessed Births during a review of Blessed Births policy and procedure manual.	
7/16/14 INV M07007-14	D(3)(c)	I	There shall be written prescriptions or orders signed by practitioner legally authorized to prescribe in South Carolina for all drugs administered to mother and infant within the birthing center. Comment The Department inspector did not observe written prescriptions or orders signed by a practitioner legally authorized to prescribe in South Carolina, for the following drugs, documented in the medical record, as administered to the mother while at the birthing center: 9:35a 1 mL Pitocin IM given to mom; 9:50a 1 mL Pitocin IM given to Mom; 10:00a 1mL Methergine IM given to mom; 10:05a 500 ML NaCl IV given to mom.	

South Carolina Department of Health and Environmental Control
DIVISION OF HEALTH LICENSING
Summary of Violations (Basis for Imposing Penalties)

(Facility)			(Facility Type)	(License Units)
BLESSED BIRTHS FAMILY WELLNESS AND BIRTH CENTER			BF	2 BIRTHING ROOMS
Date Cited	R.61-102 Section	Class	Description of Violations	
7/16/14 INV M07007-14	D(3)(d)	I	10:20a 1mL Pitocin IM given to Mom. Drugs shall be administered by personnel or clinical staff currently licensed in South Carolina to administer drugs. Comment The Department inspector was unable to determine if the medications listed below were administered by personnel or clinical staff currently licensed to administer drugs. The Department inspector did not observe signatures or initials in the medical record, associated with the documented administration of the medications. 9:35a 1 mL Pitocin IM given to mom; 9:50a 1 mL Pitocin IM given to Mom; 10:00a 1mL Methergine IM given to mom; 10:05a 500 ML NaCl IV given to mom. 10:20a 1mL Pitocin IM given to Mom.	
7/16/14 Gen	D(3)(f)	I	Drugs, medications, and chemicals shall be stored and secured in specifically designated cabinets, closets, drawers, or storerooms and made accessible only to authorized persons. Comment The Department inspector observed the following medications on a table in the Hall birthing room. The medications were unsecured and accessible to unauthorized individuals (e.g., family members of the patient laboring at the birthing center): Pitocin 10 units/ml (3) unopened vials, Erythromycin ointment 0.5% 1 opened tube, HeSpan (1) unopened 500 ml bag.	
7/16/14 M07007-14	D(6)(d)	I	At least one member of the clinical staff or a registered nurse shall be in the facility when a patient is present; and up to at least one hour after each mother's delivery. Two members of the clinical staff or one member of the clinical staff and a registered nurse shall be present during the mother's delivery. Comment	

South Carolina Department of Health and Environmental Control
DIVISION OF HEALTH LICENSING
Summary of Violations (Basis for Imposing Penalties)

(Facility)				(Facility Type)	(License Units)
BLESSED BIRTHS FAMILY WELLNESS AND BIRTH CENTER				BF	2 BIRTHING ROOMS
Date Cited	R.61-102 Section	Class	Description of Violations		
			A patient delivered at the birthing center during the time the Department was conducting the inspection. The Department inspector did not observe two (2) members of the center's clinical staff or one (1) member of the clinical staff and a registered nurse in the facility during the mother's delivery. Ms. Leland, a licensed midwife, was the only Blessed Births staff observed in the facility during the delivery. A registered nurse was not observed at the birthing center during the mother's delivery.		
7/16/14 Gen	F(5)(a)	II	General: A facility shall be kept neat, clean and free from odors. Accumulated waste material must be removed daily or more often if necessary. There must be frequent cleaning of floors, walls, ceilings, woodwork, and windows. The premises must be kept free from rodent and insect infestation. Bath and toilet facilities must be maintained in a clean and sanitary condition at all times. Comment At the time of inspection, there was a putrid odor noticed in the Hall bathroom. Five (5) white styrofoam cups were observed sitting on top of the cabinet and were labeled as follows: ** Two (2) of the cups were labeled with individual patient names, dated 7/15/14, and had times noted ** Two (2) of the cups were labeled with patient names, dated 7/15/14, and no time documented ** One (1) cup was labeled with patient name and time. In addition, two white styrofoam cups were observed in the bathroom cabinet and were labeled as follows: ** One (1) of the cups was labeled with a patient name and time ** The other cup was labeled with a patient name and time. The cups contained yellow liquid, differing in color shades and amounts.		

HEALTH REGULATION Contact Information

TELEPHONE NUMBERS:

Program Area	Telephone	Fax
Deputy Commissioner	(803) 545-4200	(803) 545-4579
Bureau of Health Facilities	(803) 545-4200	(803) 545-4579
Planning & Certificate of Need Division	(803) 545-4200	(803) 545-4579
Bureau of Health Facilities Regulation	(803) 545-4370	(803) 545-4212
Health Facilities Construction Division	(803) 545-4663	(803) 545-4212
Emergency Medical Services & Trauma Division	(803) 545-4204	(803) 545-4989
Health Licensing Division	(803) 545-4370	(803) 545-4212
Bureau of Certification	(803) 545-4205	(803) 545-4292
Nursing Home Division	(803) 545-4205	(803) 545-4292
Health Provider Division	(803) 545-4203	(803) 545-4563
Bureau of Radiological Health	(803) 545-4400	(803) 545-4412

MAILING ADDRESS: SCDHEC Health Regulation
2600 Bull Street
Columbia, SC 29201

OFFICE LOCATION: Columbia Mills Building (Co-located with the SC State Museum)
301 Gervais Street
Columbia, SC 29201

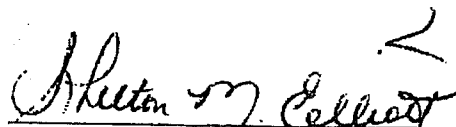
CERTIFICATE OF SERVICE

The undersigned for the South Carolina Department of Health and Environmental Control (DHEC) states that he/she has on August 6, 2014, served upon the necessary parties the letter(s) (91 7108 2133 3933 6662 3277) dated August 6, 2014, concerning DHEC's potential action against the facility listed below by depositing copies of same in the U.S. Mail, return address clearly stated with sufficient postage affixed thereto, addressed as follows:

Amy Leland
Blessed Births, Inc.
23 Mills Avenue
Greenville, S.C. 29605-4015

(If applicable) Additional copies of this letter were sent to the facility's legal representative(s) at the following address:

Randall S. Hiller, Esquire
Randall S. Hiller, P.A.
850-B Wade Hampton Boulevard
Greenville, S.C. 29609


DHEC Employee

Columbia, South Carolina

August 6, 2014
Date

Sworn to before me this 6
Day of August, 2014
Katrina S. Davis
Katrina S. Davis
NOTARY PUBLIC for S.C.
My Commission Expires: 3/23/19

Embossed Hereon is My
State of South Carolina Notary Public Seal
My Commission Expires March 23, 2019
Katrina S Davis

RANDALL S. HILLER, P.A.
ATTORNEYS AT LAW

850-B WADE HAMPTON BOULEVARD
GREENVILLE, SOUTH CAROLINA 29609

RANDALL S. HILLER
EMAIL: rsh@rshpa.org

(864) 232-0026
FAX (864) 242-4692

August 18, 2014

Via U.S. Mail &

Electronic Mail

Michell Hatcher, RN, BSN
SCDHEC Bureau of Health Facilities Licensing
2600 Bull St.
Columbia, SC 29201

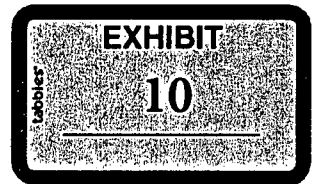
RECEIVED

AUG 21 2014

DHEC
OFFICE OF GENERAL COUNSEL

hatcheml@dhec.sc.gov

**Re: *Blessed Births Family Wellness and Birth Center
Amy Beth Leland, Midwife***



Dear Ms. Hatcher:

As you are aware I represent Blessed Births Family Wellness and Birth Center and am responding to the allegations of violations contained in your July 16, 2014 inspection report.

As you are also aware, my file is replete with correspondence extending from at least 2012 which, in my opinion, establishes unequivocally that the nature and purpose of these visits and inspections is improperly motivated. It is equally obvious that you or your superiors have predetermined your desire to close this facility and these "inspections" are simply a means to that end. This has been demonstrated numerous times over the past 18 months where you have unsuccessfully attempted to impose sanctions for violations of regulation and statute where no such regulation or statute existed. The written record demonstrates that each time I point out the invalidity of the Department's claims they are abandoned and it sets out to attempt to find a new claim to justify its improper goals.

Prior to addressing the specific allegations of violations I will document the following:

1. The policies and procedures manual maintained by the birthing facility has been in place in substantially its current form for 14 years.
2. You inspected the facility on June 23, 2014.
3. Despite the information contained in the sworn affidavit you provided to obtain a search warrant for the premises you were never denied access to the property on July 11, 2014. To the contrary, you arrived at the facility unannounced and it was closed. You then contacted the administrator via cell phone and she advised you that she was with a patient in a home visit in

Spartanburg County. Apparently placing your unwillingness to be inconvenienced ahead of the patient's welfare you demanded that the administrator terminate her visit with the patient and return to Blessed Births to allow you access. The administrator correctly declined to place your desires ahead of her patient's welfare.

4. Subsequently you demanded of the administrator her hours for the following week which she provided. Specifically she advised you that she would be available and not seeing patients on Wednesday, July 16. Despite having that information you submitted a sworn affidavit and obtained a search warrant and then proceeded to arrive at the facility with a police officer claiming that you had received a consumer complaint. When you arrived you learned that the midwife was attending to a patient who was in labor. In complete disregard of that patient and the newborn's welfare you insisted upon doing the inspection while the labor was in progress and, in fact, were still there at the time of delivery.
5. Frankly, your claims of a consumer complaint are suspect. You obtained 5 patient charts spanning from March 19, 2013 to June 3, 2014. All of these people filed a complaint between June 23, 2014 and July 11, 2014? I think not and suspect that you solicited these names from the Greenville Hospital System in order to continue your effort to damage my client.

My responses on behalf of my client to the birthing center allegations are as follows:

1. R.61-102C(3) The previous individual appointed to act in the absence of the administrator was no longer employed by the facility and the new individual had not been inserted into the policies and procedures manual. This has been corrected.
2. R.61-102D(3)(b) These policies and procedures are contained within the policy and procedure manual on pages 3-10, attached, and have remained unchanged during the entire 14 years that the facility has been licensed.
3. R.61-102D(3)(c) Written prescriptions were in the facility and available for inspection for each of the medications provided to the patient that was in labor while the inspection was occurring but were not requested or reviewed by the inspector. There is no requirement they be in the chart.
4. R.61-102D(3)(d) The drugs were administered by personnel or clinical staff licensed in South Carolina to administer drugs. There is no requirement that the chart reflect that.
5. R.61-102D(3)(f) All drugs, medications and chemicals are stored and secured in specifically designated cabinets, closets, drawers or store rooms except when they are being actively used, being administered to a patient or their imminent use is contemplated. The items listed were out and in the birthing room because at the time of the inspection the midwife was actively involved in the delivery of a child. Despite the midwife having a patient in labor the Department inspector insisted upon continuing the inspection which, by

necessity, required the indicated drugs to be out and available for use by the midwife.

