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 **FINAL DECISION AND ORDER**

APPEARANCES: For the Petitioner: Vito M. Wicevic, Esquire
For the Respondent: Randall S. Hiller, Esquire

STATEMENT OF THE CASE

This matter is before the South Carolina Administrative Law Court ("the ALC" or "the Court") for a final decision and order following a contested case hearing requested by Blessed Births, Inc., d/b/a Blessed Births Family Wellness and Birth Center ("Respondent"). On February 12. 2015, the South Carolina Department of Health and Environmental Control ("the Department") issued an Administrative Order imposing a monetary penalty against Respondent for failure to comply with the Birthing Center Licensure Act pursuant to sections 44-89-10 et seq. of the South Carolina Code (2002 and Supp. 2014), and the Standards for Licensing Birthing Centers for Deliveries by Midwives, S.C. Code Ann. Reg. 61-102 (2012). Respondent was assessed a monetary penalty of two thousand two hundred dollars ($2,200.00), pursuant to section 44-89-80(A)(3) of the South Carolina Code (2002) and regulation 61-102 A.(3)(e) of the South Carolina Code of Regulations (2012), for the alleged violations. On February 23, 2015, Respondent requested a Final Review Conference with the South Carolina Board of Health and Environmental Control ("the Board"). The Board denied Respondent's request for final review in a letter issued on March 18, 2015. On March 25, 2015, Respondent filed a Request for a Contested Case Hearing with the ALC.

Following notice to the parties, a hearing on the matter was held on October 21, 2015, at the South Carolina Administrative Law Court in Columbia, South Carolina.

FINDINGS OF FACT

Having observed the witnesses and exhibits presented at the hearing and closely passing upon their credibility, and taking into consideration the burden of persuasion by the parties, the Court makes the following findings of fact by a preponderance of the evidence:

1. Blessed Births, Inc., d/b/a Blessed Births Family Wellness and Birth Center ("the birthing center") is licensed by the Department to operate as a birthing center in Greenville County, South Carolina. The birthing center is owned and operated by Amy Beth Leland, who became a licensed midwife in 1997. Ms. Leland testified that the birthing center provides prenatal and birthing services to women who have been medically determined to have normal pregnancies and who are expected to have routine labor and deliveries.

2. On July 16, 2014, Michelle Hatcher, who is employed in the Department's Bureau of Health Facility Licensing, along with another Department employee, conducted an unannounced inspection of the birthing center. The Department initiated the inspection in response to a complaint filed against the Respondent. This was a second attempt to inspect Respondent's facility in response to the complaint, the Department was unable to gain access to the facility in its first attempt. Ms. Leland was present at the birthing center for the inspection, however, she was caring for a patient who was in active labor. The patient is referred to in Department records as "Patient I.M." Members of Patient I.M.'s family were also present.

3. Ms. Hatcher testified that she found several violations during the July 16, 2014 inspection. According to Ms. Hatcher, her review of the birthing center's Policy and Procedures Manual ("the manual") revealed that the manual failed to list the name of an individual who would act in the absence of the birthing center's administrator. When she asked Ms. Leland for the name of the person who would act in her absence, Ms. Leland could not provide a name for her at that time. Ms. Hatcher also stated that the manual failed to address how the birthing center would receive, transcribe and implement physicians' orders for the administration of prescription drugs. More specifically, the manual did not specify who would obtain prescriptions, who was responsible for documenting prescriptions in patient records, and who was responsible for administering prescribed medications.

4. In addition, as part of the inspection, Ms. Hatcher requested Ms. Leland provide a randomly selected patient file to be reviewed. The medical record for Patient K.D. was selected. Ms. Hatcher testified she reviewed Patient K.D.'s record and charts and found that Patient K.D.

was administered more medication than had been prescribed to her. Specifically, Patient K.D.'s chart showed she was prescribed 2 mL Pitocin, however, on May 28, 2014, Patient K.D. was given 3 mL Pitocin. Ms. Hatcher stated the record and charts show Patient K.D. was also given sodium chloride for which no prescription was found.

5. Also, during the inspection, Ms. Hatcher stated that the door to an unoccupied birthing room was not locked or closed and she observed medications lying on a table, unsecured and easily accessible. The medications included three (3) unopened vials of Pitocin, one (1) opened tube of Erythromycin, and one (1) unopened 500 mL bag of HeSpan. Ms. Hatcher stated that when she questioned Ms. Leland about the medications she explained that the medications were left out from a previous delivery.

6. In addition, Ms. Hatcher stated there was no other clinical staff member at the birthing center to assist Ms. Leland with Patient I.M.'s delivery. Ms. Hatcher acknowledged that Ms. Leland placed a call to someone, but the individual never showed up.

7. Finally, Ms. Hatcher testified that she detected a "putrid odor" coming from the facility's hall bathroom. When she entered the bathroom, Ms. Hatcher found several uncovered styrofoam cups containing urine samples. Three cups were labeled with patient names, dates and times. Ms. Hatcher stated that when asked about the cups, Ms. Leland explained that the urine samples were from the day before and that she had not had an opportunity to clean them up.

8. In her testimony, Ms. Leland stated that Ms. Hatcher inspected her birthing center multiple times over the last six (6) years, and during each visit, Ms. Hatcher reviewed the center's policy and procedures manual, and at no time did Ms. Hatcher ever identify a problem with the contents of the manual. Following the July 16, 2014 inspection, and after being made aware of deficiencies in the manual, Respondent added specific language to address the Department's concerns with respect to its prescription drugs policy. Ms. Leland also acknowledged that on the day of the inspection, the manual did not identify an individual who would act in the absence of the administrator. She explained that the employee previously identified quit unexpectedly, and she was in the process of locating a replacement at the time of the inspection. On October 14, 2014, Ashley Behlke, RN was identified as the alternate to the administrator.

9. Ms. Leland also addressed the medications that were administered to Patient K.D. She explained that while Patient K.D.'s medical record did not include a prescription for the third vial of Pitocin and sodium chloride, those medications were administered to Patient K.D. as a life-

saving measure in an emergency situation. According to Ms. Leland, Patient K.D. lost a significant amount of blood following her delivery. Emergency Medical Services ("EMS") was called to transport Patient K.D. to a hospital. After consulting with EMS workers, Ms. Leland administered Pitocin to Patient K.D. to help control bleeding during transport. Ms. Leland further explained that she has a prescription for every drug used in her facility, including certain medications that are maintained for use in the event of a medical emergency. The prescriptions for emergency medications are not attached to particular patients. In addition, Ms. Leland explained she has a standing order to administer intravenous fluids to patients on an as-needed basis.

10. With regards to the unsecured medications Ms. Hatcher observed in the hall birthing room, Ms. Leland explained that it is normal for these medications to be left out while a patient is in active labor. She also explained that the drugs were not put away and stored in case of an emergency situation. Ms. Leland asserts that the birthing center was closed during the inspection because a patient was in labor; therefore, the medications were not accessible to unauthorized individuals. In fact, the only other people in the birthing center at the time were Patient I.M. and her mother, husband and sister, who were all adults and in the same room as