6. R.61-102(D)(6)(d) The entire delivery on July 16, 2014 was affected and interfered with by the insistence of the inspector to conduct and continue the inspection despite the fact that the midwife was actively involved in the delivery of a child. The additional staff member or registered nurse is not required until second stage and although a call was made to the nurse the ability to assess the patient adequately and follow up with the nurses progress in arriving at the facility was continuously interrupted by the insistence of the inspector that the midwife split her time between the patient and the inspection. This, combined with the fact that the second stage was uncommonly brief for a first time mother, resulted in the nurse not arriving prior to delivery.
7. R.61-102(F)(5)(a) This clinic is impeccably clean and has never had a prior violation or written warning for sanitary violations. As indicated previously, the clinic was scheduled to be closed that day and had been closed from the afternoon before until that morning when the patient unexpectedly went into labor and the inspector even more unexpectedly arrived with a police officer to conduct an inspection while the labor was in progress. There had been a question as to the viability of the test strips utilized the day before and the urine samples were held over to be tested the following morning with new strips. That testing was necessarily deferred so the patient's needs could be addressed. The bathroom in which it was located was not in use because when she was initially considered to be put in the front delivery room (and why her meds were in that room) she was moved to the back delivery room.
8. R.61-102(A)(2)(g) As stated in the prefatory comments to these responses at the time that the inspector attempted to inspect on July 11, 2014 the facility was closed. I trust that the inspector understands that these facilities provide services to expectant mothers who wish to have natural child birth. These are not C-sections or inductions which can be scheduled between the hours of 7am and 5pm each day. The facility is open when a woman goes into labor and is open at certain times depending on its patient load and timing of prenatal visits. Otherwise it is closed. Despite the representations made in this alleged violation the phone number on the sign on front of the premises is now, and has always been 864-233-5513. The number stated in the inspection report is the administrator's personal cell phone number. Ms. Leland was in fact called on her cell phone while she was in Spartanburg County providing prenatal check up to a patient. There was no one in the facility to answer the door, there was no one in the facility who refused to answer the door and Ms. Leland did in fact refuse to abandon her patient and drive back to Greenville at the inspector's request. That action was the appropriate response for a midwife under those circumstances.

On behalf of the midwife, Amy Leland, our responses are as follows:

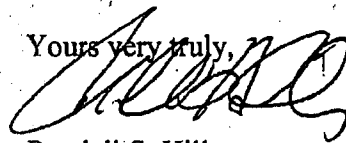
1. With regards to each of the "consumer complaints" the following applies. At no time does any physician or staff member of GHS ever provide recommendation with regards to the care or treatment of any patient of Ms. Leland or Blessed Births Family and Wellness Center. Any communication with GHS is through the transfer line where, if available, a physician may accept or reject the request to transfer the patient. No physician employed by GHS has ever been requested to provide nor would they provide any recommendation other than that they would accept the patient if the patient was in fact transported.
2. It is unnecessary to address each and every allegation of violation of the regulations with regards to the midwifery services. In each instance the Department's history of requiring an entry in the chart for activities which the regulations do not require an entry in the chart are attempted to be boot strapped into somehow being evidence that the requirement was not fulfilled. All of the required visits were made, all drugs were prescribed by a physician after consultation with a physician, all patients were ultimately transferred to a hospital after consultation with a physician and drugs administered to those patients prior to transfer at the request of a physician and were administered by those entitled to administer them according to law.

In light of the threat of an enforcement action contained within the Department's letter dated August 6, 2014, we hereby demand that you preserve all documents, tangible things and electronically stored information potentially relevant to any of the issues involved with any inspection or enforcement action by the Department of Health and Environmental Control and their respective employees, agents, attorneys or otherwise. Specifically we seek that you retain and set aside any and all documents, whether written or maintained in electronic form, emails or correspondence, memoranda or otherwise, either internal or directed to or from outside parties and in any way involving or referencing either Blessed Births Family Wellness and Birth Center or Amy Leland. You should anticipate that much of the information subject to this demand for preservation, disclosure or responsive to subsequent discovery in this matter may be stored in your current and former computer systems and other media and devices (including personal digital assistants, voice messaging systems, online repositories, cell phones and laptops). Electronically stored information should be afforded the broadest possible definition and includes any potentially relevant information electronically, magnetically or optically stored.

Finally, past experience has proven that the meeting contemplated by the aforementioned letter results in a pre-prepared consent order being presented by the Department with the option of signing or not signing. If that is the case then it would not be a prudent use of my client's time or money to attend and we respectfully decline to do so.

I trust this is responsive to the issues you have raised.

Yours very truly,



Randall S. Hiller

RSH/ak

Enclosures.

cc: Blessed Births

Terry English, DHEC

Gwen C. Thompson, DHEC

Melinda W. Bradshaw, DHEC

Vito Wicevic, Esq., DHEC ✓

Rupinderjit Grewal, Esq.

A. Governing Authority and Management

1. General: Facility shall be organized, equipped, manned, and administered to provide adequate care for each person admitted.
2. Governing Authority: The governing authority Amy B. Leland, LMW, CPM shall be the supreme authority responsible for the management control of the facility and shall develop a written set of bylaws or other appropriate policies and procedures for operation of the facility. This list is included and addressed herein:
 - a. Purpose of the facility: The purpose of the facility is to provide delivery services to low risk women.
 - b. Name of person to whom responsibility for operating and maintenance of the facility is delegated to Amy B. Leland, LMW, CPM. Method established by the governing authority for holding such individual responsible shall be the provision of at least annual meetings of the governing authority and the Director of Midwifery, ~~Laura Gilbert~~, CNM, MS.
Dana Curtis
 - c. Provision for this policies and procedures manual which is designed to ensure Professional and safe care for the patients is to include but is not limited to:
 - (1) Admission Criteria: Patients will be admitted for care if they are low risk and have a signed informed consent statement.
 - (2) Extent of Physician Participation in Services Offered: Physician participation shall include but not be limited to two visits made to consulting physician's office with one of these visits being in the last six weeks of pregnancy. The physician will provide a statement that patient is low risk to remain eligible for delivery at the center.
 - (3) Rights and Responsibilities of Patients:
 - ✓ The right to be treated with dignity and without prejudice.
 - ✓ The right to informed consent concerning her care, having relevant information upon which to base decisions.
 - ✓ The right to full disclosure of the costs of her care.
 - ✓ The right to know who will participate in her care and to obtain additional consultation of her choice.
 - ✓ The right to privacy except where this right is preempted by law or inhibits the quality of care.
 - (4) Midwife Rights:
 - ✓ The right to refuse care to clients with whom no midwife/client relationship has been established.

- ✓ The right to discharge clients from her care, provided a referral to other care is extended.
- ✓ The right to receive, honest relevant information from clients upon which to base care.

(5) **Patients Grievance Procedures:** Patients will have the right to submit any grievances in writing to the person responsible for the operation and maintenance of the facility. There will also be a consumer feed back form provided to each patient at the completion of delivery that is self addressed to the Division of Health Licensing, S.C., Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201.

(6) **Infection Control Procedures:** See section D

(7) **Personnel Training Requirements:** See section A.5

(8) **Transfer of Mothers who During the Course of Pregnancy, Delivery or Recovery are Determined Ineligible for Care:** The primary goal in any birth is to have a healthy outcome regardless of the birth setting. Circumstances can occur where for either psychosocial or physiological reasons a transfer of care is deemed appropriate. If client care is transferred all pertinent prenatal and/or delivery records shall be given to the new provider to facilitate and promote continuous care. Termination of care can be made because of but not limited to the following list of reasons:

- Patient at any time in the course of care is no longer considered low risk.
- Patient is irresponsible and/or unwilling to change detrimental habits.
- Dishonesty, intentional breach of contract
- Unstable or dangerous home environment.
- Immaturity or questionable emotional status.
- Refusal to submit to specified testing, emergency medical care or transport as determined necessary by midwife or physician.
- Unresolved conflicts or personality differences between client and midwife.
- Not honoring financial contract/commitment.

The midwife is not ethically, morally, or legally bound to keep a client if it is not in the best interest of both parties.

(9) **The Use of IV's, Foods, Fluids, Analgesia/Anesthesia, Antihemorrhagics, Antibiotics, Episiotomies, and Positions for Delivery.**

- IV's, antibiotics and antihemorrhagics shall be administered only when medically necessary by those certified to so.
- Food and fluids shall be permitted and encouraged throughout labor and delivery when seen to be of benefit.

- Analgesia/Anesthesia - A local anesthetic may be infiltrated to facilitate perineal repair.
 - Episiotomies will not be routinely performed and only utilized when medically necessary.
 - Delivery position choice by patient is permitted as long as it is assessed to be a healthy choice.
- (10) Provisions for the education of mother, family and others, as appropriate in birthing, newborn care and maternal postpartum care. It is impossible to write exhaustive plans of client education because an educational experience in which real learning occurs requires that each client be assessed individually for her educational needs. Tailoring education to client interests and needs follows the principals of personalized midwifery care. Educational topics shall include but not be limited to:
- Nutrition - prenatal and during lactation
 - Maternal changes and common experiences/discomforts
 - Fetal Development
 - Danger Signs
 - Drugs/smoking/alcohol/work place environmental hazard during pregnancy
 - Normal labor, birth and postpartum
 - Discuss complications
 - Essentials of newborn care
 - Preparations for giving birth in the selected birth site, including sibling preparation and comfort measures
 - Emergency plans
 - Sexuality during pregnancy and early postpartum
 - Family Planning
 - Family relationships
 - Breastfeeding
 - Exercise and activity
 - Prenatal visits
 - Routine and special prenatal testing
 - Child development
 - Circumcision -> Refer to MD care*
- (11) Plans for follow up of mother and infant after discharge from center: Within 24 to 36 hours after delivery, the midwife shall communicate with the mother/infant; however if the midwife is present for the first 20 to 24 hours after delivery the consultation at 24 to 36 hours is not considered mandatory. A follow up visit shall be made ^{WITHIN 1-2 days} at which assessments of both mother and baby will be made and newborn screening offered.
- Plans for tests/treatments including, but not limited to; prenatal labs/cultures, newborn screen, bilirubin, blood type, Rh factor, ophthalmic prophylaxis, prophylaxis for hemorrhagic newborn disease.

PKU: Neonates will be tested for PKU within 72 hours to 2 weeks post-birth unless the parents provide a written refusal.

Bilirubin: If need presents for testing, infant will be referred to a pediatrician if levels are found to be high.

Rh factor: Infants of Rh negative mothers will be blood typed at birth. If a positive blood type is found, a titer will be drawn on the mother and Rhogam administered within 72 hours of birth.

Ophthalmic Prophylaxis: Ophthalmic erythromycin shall be administered in neonate's eyes within one hour of birth.

Prophylaxis for neonatal hemorrhagic disease: Vitamin K shall be administered to the neonate via intramuscular injection or oral administration at the parent's request or if the midwife determines that it is necessary.

(12) Plans for circumcision: Infants will be referred to pediatrician for circumcision to be performed on the eighth day post-birth. ^{OR FP/MD} ~~Also at~~ ^{NO LONGER APPLIES}

~~THIS WILL BE PERFORMED AT BIRTH CENTER BY KAREN ARDS, MD~~

- d. There will be annual reviews and evaluations of the facility's policies, procedures, management and operation.
- e. There will be a facility wide quality assurance program to evaluate the provision of patient care. The program shall be ongoing. The written plan of implementation is to provide patients with an in house feedback form that is to filed at their choosing with the center.
3. Administrator: The chief administrative officer shall be selected by the governing authority and shall have charge of and be responsible for the management and administration of the facility in all its branches and departments and shall see that the bylaws and amendments are reported immediately by the governing authority to the Department in writing. An alternate staff member shall be appointed to act in the absence of the administrator. The chief administrative officer is AMY LELAND LMW. CPM IN THE ABSENCE OF CHIEF ADMINISTRATOR
→ WILL ACT AS ADMINISTRATOR.
4. Administrative Records: The following essential documents and references shall be on file in the administrative office of the facility:
 - a. Bylaws, policies and procedures of governing authority;
 - b. Minutes of the governing authority meetings if applicable;
 - c. Minutes of the facility's professional and administrative staff meetings;
 - d. A current copy of regulation 61-102 - Standards For Licensing Birthing Centers For Deliveries By Midwives;
 - e. Reports of inspections, reviews and corrective actions made related to licensure;
 - f. Contracts and agreements to which the facility is a party;
 - g. A record of each accident or incident occurring in the facility;
 - h. Appropriate documentation showing control and ownership.

5. **Personnel:** Qualified personnel shall be employed in sufficient numbers to carry out the functions of the facility. The licensee shall obtain written applications for employment from all employees. Such applications shall contain accurate information as to education, training, experience health, and personal background of each employee. All applications for licensed personnel shall contain the South Carolina license number and/or current renewal number if applicable. Personnel training requirements will be seen to by the chief administrator with personnel placements being determined when educational/training requirements are met.
- a. All new employees who have contact with patients shall have a physical examination prior to employment, which shall include a tuberculin skin test, unless a previous positive reaction can be documented. The intradermal (Mantoux) method, using five tuberculin units of stabilized purified protein derivative (PPD) is recommended. Employees with positive reactions to the pre-employment tuberculin test shall follow and those who are documented with previously positive reactions shall be given a chest x-ray to determine whether tuberculin disease is present. If tuberculosis is diagnosed appropriate treatment shall be required prior to employment.
 - b. **Personnel Records:** A personnel record shall be maintained for each employee. The folder shall contain history and physicals, laboratory test results, resumes of training and experience, current job description that reflects the employee's responsibilities and work assignments, orientation and periodic evaluations.
6. **Emergency:**
- a. All practicing and/or consulting physicians shall have admitting privileges at one or more hospitals with appropriate obstetrical services or other arrangements approved by the Department for the transfer of emergency cases when hospitalization becomes necessary.
 - b. Equipment and services shall be provided to render emergency resuscitative and life support procedures pending transfer to a hospital for both mother and infant.
 - c. The center shall enter into a signed agreement with an ambulance service licensed in this state to ensure the immediate transfer of mothers and/or newborns in emergencies, where appropriate.
- Hospital to transport to Greenville Memorial*
7. **Clients Rights**
- a. The birthing center has this written policies and procedures to assure the individual client the right to privacy, dignity and safety.
 - b. This birthing center shall display in a conspicuous place on the premises, a copy of rights of patients.

B. Professional Care

1. **Limitation of Services Offered by Birthing Center:** in order to be delivered in this birthing center, the woman and/or infant shall exhibit no evidence of:

- Severe anemia;
- Diabetes mellitus;
- Symptomatic heart disease;
- Severe hypertension or preeclampsia;
- Renal disease;
- Thrombophlebitis;
- Multiple gestation that is considered high risk;
- Active herpes (within one week of delivery), syphilis, or HIV positive;
- Placental abnormalities;
- Premature labor;
- Intrauterine growth retardation;
- Fetal disease;
- Previous cesarean delivery with classical incision;
- Desire for transfer;
- Anticipated macrosomia;
- Breech birth;
- Six or more (non-miscarriage or non-abortion) pregnancies;
- Polyhydramnios or oligohydramnios, or chorionitis;
- Malformed fetus;
- Any other high risk condition.

2. **Birthing Center Policies and Procedures:** This written policies and procedures shall include but not be limited to:

- a. Informed consent shall be obtained before onset of labor and shall include evidence of an explanation by personnel of the birthing service offered and potential risks. Documentation of the informed consent shall be filed in the patient's chart.
- b. Registration of birth and death certificates shall be filed within three days unless circumstances prohibit such and then it will be filed as soon as possible.
- c. Infection control committee duties and responsibilities shall include the development and implementation of specific patient care and administrative policies aimed at investigating, controlling and preventing infections within the facility.
- d. Arrangement shall be made for all mothers to be screened for blood typed and Rh factor (see section A.2.c.12)
- e. The physician or midwife shall, upon the birth of a child, instill or cause to be instilled in each eye of such newborn antibiotics of current efficacy in preventing development of ophthalmia neonatorum. A maximum delay of one hour shall be allowed between the time of birth and the administration of an approved prophylactic agent.

3. Pharmaceutical Services:

- All pharmaceuticals will be stored in a locked cabinet.
- Each item shall have a label containing name, strength and expiration date.
- Rhogam will be refrigerated in a medicinal refrigeration unit separate from foods. It will have a thermometer to insure maintenance of proper temperature.
- There shall be a written prescriptions or orders signed by a practitioner legally authorized to prescribe in South Carolina for all drugs administered to mother and infant with in the birthing center.
- Drugs shall be administered by personnel or clinical staff currently licensed in South Carolina to administer drugs.

4. Laboratory Services:

Lab to be used is the DHEC lab in Columbia, SC or other lab with whom arrangements are made.

5. Birth Center Equipment and Supplies: There shall be appropriate equipment and supplies maintained for the mother and newborn to include but not be limited to:

- A bed suitable for labor, delivery, birth and recovery;
- Oxygen flow with meters and masks or equivalent;
- Mechanical suction and bulb suction (immediately available);
- Resuscitation equipment to include resuscitation bags, endotracheal tubes and oral airways for mother and newborn;
- Firm surfaces suitable for resuscitation;
- Emergency medications, intravenous fluids, and related supplies and equipment for both mother and newborn;
- Fetal monitoring equipment;
- Means of monitoring and maintaining the optimal temperature of the newborn;
- A clock with a sweep second hand;
- Sterile suturing equipment and supplies;
- Adjustable examination light;
- Containers for soiled linen and waste materials which shall be closed;
- A refrigeration unit;
- Matching identification for the mother and baby;

6. Clinical Staff

- a. Clinical staff shall be organized and shall meet at least quarterly with minutes maintained of such meetings.

(1) A physician will be on call and available to provide medical assistance via phone at the birthing center at all times it is serving the public.

- (2) A physician shall make a written determination that the planned birth is low risk.
 - (3) The center shall have a signed written agreement with an obstetrician(s) and a pediatrician(s) to ensure their availability to the staff via phone and mother at all times it is serving the public.
- b. The facility shall have an organized midwifery department under the supervision of a Director of Midwifery.
- (1) The Director of Midwifery shall be a certified nurse midwife and be responsible and accountable for all midwifery services to include:
 - A. Delivery of midwifery services to patients;
 - B. Development and maintenance of midwifery service objectives, standards of midwifery practice, midwifery policy and procedure manuals (reviewed annually), written job descriptions for each type of midwifery personnel;
 - C. Coordination of midwifery services with other patient services;
 - D. Establishment of a means of assessing the midwifery care needs of patients and staffing to meet those needs;
 - E. Staff development.
- c. An adequate number of licensed and ancillary midwifery personnel shall be on duty to meet the total midwifery needs of patients. Midwifery personnel shall be assigned to duties consistent with their training and experience.
- d. At least one member of the clinical staff or a registered nurse shall be in the facility when a patient is present; and up to at least one hour after each mother's delivery. Two members of the clinical staff or one member of the clinical staff and a registered nurse shall be present during the mother's delivery.
7. Medical Records:
- a. An accurate complete legible medical record shall be maintained in ink for each patient and shall include the following:
 - (1) Admitting identification data including patient history and physical examination;
 - (2) Signed consent;
 - (3) Orders of physician or certified practitioner;
 - (4) Laboratory tests;
 - (5) Prenatal care record containing at least prenatal blood serology, Rh factor determination, obstetrical history and physical examination;
 - (6) Labor and delivery record;
 - (7) Records of anesthesia/analgesia and medication given in the course of labor, delivery and postpartum;
 - (8) Recovery and other progress notes;
 - (9) Record of all medications ordered and administered;



Catherine B. Templeton, Director

Promoting and protecting the health of the public and the environment

September 26, 2014

Randall S. Hiller, Esquire
Attorneys at Law
850-B Wade Hampton Blvd.
Greenville, S.C. 29609

CERTIFIED MAIL
ELECTRONIC RECEIPT REQUESTED

91 7199 9991 7033 6624 2984

Re: Blessed Births Family Wellness and Birth Center (License No. BC-0003)
23 Mills Avenue, Greenville, SC 29605-4015



Dear Mr. Hiller:

By letter, dated August 6, 2014, the Department advised your client, Blessed Births Family Wellness and Birth Center ("Blessed Births"), of an enforcement conference scheduled for August 26, 2014. The letter stated that during this meeting the Department would explain its role, authority, and responsibilities regarding the licensure of birthing centers and administration of the Birthing Center Licensure Act, S.C. Code Ann. §§ 44-89-10, et seq. (2002), and Standards for Licensing Birthing Centers For Deliveries By Midwives, 8 S.C. Code Ann. Regs. 61-102 (2012). The letter also explained that during the meeting Blessed Births and its representatives would be given the opportunity to discuss the pending enforcement matter in an effort to establish a mutual resolution.

In your letter of response dated August 18, 2014, after stating your objections to the Department's cited violations, you wrote:

[P]ast experience has proven that the meeting contemplated by the aforementioned letter results in a pre-prepared consent order being presented by the Department with the option of signing or not signing. If that is the case then it would not be a prudent use of my client's time or money to attend and we respectively decline to do so.

To the contrary, the Department does not have a pre-prepared consent order that is presented on a take-it or leave-it basis. The purpose of the proposed enforcement conference is for the parties to discuss the cited violations, allow the facility to present evidence to show why the cited violations are unwarranted, and to leave the conference with a mutual understanding of what the applicable law requires. Should the parties agree to resolve the enforcement matter, the terms of a consent order may be agreed upon and Department staff will draft a consent order.

Therefore, the Department again invites you and your client to an enforcement conference scheduled for October 7, 2014 at 1:30 PM to discuss the above matter. Please advise the Department by October 3, 2014 of your intentions to attend the enforcement conference.

Regulation 61-102 § A.(2)(i) states in relevant part, "[w]hen noncompliances with the Licensing Standards are detected, the applicant or licensee will be notified of the violations and

at the same time requested to *provide information as to how and when such items will be corrected.*" (Emphasis added). The Department has yet to receive information as to how and when the violations cited as a result of the July 11 and 16, 2014 inspections were corrected.

If Blessed Births asserts that any cited violation is invalid and that it is in compliance with applicable law, please provide the Department with *any and all* relevant information to demonstrate such compliance. Statements such as "policies and procedures are contained within the policy and procedure manual" and "[prescriptions] were not requested or reviewed by the inspector" do not assist the Department in verifying Blessed Births' compliance. The Department has the following replies to your responses regarding the cited violations:

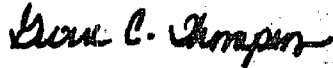
1. For the Section C.(3) violation, you note the new individual appointed to act in the absence of the administrator had not been inserted into the policies and procedures manual and that this error was corrected. Please provide the Department with the name of the new individual appointed to act in the absence of the administrator.
2. For the Section D.(3)(b) violation, you note the "policies and procedures [addressing the receiving, transcribing, and implementing of orders for administration of drugs] are contained within the [attached] policy and procedure manual" While there are provisions in such manual regarding the use of IVs, analgesia/anesthesia, antihemorrhagics, antibiotics, episiotomies, and pharmaceutical services, Department staff could not locate policies and procedures regarding the *receipt, transcription, and implementation of orders for administration of drugs*. Please direct the Department to the applicable provisions evidencing compliance or please amend/supplement the policies and procedures manual to address the receiving, transcribing, and implementing of orders for administration of drugs and provide the Department with documentation of such amendments/supplements.
3. For the Section D.(3)(c) violation, you state "[w]ritten prescriptions were in the facility and available for inspection . . . but were not requested or reviewed by the inspector." As noted in the report of visit, Department staff requested and received copies of the medical records. Regulation 61-102 requires birthing centers to maintain an accurate medical record for each patient, which includes, among other things, orders of physicians or certified practitioners. Regulation 61-102 § D.(7)(a)(3). Please provide the Department with copies of the written prescriptions (patient Patient KD [REDACTED] as noted in the Report of Visit) for the medications referred to in the July 16, 2014 report of visit.
4. For the Section D.(3)(d) violation, you wrote "[t]he drugs were administered by personnel or clinical staff licensed in South Carolina to administer drugs." Please provide the Department with the names of the individuals who administered the drugs (patient Kylie D'Hoostelaere) referenced in the July 16, 2014 report of visit and any and all documentation evidencing the same.

Your responses do not demonstrate compliance with applicable laws and regulation. Accordingly, the Department determined not to rescind any of the cited violations included in the the July 16, 2014 reports of visit.

Randall S. Hiller, Esq.
September 26, 2014
Page 3

Should you have any questions, please contact me at (803) 545-4370.

Sincerely,



Gwen C. Thompson, Bureau Chief
Bureau of Health Facilities Licensing

GCT:sme

Enclosures: Synopsis of Violations
Office Directions

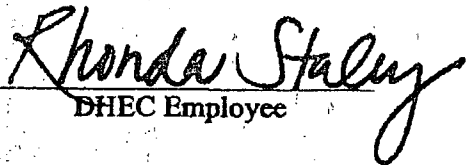
CC: Lauren A. Shuster, DHEC
Vito Wicevic, Esquire, DHEC
Terry English, DHEC

Michell Hatcher, DHEC
Rupinderjit Grewal, Esquire, DHEC

CERTIFICATE OF SERVICE

The undersigned for the South Carolina Department of Health and Environmental Control (DHEC) states that he/she has on August 6, 2014, served upon the necessary parties the letter(s) dated September 26, 2014, concerning DHEC's potential action against the facility listed below by depositing copies of same in the U.S. Mail, return address clearly stated with sufficient postage affixed thereto, addressed as follows:

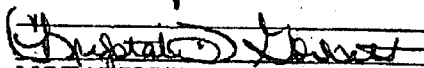
**Randall S. Hiller, Esquire
Randall S. Hiller, P.A.
850-B Wade Hampton Boulevard
Greenville, S.C. 29609**


DHEC Employee

Columbia, South Carolina

September 26, 2014
Date

Sworn to before me this 26th
Day of September, 2014


NOTARY PUBLIC for S.C.
My Commission Expires: 9/16/2019

South Carolina Department of Health and Environmental Control
DIVISION OF HEALTH LICENSING
Summary of Violations (Basis for Imposing Penalties)

(Facility)			(Facility Type)	(License Units)
BLESSED BIRTHS FAMILY WELLNESS AND BIRTH CENTER			BF	2 BIRTHING ROOMS
Date Cited	R.61-102 Section	Class	Description of Violations	
7/16/14 Gen	C(3)	I	Administrator: The chief administrative officer shall be selected by the governing authority and shall have charge of and be responsible for the management and administration of the facility in all its branches and departments and shall see that the bylaws and amendments thereto are complied with. Any change in the position of the chief administrative officer shall be reported immediately by the governing authority to the Department in writing. An individual shall be appointed to act in the absence to the administrator. Comment The Department inspector did not observe an individual named to act in the absence of the administrator at the time of policy and procedure manual review.	
7/16/14 INV M07007-14	D(3)(b)	I	There shall be policies and procedures addressing the receiving, transcribing, and implementing of orders for administration of drugs. Comment The Department inspector did not observe a policy/procedure addressing the receiving, transcribing, and implementing of orders for administration of drugs at Blessed Births during a review of Blessed Births policy and procedure manual.	
7/16/14 INV M07007-14	D(3)(c)	I	There shall be written prescriptions or orders signed by practitioner legally authorized to prescribe in South Carolina for all drugs administered to mother and infant within the birthing center. Comment The Department inspector did not observe written prescriptions or orders signed by a practitioner legally authorized to prescribe in South Carolina, for the following drugs, documented in the medical record, as administered to the mother while at the birthing center: 9:35a 1 mL Pitocin IM given to mom; 9:50a 1 mL Pitocin IM given to Mom; 10:00a 1mL Methergine IM given to mom; 10:05a 500 ML NaCl IV given to mom.	

South Carolina Department of Health and Environmental Control
DIVISION OF HEALTH LICENSING
Summary of Violations (Basis for Imposing Penalties)

(Facility)			(Facility Type)	(License Units)
BLESSED BIRTHS FAMILY WELLNESS AND BIRTH CENTER			BF	2 BIRTHING ROOMS
Date Cited	R.61-102 Section	Class	Description of Violations	
7/16/14 INV M07007-14	D(3)(d)	I	10:20a 1mL Pitocin IM given to Mom. Drugs shall be administered by personnel or clinical staff currently licensed in South Carolina to administer drugs. Comment The Department inspector was unable to determine if the medications listed below were administered by personnel or clinical staff currently licensed to administer drugs. The Department inspector did not observe signatures or initials in the medical record, associated with the documented administration of the medications. 9:35a 1 mL Pitocin IM given to mom; 9:50a 1 mL Pitocin IM given to Mom; 10:00a 1mL Methergine IM given to mom; 10:05a 500 ML NaCl IV given to mom. 10:20a 1mL Pitocin IM given to Mom.	
7/16/14 Gen	D(3)(f)	I	Drugs, medications, and chemicals shall be stored and secured in specifically designated cabinets, closets, drawers, or storerooms and made accessible only to authorized persons. Comment The Department inspector observed the following medications on a table in the Hall birthing room. The medications were unsecured and accessible to unauthorized individuals (e.g., family members of the patient laboring at the birthing center): Pitocin 10 units/ml (3) unopened vials, Erythromycin ointment 0.5% 1 opened tube, HeSpan (1) unopened 500 ml bag.	
7/16/14 M07007-14	D(6)(d)	I	At least one member of the clinical staff or a registered nurse shall be in the facility when a patient is present; and up to at least one hour after each mother's delivery. Two members of the clinical staff or one member of the clinical staff and a registered nurse shall be present during the mother's delivery. Comment	

South Carolina Department of Health and Environmental Control
DIVISION OF HEALTH LICENSING
Summary of Violations (Basis for Imposing Penalties)

(Facility)			(Facility Type)	(License Units)
BLESSED BIRTHS FAMILY WELLNESS AND BIRTH CENTER			BF	2 BIRTHING ROOMS
Date Cited	R.61-102 Section	Class	Description of Violations	
			A patient delivered at the birthing center during the time the Department was conducting the inspection. The Department inspector did not observe two (2) members of the center's clinical staff or one (1) member of the clinical staff and a registered nurse in the facility during the mother's delivery. Ms. Leland, a licensed midwife, was the only Blessed Births staff observed in the facility during the delivery. A registered nurse was not observed at the birthing center during the mother's delivery.	
7/16/14 Gen	F(5)(a)	II	General: A facility shall be kept neat, clean and free from odors. Accumulated waste material must be removed daily or more often if necessary. There must be frequent cleaning of floors, walls, ceilings, woodwork, and windows. The premises must be kept free from rodent and insect infestation. Bath and toilet facilities must be maintained in a clean and sanitary condition at all times. Comment At the time of inspection, there was a putrid odor noticed in the Hall bathroom. Five (5) white styrofoam cups were observed sitting on top of the cabinet and were labeled as follows: ** Two (2) of the cups were labeled with individual patient names, dated 7/15/14, and had times noted ** Two (2) of the cups were labeled with patient names, dated 7/15/14, and no time documented ** One (1) cup was labeled with patient name and time. In addition, two white styrofoam cups were observed in the bathroom cabinet and were labeled as follows: ** One (1) of the cups was labeled with a patient name and time ** The other cup was labeled with a patient name and time. The cups contained yellow liquid, differing in color shades and amounts.	

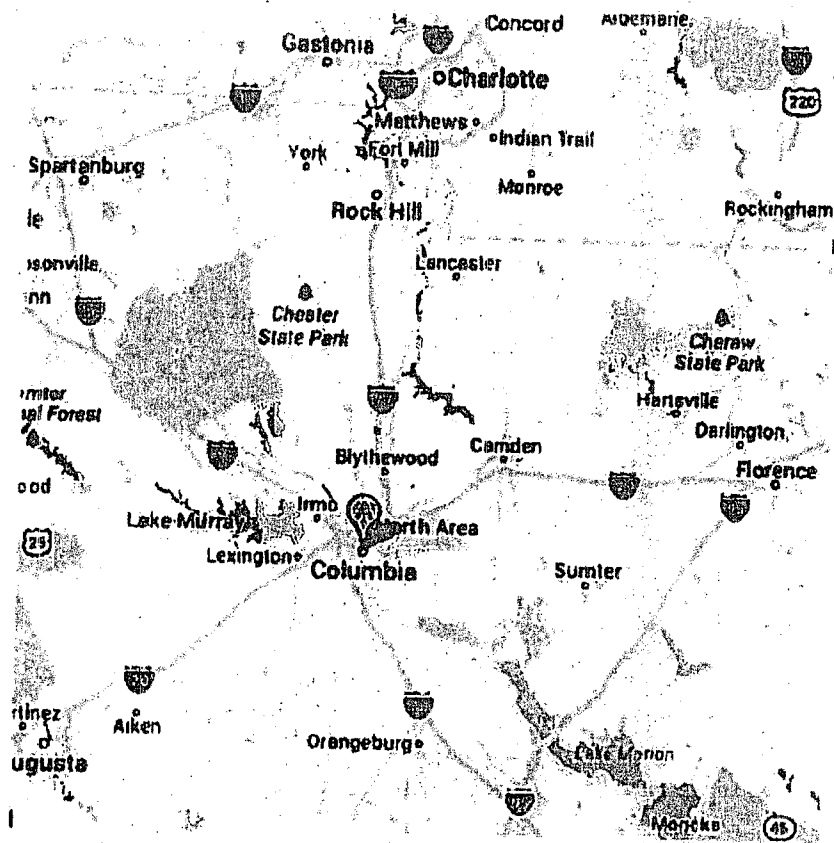
HEALTH REGULATION Contact Information

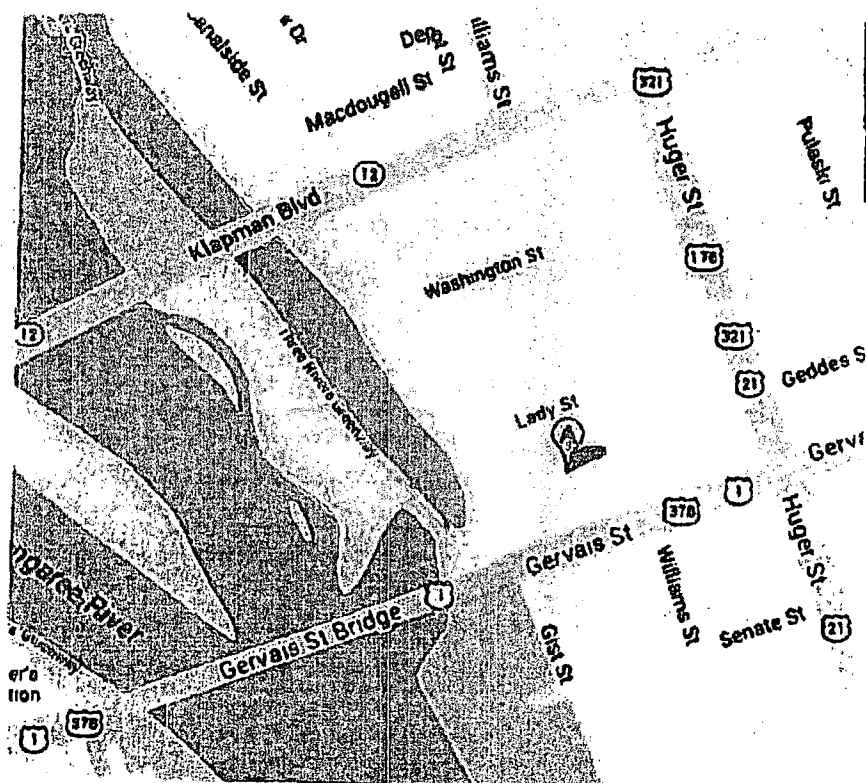
TELEPHONE NUMBERS:

Program Area	Telephone	Fax
Deputy Commissioner	(803) 545-4200	(803) 545-4579
Bureau of Health Facilities	(803) 545-4200	(803) 545-4579
Planning & Certificate of Need Division	(803) 545-4200	(803) 545-4579
Bureau of Health Facilities Regulation	(803) 545-4370	(803) 545-4212
Health Facilities Construction Division	(803) 545-4663	(803) 545-4212
Emergency Medical Services & Trauma Division	(803) 545-4204	(803) 545-4989
Health Licensing Division	(803) 545-4370	(803) 545-4212
Bureau of Certification	(803) 545-4205	(803) 545-4292
Nursing Home Division	(803) 545-4205	(803) 545-4292
Health Provider Division	(803) 545-4203	(803) 545-4563
Bureau of Radiological Health	(803) 545-4400	(803) 545-4412

MAILING ADDRESS: SCDHEC Health Regulation
2600 Bull Street
Columbia, SC 29201

OFFICE LOCATION: Columbia Mills Building (Co-located with the SC State Museum)
301 Gervais Street
Columbia, SC 29201





RANDALL S. HILLER, P.A.
ATTORNEYS AT LAW
850-B WADE HAMPTON BOULEVARD
GREENVILLE, SOUTH CAROLINA 29609

RANDALL S. HILLER
EMAIL: rsh@rshpa.org

October 14, 2014

(864) 232-0026
Fax (864) 242-4692

Gwendolyn Thompson, Chief
Bureau of Health Facilities Licensing
SCDHEC
2600 Bull St.
Columbia, SC 29201

Re: *Blessed Births Family Wellness and Birth Center*
23 Mills Avenue, Greenville, SC 29605

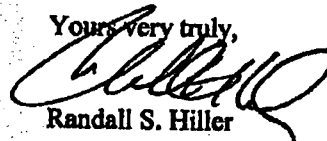
Dear Ms. Thompson:

In partial response to your September 26, 2014 letter, and despite my belief as previously expressed in my numerous responses to the continuing efforts to revoke my client's license, I make the following responses to your numbered paragraphs:

1. Ashley Behlke
2. See attached prescription request form for Patient KD
3. See attached acknowledgement by Ashley Behlke, RN
4. Amy Leland and Ashley Behlke, RN

I trust this is responsive to the substantive portions of your letter.

Yours very truly,


Randall S. Hiller

RSH/ak
Enclosures.

cc: Blessed Births Family Wellness and Birth Center



Blessed Births Attachment Item T
Family Wellness & Birth Center
23 Mills Avenue, Greenville, SC 29605 (864) 233-5513

July 28, 2014

To DHEC Health Licensing,

This letter is to inform you that I was present at Patient KD delivery.



Ashley Behlke, RN

From: unknown

Page: 3/3

Date: 7/30/2014 2:17:58 PM

Blessed Births Family Wellness & Birth Center

23 Mills Avenue, Greenville, SC 29605 (864) 233-5513

Prescription Request Update Medical Pharmacy Phone: 455-8810 / Fax: 455-8403

Date: 5-12-14 Patient Name: [REDACTED] Patient ID: [REDACTED] Date of Birth: [REDACTED]
 Address: [REDACTED] City/State: Simpsonville, SC
 Phone: [REDACTED] Allergies: NKA
 Insurance Type: BCRS (copy of card to follow)

Please dispense checked items:

- ☒ #2 Amps Pitocin - As needed for bleeding postpartum
- ☒ #2 Amps Methergine - As needed for bleeding postpartum
- ☒ #8 Methergine 2mg tablets - As needed for bleeding postpartum
- ☐ #20 Cytotec 100 mcg - As needed for bleeding postpartum
- ☒ #1 Ophthalmic Erythromycin - To be instilled within 1 hour of birth into baby's eyes.
- ☒ #4 Syringes 3cc, 21ga, 1.5in
- ☒ #2 Syringes 1cc, 27ga, 5/8in
- ☐ #1 Rhogam Full Dose (or equivalent) - For prenatal prophylaxis.
- ☒ #1 Rhogam Full Dose (or equivalent) - To be administered within 72 hours of delivery
- ☒ #20 Motrin 800mg - 1 PO q 6 hrs prn cramping.
- ☒ #1 Vitamin K (1mg/0.5ml neonatal dose) Disp. 5 ml - for baby - inject SQ/IM.
- ☐ #3 Penicillin 5million units - 5million units at start of labor, 2.5million units q 4hours until delivery.
- ☐ #3 Clindamycin 900mg - 900mg q 8hours until delivery
- ☐ #1 Epi Pen - Use as directed.

Dispense as Written

Requested by: DR. KEITH STAFFORD

Pharmacy Disregard This: Q2 to be dispensed at 5 LPM as needed for mother or baby

STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

South Carolina Department of Health
And Environmental Control,

Petitioner,

VS.

Blessed Births, Inc. d/b/a Blessed Births
Family Wellness and Birth Center,

Respondent.

Docket No. 15-ALJ-07-0148-CC

**RESPONSES TO REQUESTS
FOR ADMISSIONS**

1. On July 16, 2014, Blessed Births did not have an individual appointed to act in the absence of the administrator.

ANSWER: Denied.

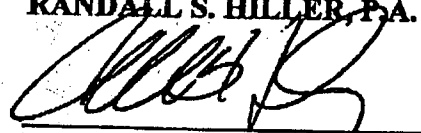
2. On July 16, 2014, Blessed Births did not have policies and procedures addressing the receiving, transcribing, and implementing of orders for administration of drugs.

ANSWER: Denied.

3. On July 16, 2014, Blessed Births did not have two staff members of the clinical staff or one member of the clinical staff and a registered nurse present during Mother I.M. delivery.

ANSWER: Admitted.

RANDALL S. HILLER, P.A.



Randall S. Hiller (SCB#2513)
850 Wade Hampton Blvd.
Greenville, SC 29609
864-232-0026
864-242-4692 Fax

July B, 2015

Greenville, South Carolina



Assessment Corrections: Non-Compliant

Facility Information / Contact Information

Permit Number: BC-0003
Facility Name: BLESSED BIRTHS FAMILY WELLNESS AND
BIRTH CENTER
Address: 23 MILLS AVE
City/State/Zip: GREENVILLE, SC 29605-4015 Greenville
Phone 1: 864-233-5513
Email: BABYCATCHER@BLESSEDBIRTHS.COM

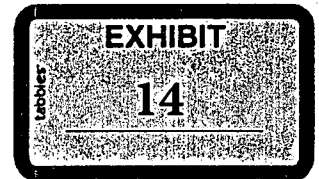
Audit Information

Audit Name: Birthing Center ROV 20140627
Type: L01 Routine
Start Date: 11 Jul 2014 01:49 PM
End Date: 11 Jul 2014 01:49 PM
Inspector: Michell Hatcher
Location Rep Name: Amy Leland
Application Version: MAPC 9.0.4051.21749

Contact Name: SUSANNAH BALDWIN
Contact Phone: 864-233-5513
Contact Email:

Audit Level Notes:

October 23, 2014, forwarded to enforcement - Terry L. English



1-9/9 | All

REPORT NOTICE

Bureau of Health Facilities Licensing
2600 Bull St
Columbia SC 29201-1708

Answer	Points
Report Notice	0

REPORT NOTICE: If applicable, this Report of Visit includes a detailed description of the conditions, conduct or practices that were found to be in violation of requirements. This inspection or investigation is not to be construed as a check of every condition that may exist, nor does it relieve the licensee (owner) from the need to meet all applicable standards, regulations and laws. The South Carolina Code of Laws requires this Department to establish and enforce basic standards for the licensure (permitting), maintenance, and operation of health facilities and services to ensure the safe and adequate treatment of persons served in this State. It also empowers the Department to require reports and make inspections and investigations as considered necessary. Furthermore, the Code authorizes the Department to deny, suspend, or revoke licenses (permits) or to assess a monetary penalty against a person or facility for (among other reasons), violating a provision of law or departmental regulations or conduct or practices detrimental to the health or safety of patients, residents, clients, or employees of a facility or service. If applicable to the type of report being made, the signature of the activity representative indicates that all of the items cited were reviewed during the visit discussion. If this Report of Visit is required by regulation to be made available in a conspicuous place in a public area within the facility, redaction of the names of those individuals in the report is required as provided by Sections 44-7-310 and 44-7-315 of the S.C. Code of Laws, 1976, as amended.

ADMINISTRATOR'S SIGNATURE - PLAN OF CORRECTION

PLAN OF CORRECTION - Administrator's Certification: I certify that the attached plan of correction describes:
(1) the actions taken to correct each cited deficiency.

Answer	Points
POC REQUIRED	0

8/23/2015 8:26:52 AM

Proprietary and Confidential

1 of 3

DHEC 00213

76

- (2) the actions taken to prevent similar recurrences, and
(3) the actual or expected completion dates of those actions.

PRINT NAME: _____

TITLE: _____

SIGNATURE: _____

DATE: _____

Any violations cited in this report of visit were observed at the time of the inspection.

Administrator returns a copy of this report (original signature required) with description of corrective actions to:

SCDHEC, Bureau of Health Facilities Licensing, 2600 Bull St, Columbia, SC, 29201

Your response to this report must be received in our office by close of business (5:00 p.m.) no later than the date listed below.

Comments

- The date Plan of Correction is due will be determined at a later date.

INSPECTION INFORMATION

- ☒ Inspection Includes Licensing:
 - ☒ Inspection Includes Fire & Life Safety:
 - ☒ Is this an On-Site Visit?
 - ☒ Date Agency (DHEC) Notified of Complaint:
- Comments**
- N/A. Not a complaint.

Answer	Points
YES	0
NO	0
YES	0
Date	0
Agency (DHEC)	
Notified of Complaint	
YES	0

- ☒ Are there any other individuals accompanying the auditor for this visit?
- Comments**

- James Harmon, HFOD Field Manager, DHEC Health Facilities Licensing

BC REGULATION SECTIONS A-G 61-102

- ☒ A.(2)(g) Inspections: Each facility submitting an application for licensing or re-licensing shall be inspected prior to initial licensure and at least annually by authorized representatives of the Department. All licensed and prospective licensed facilities are subject to inspection at any time. All facilities to which these requirements apply shall permit entrance to all properties and access to every area, object and records and reports by representatives of the Department. (Class III Violation)

Comments

- The facility administrator did not allow a duly authorized representative access to the facility to conduct an inspection/investigation. At the time of inspection, there was no staff observed at the facility. The inspector went to the door and knocked, and no one answered the door. A phone call was placed to the number (864-905-0255) on the business sign in the parking lot. Ms. Leland answered the phone, and informed the inspector that she was busy doing a home visit, and could not come to the birthing center at this time. The inspector asked Ms. Leland when would she be able to meet her at the birthing center. Ms. Leland offered to make an appointment to meet the inspector at the birthing center on Wednesday, July 16, 2014 at 10:30 am. The inspector informed Ms. Leland that the Department does not make appointments for routine inspections. At the time of the visit, there were no business hours of operation posted on the door. The inspector requested that the facility's hours of operation be emailed to the inspector's email address no later than Monday, July 14, 2014.

Answer	Points
OUT	0

RECORD RETENTION

DHEC 0282 (05/2010) AUDIT - [Records Retention Schedule #SBH-F&S-17]

Answer	Points
Retention	0

E COPY

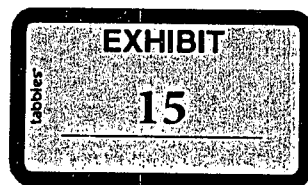
STATE OF SOUTH CAROLINA

County of Greenville

Case # M0700714

SEARCH WARRANT

Date 7/16/14



STATE OF SOUTH CAROLINA

)

) Affidavit for Administrative Inspection Warrant
) pursuant to S.C. Code Ann. § 44-7-295

COUNTY OF GREENVILLE

)

To: THE HONORABLE JAMES E. HUDSON, MAGISTRATE

MICHELL HATCHER, a duly authorized inspector of the Bureau of Health Facilities Licensing, South Carolina Department of Health and Environmental Control (DHEC or Department), hereby applies for an administrative inspection warrant pursuant to S.C. Code Ann. § 44-7-295 (Supp. 2013), to conduct an administrative inspection of the following establishment, premises, or component thereof:

Blessed Births Family Wellness and Birthing Center (Blessed Births)
23 Mills Avenue
Greenville, South Carolina 29605

DESCRIPTION OF PREMISES TO BE SEARCHED

The location to be searched is Blessed Births, 23 Mills Avenue, Greenville, South Carolina. This is a birthing center licensed by the Department. Inspection of the property will extend to all buildings, rooms, appurtenances, medications and medication storage rooms, records, all pertinent supplies and equipment, as well as any and all areas or facilities that the Department inspectors determine as necessary to inspect to ensure compliance with the *State Certification of Need and Health Facility Licensure Act*, S.C. Code Ann. §§ 44-7-110, *et seq.* (2002 and Supp. 2013), the *Birthing Center Licensure Act*, S.C. Code Ann. §§ 44-89-10, *et seq.* (2002), and *Standards for Licensing Birthing Centers for Deliveries by Midwives*, 8 S.C. Code Ann. Regs. 61-102 (2012). The inspection will also include all records, papers, and other documents relevant to the facilities or sources regulated by the Department. The inspection may also include private interviews with employees of Blessed Births.

DESCRIPTION OF PROPERTY SOUGHT

The Department's representatives may make copies of any records, data, or memoranda pertaining to the Blessed Births. Inspectors may also take photographs of the premises.

REASON FOR AFFIANT'S BELIEF THAT THE PROPERTY REQUIRES ADMINISTRATIVE INSPECTION

* The Department is the agency of the State of South Carolina responsible for administering the *State Certification of Need and Health Facility Licensure Act* (Licensing Act), S.C. Code Ann. §§ 44-7-110, *et seq.* (2002 and Supp. 2013), the *Birthing Center Licensure Act*, S.C. Code Ann. §§ 44-89-10, *et seq.* (2002), and *Standards for Licensing Birthing Centers for Deliveries by Midwives*, 8 S.C. Code Ann. Regs. 61-102 (2012).

* Pursuant to S.C. Code Ann. §§ 44-7-150(1) (2002), 44-7-295 (Supp. 2013), 44-89-60 (2002), and 8 S.C. Code Ann. Regs. 61-102 § A.(2)(g) (2012), the Department is empowered to enter and inspect the property and the records of any facility or service, whether public or private, licensed by the department or unlicensed, for the purpose of inspecting and investigating conditions relating to compliance with this article and regulations of the Department. Additionally, if such entry or inspection is denied or not consented to and no emergency exists, the Department is empowered to obtain a warrant to enter and inspect the property and its records from the magistrate in the jurisdiction in which the property is located. S.C. Code Ann. § 44-7-295 (Supp. 2013).

* The Department may take enforcement action, including the suspension or revocation of licenses, or assessment of a monetary penalty, or both, against a person or facility for violation of the Licensing Act, Birthing Center Licensure Act, or departmental regulation. S.C. Code Ann. §§ 44-7-320(A)(1)(a) (Supp. 2013), 44-89-80(A)(3) and 8 S.C. Code Ann. Regs. 61-102 § A.(3)(e) (2012).

* On July 11, 2014, Department representatives conducted a visit at the above noted location for the purpose of investigating a complaint received by the Department. However, Department representatives were denied access to the Facility's premises, thus depriving them from completing their investigation. Based upon the Facility's history of



compliance and the allegations in the complaint, Department representatives have a reasonable suspicion of regulatory violations at Blessed Births.

• For the foregoing reasons, the property described requires an administrative inspection allowing for observation and review of all records and areas of the facility to ensure compliance with applicable law and regulation.

Sworn to and Subscribed before me

This 16th day of July, 2014.


Signature of Judge

STATE OF SOUTH CAROLINA

COUNTY OF GREENVILLE



Affiant: Michell Hatcher

Address: SCDHEC
2600 Bull Street
Columbia, SC 29201

Phone: (803) 545-4370
Administrative Inspection Warrant

STATE OF SOUTH CAROLINA

Application for Administrative Inspection
Warrant pursuant to S.C. Code Ann. § 44-7-295

COUNTY OF GREENVILLE

To: THE HONORABLE JAMES E. HUDSON, MAGISTRATE

Michell Hatcher a duly authorized Bureau of Health Facilities Licensing inspector of the South Carolina Department of Health and Environmental Control (DHEC or Department), hereby applies for an administrative inspection warrant pursuant to S.C. Code Ann. § 44-7-295 (Supp. 2013) and 8 S.C. Code Regs. 61-102, § A.(2)(g) (2012), to conduct an administrative inspection of the following establishment, premises, or component thereof:

Blessed Births Family Wellness and Birthing Center (Blessed Births)
23 Mills Avenue
Greenville, South Carolina 29605

- State Law requires that birthing centers licensed by DHEC allow authorized agents of the Department to enter at all times in or on the property for the purpose of inspecting and investigating conditions relating to compliance with the statute or regulations of the Department. S.C. Code Ann. §§ 44-7-150(1) (2002), 44-7-295 (Supp. 2013), 44-89-60 (2002) and 8 S.C. Code Ann. Regs. 61-102 § A.(2)(g) (2012).
- Blessed Births is a birthing center licensed by the Department and has two birthing rooms. A birthing center is a facility or other place where human births are planned to occur, but does not include the usual resident of the mother or any facility licensed as a hospital or the private practice of a physician who attends births. S.C. Code Ann. §§ 44-7-130(24) (Supp. 2013), 44-89-30(1), and 8 S.C. Code Ann. Regs. 61-102 § A.(1)(b) (2012).
- The establishment at the above address and its premises or component thereof was previously visited on July 11, 2014, when Department representatives attempted to conduct a complaint investigation. At that time, Department representatives were denied access to the premises for the purpose of conducting the investigation.
- The requested investigation is undertaken as part of an inspection program, authorized by statute and the regulations issued thereunder, designed to assure compliance with the provisions of the South Carolina Code of Laws, 1976, as amended, and the regulations issued pursuant to those provisions, specifically, the *State Certification of Need and Health Facility Licensure Act*, S.C. Code Ann. §§ 44-7-110, *et seq.* (2002 and Supp. 2013), the *Birthing Center Licensure Act*, S.C. Code Ann. §§ 44-89-10, *et seq.* (2002), and *Standards for Licensing Birthing Centers for Deliveries by Midwives*, 8 S.C. Code Ann. Regs. 61-102 (2012).

AND

This visit is made to conduct an annual inspection and investigate one complaint filed with the Department and to determine compliance of Blessed Births with applicable state laws and regulation.

- The inspection will be conducted at a reasonable time. If the licensee is present, the inspector will present her credentials. The inspection will begin as soon as practicable after the issuance of the administrative inspection warrant, and the inspection shall be completed with reasonable promptness, within ten (10) days of the issuance of the administrative inspection warrant.
- The inspection will extend to the establishment and premises, including any appurtenances, medications and medication storage rooms, all pertinent supplies and equipment, and all records, papers and documents relevant to the facilities regulated by DHEC, and may include private interviews with all employees.
- The named health licensing inspector may be accompanied by one or more inspectors or other duly authorized employees of the Department of Health and Environmental Control, as well as law enforcement officers.

Subscribed by:

Michell Hatcher RD

Michell Hatcher, Inspector
Bureau of Health Facilities Licensing
South Carolina Department of Health and Environmental Control

Sworn to and Subscribed before me

This 15 day of July, 2014

Debra Brockman

NOTARY PUBLIC FOR SOUTH CAROLINA

My Commission expires: 4/1/21

8

TO ANY DULY AUTHORIZED HEALTH LICENSING INSPECTOR/PUBLIC HEALTH
OFFICER OF THE SOUTH CAROLINA DEPARTMENT OF HEALTH AND
ENVIRONMENTAL CONTROL:

It appears from the attached sworn application that there are reasonable grounds to conduct an administrative inspection pursuant to Sections 44-7-150(1), 44-7-295, and 44-89-60 of the Code of Laws of South Carolina, 1976, as amended, at the following described establishment, premises, or component thereof:

Blessed Births Family Wellness and Birthing Center
23 Mills Avenue
Greenville, South Carolina 29605-4015

Now, therefore, you are hereby authorized to conduct an administrative inspection at the subject establishment, including premises, or component thereof as described above and to collect and retain such samples, information, and/or data described below as are necessary for a reasonable administrative inspection:

- A) Interviews with employees/staff.
- B) Review of facility supplies and equipment.
- C) Inspection of facility premises.
- D) Review of patient records, employee/staff records, medication documents, health records, and facility policies and procedures.

This inspection warrant shall not be valid for more than ten (10) days from the date of issuance.

A written inventory of all samples, information, and/or data collected pursuant to the Inspection Warrant shall be made to:

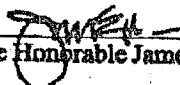
The Honorable James E. Hudson, Magistrate

Within ten (10) days from the date of this warrant, such inventory is to be signed by the officer executing this warrant, and a copy of such inventory shall be furnished to the person whose establishment, premises, or component thereof are inspected if demand for such copy is made.

A copy of this Inspection Warrant shall be delivered to the person in charge of the establishment, premises, or component thereof inspected at the time of such inspection if practicable; if not, to such person as soon thereafter as is practicable. In the event the identity of the person in charge is not known or if such person cannot be found after reasonable diligence in attempting to locate the person, a copy shall be attached to a prominent place on such establishment, premises, of component thereof.

Greenville, SC

July 16, 2014.


The Honorable James E. Hudson, Magistrate

1055 hrs

STATE OF SOUTH CAROLINA

Application for Administrative Inspection
Warrant pursuant to S.C. Code Ann. § 44-7-295

COUNTY OF GREENVILLE

To: THE HONORABLE JAMES E. HUDSON, MAGISTRATE

Michell Hatcher a duly authorized Bureau of Health Facilities Licensing inspector of the South Carolina Department of Health and Environmental Control (DHEC or Department), hereby applies for an administrative inspection warrant pursuant to S.C. Code Ann. § 44-7-295 (Supp. 2013) and 8 S.C. Code Regs. 61-102, § A.(2)(g) (2012), to conduct an administrative inspection of the following establishment, premises, or component thereof:

Blessed Births Family Wellness and Birthing Center (Blessed Births)
23 Mills Avenue
Greenville, South Carolina 29605

- State Law requires that birthing centers licensed by DHEC allow authorized agents of the Department to enter at all times in or on the property for the purpose of inspecting and investigating conditions relating to compliance with the statute or regulations of the Department. S.C. Code Ann. §§ 44-7-150(1) (2002), 44-7-295 (Supp. 2013), 44-89-60 (2002) and 8 S.C. Code Ann. Regs. 61-102 § A.(2)(g) (2012).
- Blessed Births is a birthing center licensed by the Department and has two birthing rooms. A birthing center is a facility or other place where human births are planned to occur, but does not include the usual residence of the mother or any facility licensed as a hospital or the private practice of a physician who attends births. S.C. Code Ann. §§ 44-7-130(24) (Supp. 2013), 44-89-30(1), and 8 S.C. Code Ann. Regs. 61-102 § A.(1)(b) (2012).
- The establishment at the above address and its premises or component thereof was previously visited on July 11, 2014, when Department representatives attempted to conduct a complaint investigation. At that time, Department representatives were denied access to the premises for the purpose of conducting the investigation.
- The requested investigation is undertaken as part of an inspection program, authorized by statute and the regulations issued thereunder, designed to assure compliance with the provisions of the South Carolina Code of Laws, 1976, as amended, and the regulations issued pursuant to those provisions, specifically, the *State Certification of Need and Health Facility Licensure Act*, S.C. Code Ann. §§ 44-7-110, *et seq.* (2002 and Supp. 2013), the *Birthing Center Licensure Act*, S.C. Code Ann. §§ 44-89-10, *et seq.* (2002), and *Standards for Licensing Birthing Centers for Deliveries by Midwives*, 8 S.C. Code Ann. Regs. 61-102 (2012).

AND

This visit is made to conduct an annual inspection and investigate one complaint filed with the Department and to determine compliance of Blessed Births with applicable state laws and regulation.

- The inspection will be conducted at a reasonable time. If the licensee is present, the inspector will present her credentials. The inspection will begin as soon as practicable after the issuance of the administrative inspection warrant, and the inspection shall be completed with reasonable promptness, within ten (10) days of the issuance of the administrative inspection warrant.
- The inspection will extend to the establishment and premises, including any appurtenances, medications and medication storage rooms, all pertinent supplies and equipment, and all records, papers and documents relevant to the facilities regulated by DHEC, and may include private interviews with all employees.
- The named health licensing inspector may be accompanied by one or more inspectors or other duly authorized employees of the Department of Health and Environmental Control, as well as law enforcement officers.

Subscribed by:

Michell Hatcher RD

Michell Hatcher, Inspector
Bureau of Health Facilities Licensing
South Carolina Department of Health and Environmental Control

Sworn to and Subscribed before me

This 15 day of July, 2014

Debra A. Beckett

NOTARY PUBLIC FOR SOUTH CAROLINA

My Commission expires: 4/1/21

8

COPY

RETURN

I received the attached Administrative Inspection Warrant, and have executed it as follows:

On July 16, 2014, at approximately 11:40 A.M., I searched the premises at Blessed Births Family Wellness and Birthing Center, 23 Mills Avenue, Greenville, South Carolina, described in the warrant. I left a copy of the warrant with Amy Leland together with a receipt for the items seized.

The following activities were conducted at the site:

1. Gained access to the Facility, to include a walk-through.
2. Interviewed the Facility's Administrator
3. Reviewed the Facility's policy and procedure manual, to include obtaining copies of pages of the policies and procedures related to physician involvement and patient care (pages 3-11).
4. Reviewed five (5) patient medical records, to include obtaining copies of:
 - a. Medical History-patient information and registration Forms
 - b. Informed Consent Forms
 - c. Acknowledgement of Receipt of Notice of Privacy Practices Forms
 - d. Prenatal Visits Forms
 - e. History and Physical Forms
 - f. OB 2nd/3rd Trimester Reports
 - g. Prescription Request Forms
 - h. Physician Notes
 - i. Vitamin K and Ophthalmic Erythromycin Choices Forms
 - j. Birthing Record Forms
 - k. Labor and Delivery Notes
 - l. Admission and Identification Forms
 - m. Labor Transport Summaries
 - n. Maternity Superbill Forms
 - o. Hospital Interim Report and Outpatient Final Episode Reports
 - p. Newborn Admission/Discharge Forms
 - q. Pregnancy Reports
 - r. Insurance Registration Forms
 - s. Patient Registration Forms
 - t. Ultrasound Exam Order Forms
 - u. Hospital Laboratory Reports
 - v. Post Partum Visit Forms
 - w. Patient Phone Consultation Forms

Am

- x. DHEC Laboratory Report
- y. Obstetrics-2nd Trimester Forms
- z. Abdominal Ultrasound Reports
- aa. Study Data Reports
- bb. September 19, 2013 Letter from Blessed Births to North Grace Dental

The following is an inventory of property taken pursuant to the warrant:

1. No property was seized or taken.

This inventory was made in the presence of Amy Leland, Randall S. Hiller, Esquire, Officer Andrew Sturman AND James Harmon.

I swear that the inventory is a true and detailed account of all the property taken by me on the warrant.

Sworn to and Subscribed before me
This 25th day of July, 2014.

[Signature]
Signature of Judge

[Signature]
Signature of Department Employee
Executing Warrant

1100 hrs

Assessment Corrections: Non-Compliant

Facility Information / Contact Information

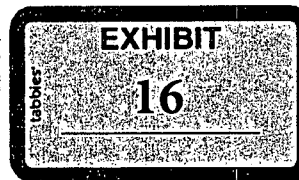
Permit Number: BC-0003
Facility Name: BLESSED BIRTHS FAMILY WELLNESS AND
BIRTH CENTER
Address: 23 MILLS AVE
City/State/Zip: GREENVILLE, SC 29605-4015 Greenville
Phone 1: 864-233-5513
Email: BABYCATCHER@BLESSEDBIRTHS.COM

Contact Name: SUSANNAH BALDWIN
Contact Phone: 864-233-5513
Contact Email:

Audit Information

Audit Name: Birthing Center ROV 20140627
Type: L07 Investigation
Start Date: 25 Mar 2015 11:15 AM
End Date: 25 Mar 2015 11:55 AM
Inspector: Michell Hatcher
Location Rep Name: SUSANNAH BALDWIN
Fax Back:
Email Back:
Application Version: 360n 139 windows_6 1.7601.65536

Audit Level Notes:



1 - 15 / 15 All

REPORT NOTICE

Bureau of Health Facilities Licensing
2600 Bull St
Columbia SC 29201-1708

Answer Points
Report Notice 0

REPORT NOTICE: If applicable, this Report of Visit includes a detailed description of the conditions, conduct or practices that were found to be in violation of requirements. This inspection or investigation is not to be construed as a check of every condition that may exist, nor does it relieve the licensee (owner) from the need to meet all applicable standards, regulations and laws. The South Carolina Code of Laws requires this Department to establish and enforce basic standards for the licensure (permitting), maintenance, and operation of health facilities and services to ensure the safe and adequate treatment of persons served in this State. It also empowers the Department to require reports and make inspections and investigations as considered necessary. Furthermore, the Code authorizes the Department to deny, suspend, or revoke licenses (permits) or to assess a monetary penalty against a person or facility for (among other reasons), violating a provision of law or departmental regulations or conduct or practices detrimental to the health or safety of patients, residents, clients, or employees of a facility or service. If applicable to the type of report being made, the signature of the activity representative indicates that all of the items cited were reviewed during the exit discussion. If this Report of Visit is required by regulation to be made available in a conspicuous place in a public area within the facility, redaction of the names of those individuals in the report is required as provided by Sections 44-7-310 and 44-7-315 of the S.C. Code of Laws, 1976, as amended.

ADMINISTRATOR'S SIGNATURE - PLAN OF CORRECTION

PLAN OF CORRECTION - Administrator Certification: I certify that the attached plan of correction describes:
(1) the actions taken to correct each cited deficiency,
(2) the actions taken to prevent similar recurrences, and
(3) the actual or expected completion dates of those actions.

Answer Points
POC 0
REQUIRED

PRINT NAME: _____

TITLE: _____

SIGNATURE: _____

DATE: _____

Any violations cited in this report of visit were observed at the time of the inspection.

Administrator returns a copy of this report (original signature required) with description of corrective actions to:

SCDHHC, Bureau of Health Facilities Licensing, 2600 Bull St, Columbia, SC, 29201

Your response to this report must be received in our office by close of business (5:00 p.m.) no later than the date listed below.

Comments

- Plan of Correction due before 5:00pm on July 11, 2015.

INSPECTION INFORMATION

Comments: Please change administrator to Amy Leland

	Answer	Points
☒ Inspection Includes Licensing	YES	0
☒ Inspection Includes Fire & Life Safety	NO	0
☒ Is this an On-Site Visit?	YES	0
☒ Select the Type of Inspection to be Performed	Birthing Center Complaint Investigation	0
☒ Section Team Log Number	Section Team Log Number	0
Comments • F03002-15		
☒ Complaint Allegation(s)	Complaint Allegation(s)	0
Comments • 1) I found out I was being risked out on the 23rd through the grapevine because Amy was not coming back in time 2) BB (Blessed Births) dropped me without finding another provider 3) Delay in receiving Glucose test results (test performed on January 28th, and results not received until February 23rd) 4) Did not take my heart rate/weakness seriously, and never consulted with Dr. Stafford related to heart rate/weakness 5) Don't have 2 midwives present 6) Labs are under a different Dr.'s name (Dr. Gamble, not Dr. Stafford) 7) Lies in my chart about last pregnancy- saying I resisted transfer until 35 weeks 8) Midwives (Amy and Merienda) never had a discussion with me that this may be a possible outcome 9) The midwife who agreed to do my birth left for an extended time, leaving someone in charge who was not comfortable with my care 10) There was a complete lack of communication during the 8 weeks she (Merienda) treated me, which left me scrambling and hanging my last few weeks of pregnancy		
☒ What is the Source of the Complaint	Consumer Complaint	0
☒ Date Agency (DHEC) Notified of Complaint	Date Agency (DHEC) Notified of Complaint	0
Comments • 03/02/2015		
☒ Detailed Results of this Investigation	Detailed Results	0
Comments • Violation(s) of Health Licensing standards were cited as a result of this investigation.		

Name of Reviewer
Comments
• Terry English

Name of Reviewer 0

BC REGULATION SECTIONS A-G 61-102

A.(2)(g) Inspections: Each facility submitting an application for licensing or re-licensing shall be inspected prior to initial licensure and at least annually by authorized representatives of the Department. All licensed and prospective licensed facilities are subject to inspection at any time. All facilities to which these requirements apply shall permit entrance to all properties and access to every area, object and records and reports by representatives of the Department (Class III Violation)

Answer Points
OUT 0
(Repeat)

Comments

The Department representatives (Michell Hatcher and Whitney McFadden) visited Blessed Births on Wednesday, March 25, 2015, which is a regular scheduled day of operations per email sent by Ms. Leland on July 14, 2014. At the time of visit, Blessed Births administrator, Amy Leland, did not allow a Department representative entrance in Blessed Births or access to the Blessed Births' area, objects, and records. The Department arrived at Blessed Births on March 25, 2015, at 11:15 a.m. The door to Blessed Births was locked. The Department representative knocked on the door, but no one answered. The Department representative then called the Blessed Births' published telephone number (864-233-5513) and heard a voice message that provided a number to call (864-905-0255) if you needed to speak with a midwife immediately. The Department representative called the number (864-905-0255) at 11:28 a.m. and spoke to Ms. Leland. The Department representative explained that she was at Blessed Births to investigate a complaint. Ms. Leland told the representative that she would have to call her back. A man exited the front door of the Blessed Births carrying suitcases. The Department representative spoke to the man and asked him if there was anyone inside the facility. The man replied "yes, my wife is." The Department representative asked the man if his wife had given birth and he replied "yes." The man placed his bags in his vehicle and then returned into the facility and locked the door behind him. The Department representative called Ms. Leland back (864-905-0255) at 11:38 a.m. and reached her voice mail. The Department representative then left a message for Ms. Leland to call her back. Ms. Leland called the Department representative back at 11:47 a.m. and stated, "I will not be meeting with you today, Michell." Ms. Leland was reminded by the Department representative several times that the Regulation 61-102 required birthing centers to permit entrance to all properties and access to every area, object and records by representatives of the Department. Ms. Leland repeated that she would not be meeting with Department representative today. The Department representative asked that if Ms. Leland was in the building to please let her presence be known. Ms. Leland presented herself in the front lobby of the facility, visible to the Department representative through the glass of the facility front door, while holding her phone in her hand. Ms. Leland stated "Here I am Michell. Do you see me?" The Department representative acknowledged Ms. Leland's presence and again explained that Blessed Births would be in violation of the Regulation 61-102 if she did not permit the Department representative entrance into the facility to conduct the complaint investigation. Ms. Leland said again, "I will not be meeting with you today Good-bye." Ms. Leland hung up the phone. The Department representative departed the facility at 11:55 a.m.

RECORD RETENTION

DHBC 0282 (05/2010) AUDIT - [Records Retention Schedule #SBH-F&S-17]

Answer Points
Retention 0

PROTECTED INFORMATION

Is this information CONFIDENTIAL? This section names or identifies certain individuals related to cited violations. If you identify by name any patient, client, resident, or participant, you must check 'YES' by CONFIDENTIAL. Otherwise, check 'NO'. (The names of facility/activity staff members are NOT considered

Answer Points
YES 0

CONFIDENTIAL. If required for the audit, list the names of staff members in the citation.)

Comments

- The man who is mentioned in the report as exiting the building is Patient ZS. His wife who is mentioned in the report, and reportedly had given birth is Patient SS.

COPY

STATE OF SOUTH CAROLINA

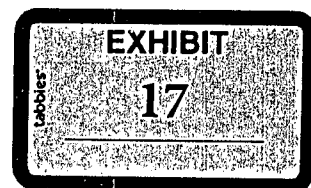
County of Greenville

SEARCH WARRANT

ORIGINAL

Date: 3/31/15

MICHELL HATCHER, SCDHEC



STATE OF SOUTH CAROLINA

COUNTY OF GREENVILLE

Application for Administrative Inspection

Warrant pursuant to S.C. Code Ann. § 44-7-295

To: THE HONORABLE JAMES E. HUDSON, MAGISTRATE

Michell Hatcher a duly authorized Bureau of Health Facilities Licensing inspector of the South Carolina Department of Health and Environmental Control (DHEC or Department), hereby applies for an administrative inspection warrant pursuant to S.C. Code Ann. § 44-7-295 (Supp. 2014) and 8 S.C. Code Regs. 61-102 § A.(2)(g) (2012), to conduct an administrative inspection of the following establishment, premises, or component thereof:

Blessed Births Family Wellness and Birthing Center (Blessed Births)
23 Mills Avenue
Greenville, South Carolina 29605

1. State Law requires that birthing centers licensed by DHEC allow authorized agents of the Department to enter at all times in or on the property for the purpose of inspecting and investigating conditions relating to compliance with the statute or regulations of the Department. S.C. Code Ann. §§ 44-7-150(1) (2002), 44-7-295 (Supp. 2014), 44-89-60 (2002) and 8 S.C. Code Ann. Regs. 61-102 § A.(2)(g) (2012).
2. Blessed Births is a birthing center licensed by the Department and has two birthing rooms. A birthing center is a facility or other place where human births are planned to occur, but does not include the usual residence of the mother or any facility licensed as a hospital or the private practice of a physician who attends births. S.C. Code Ann. §§ 44-7-130(24) (Supp. 2014), 44-89-30(1), and 8 S.C. Code Ann. Regs. 61-102 § A.(1)(b) (2012).
3. The establishment at the above address and its premises or component thereof was previously visited on March 25, 2015, when Department representatives attempted to conduct a complaint investigation. At that time, Department representatives were denied access to the premises for the purpose of conducting the investigation.
4. The requested investigation is undertaken as part of an inspection program, authorized by statute and the regulations issued thereunder, designed to assure compliance with the provisions of the South Carolina Code of Laws, 1976, as amended, and the regulations issued pursuant to those provisions, specifically, the *State Certification of Need and Health Facility Licensure Act*, S.C. Code Ann. §§ 44-7-110, *et seq.* (2002 and Supp. 2014), the *Birthing Center Licensure Act*, S.C. Code Ann. §§ 44-89-10, *et seq.* (2002), and *Standards for Licensing Birthing Centers for Deliveries by Midwives*, 8 S.C. Code Ann. Regs. 61-102 (2012).

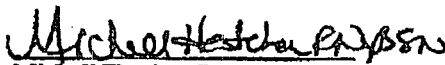
AND

This visit is made to conduct an investigate one complaint filed with the Department and to determine compliance of Blessed Births with applicable state laws and regulation.



5. The inspection will be conducted at a reasonable time. If the licensee is present, the inspector will present her credentials. The inspection will begin as soon as practicable after the issuance of the administrative inspection warrant, and the inspection shall be completed with reasonable promptness, within ten (10) days of the issuance of the administrative inspection warrant.
6. The inspection will extend to the establishment and premises, including any appurtenances, medications and medication storage rooms, all pertinent supplies and equipment, and all records, papers and documents relevant to the facilities regulated by DHEC, and may include private interviews with all employees.
7. The named health licensing inspector may be accompanied by one or more inspectors or other duly authorized employees of the Department of Health and Environmental Control, as well as law enforcement officers.

Subscribed by:



Michael Hatcher, Inspector
Bureau of Health Facilities Licensing
South Carolina Department of Health and Environmental Control

Sworn to and Subscribed before me
This 31 day of March, 2015



NOTARY PUBLIC FOR SOUTH CAROLINA
My Commission expires: 3/23/19

Notarized Before Me by
State of South Carolina, Notary Public and
Jury Commission Expires March 23, 2019
Notary S. Davis

1246 hrs

STATE OF SOUTH CAROLINA

)
) Affidavit for Administrative Inspection Warrant
) pursuant to S.C. Code Ann. § 44-7-295
)

COUNTY OF GREENVILLE

)

To: THE HONORABLE JAMES E. HUDSON, MAGISTRATE

MICHELL HATCHER, a duly authorized inspector of the Bureau of Health Facilities Licensing, South Carolina Department of Health and Environmental Control (DHEC or Department), hereby applies for an administrative inspection warrant pursuant to S.C. Code Ann. § 44-7-295 (Supp. 2014), to conduct an administrative inspection of the following establishment, premises, or component thereof:

Blessed Births Family Wellness and Birthing Center (Blessed Births)
23 Mills Avenue
Greenville, South Carolina 29605

DESCRIPTION OF PREMISES TO BE SEARCHED

The location to be searched is Blessed Births, 23 Mills Avenue, Greenville, South Carolina. This is a birthing center licensed by the Department. Inspection of the property will extend to all buildings, rooms, appurtenances, medications and medication storage rooms, records, all pertinent supplies and equipment, as well as any and all areas or facilities that the Department inspectors determine as necessary to inspect to ensure compliance with the *State Certification of Need and Health Facility Licensure Act*, S.C. Code Ann. §§ 44-7-110, *et seq.* (2002 and Supp. 2014), the *Birthing Center Licensure Act*, S.C. Code Ann. §§ 44-89-10, *et seq.* (2002), and *Standards for Licensing Birthing Centers for Deliveries by Midwives*, 8 S.C. Code Ann. Regs. 61-102 (2012). The inspection will also include all records, papers, and other documents relevant to the facilities or sources regulated by the Department. The inspection may also include private interviews with employees of Blessed Births.

DESCRIPTION OF PROPERTY SOUGHT

The Department's representatives may make copies of any records, data, or memoranda pertaining to the Blessed Births. Inspectors may also take photographs of the premises.

REASON FOR AFFIANT'S BELIEF THAT THE PROPERTY REQUIRES ADMINISTRATIVE INSPECTION

1. The Department is the agency of the State of South Carolina responsible for administering the *State Certification of Need and Health Facility Licensure Act* (Licensing Act), S.C. Code Ann. §§ 44-7-

110, *et seq.* (2002 and Supp. 2014), the *Birthing Center Licensure Act* (Birthing Center Licensure Act), S.C. Code Ann. §§ 44-89-10, *et seq.* (2002), and *Standards for Licensing Birthing Centers for Deliveries by Midwives*, 8 S.C. Code Ann. Regs. 61-102 (2012).

2. Pursuant to S.C. Code Ann. §§ 44-7-150(1) (2002), 44-7-295 (Supp. 2014), 44-89-60 (2002), and 8 S.C. Code Ann. Regs. 61-102 § A.(2)(g) (2012), the Department is empowered to enter and inspect the property and the records of any facility or service, whether public or private, licensed by the department or unlicensed, for the purpose of inspecting and investigating conditions relating to compliance with this article and regulations of the Department. Additionally, if such entry or inspection is denied or not consented to and no emergency exists, the Department is empowered to obtain a warrant to enter and inspect the property and its records from the magistrate in the jurisdiction in which the property is located. S.C. Code Ann. § 44-7-295 (Supp. 2014).

3. The Department may take enforcement action, including the suspension or revocation of licenses, or assessment of a monetary penalty, or both, against a person or facility for violation of the Licensing Act, Birthing Center Licensure Act, or departmental regulation. S.C. Code Ann. §§ 44-7-320(A)(1)(a) (Supp. 2014), 44-89-80(A)(3) and 8 S.C. Code Ann. Regs. 61-102 § A.(3)(c) (2012).

4. On March 25, 2015, a Department representative conducted a visit at the above noted location for the purpose of investigating a complaint received by the Department. However, the Department representative was denied access to the Facility's premises, thus depriving them from completing their investigation. Based upon the Facility's history of compliance and the allegations in the complaint, Department representatives have a reasonable suspicion of regulatory violations at Blessed Births.

5. For the foregoing reasons, the property described requires an administrative inspection allowing for observation and review of all records and areas of the facility to ensure compliance with applicable law and regulation.

[Signature page follows]



RETURN

I received the attached Administrative Inspection Warrant, and have executed it as follows:

On March 31, 2015 at 1:10 o'clock P.M., I searched the premises at Blessed Births Family Wellness and Birthing Center, 23 Mills Avenue, Greenville, South Carolina, described in the warrant. I left a copy of the warrant with Amry Leland together with a receipt for the items seized.

The following activities were conducted at the site:

1. Review of two (2) medical records (mothers and newborns).
2. Review of one (1) personnel file for a staff member.
3. Attempted interview with the licensee of record.
- 4.

The following is an inventory of property taken pursuant to the warrant:

1. Made copies of the medical records for two mothers and newborns.
- 2.
- 3.
- 4.

This inventory was made in the presence of Officer T.S. Moore (City of Greenville Police Department), Officer K.A. Donohue (City of Greenville Police Department) AND Whitney McFadden (DHEC).

I swear that the inventory is a true and detailed account of all the property taken by me on the warrant.

Sworn to and Subscribed before me
This 7th day of April, 2015.

L. T. Summers
Signature of Judge 1109hrs

Michael Hatcher, RN, BSN
Signature of Department Employee Executing
Warrant

STATE OF SOUTH CAROLINA

Administrative Inspection Warrant

COUNTY OF GREENVILLE

TO ANY DULY AUTHORIZED HEALTH LICENSING INSPECTOR/PUBLIC HEALTH OFFICER
OF THE SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL:

It appears from the attached sworn application that there are reasonable grounds to conduct an administrative inspection pursuant to Sections 44-7-150(1), 44-7-295, and 44-89-60 of the Code of Laws of South Carolina, 1976, as amended, at the following described establishment, premises, or component thereof:

Blessed Births Family Wellness and Birthing Center
23 Mills Avenue
Greenville, South Carolina 29605-4015

Now, therefore, you are hereby authorized to conduct an administrative inspection at the subject establishment, including premises, or component thereof as described above and to collect and retain such samples, information, and/or data described below as are necessary for a reasonable administrative inspection:

- A) Interviews with employees/staff.
- B) Review of facility supplies and equipment.
- C) Inspection of facility premises.
- D) Review of patient records, employee/staff records, medication documents, health records, and facility policies and procedures.

This inspection warrant shall not be valid for more than ten (10) days from the date of issuance.

A written inventory of all samples, information, and/or data collected pursuant to the Inspection Warrant shall be made to:

The Honorable James B. Hudson, Magistrate

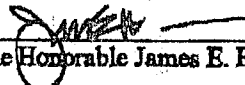
Within ten (10) days from the date of this warrant, such inventory is to be signed by the officer executing this warrant, and a copy of such inventory shall be furnished to the person whose establishment, premises, or component thereof are inspected if demand for such copy is made.

A copy of this Inspection Warrant shall be delivered to the person in charge of the establishment, premises, or component thereof inspected at the time of such inspection if practicable; if not, to such person as soon thereafter as is practicable. In the event the identity of the person in charge is not known or if such person cannot be found after reasonable diligence in attempting to locate the person, a copy shall be attached to a prominent place on such establishment, premises, or component thereof.

Greenville, SC

March 31, 2015.

1240 hrs.


The Honorable James B. Hudson, Magistrate

THE STATE OF SOUTH CAROLINA
In The Court of Appeals

APPEAL FROM GREENVILLE COUNTY
Administrative Law Court

Shirley C. Robinson, Administrative Law Judge

Case No. 15-ALJ-07-0148-CC

South Carolina Department of
Health and Environmental
Control,

Respondent,

v.

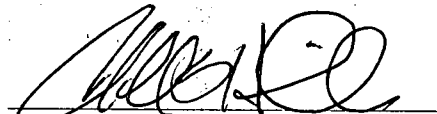
Blessed Births, Inc. d/b/a
Blessed Births Family
Wellness and Birth Center,

Appellant.

CERTIFICATE OF COUNSEL

The undersigned certified that this Supplement to Record on Appeal complies with Rule 212(b), SCACR.

June 14, 2016



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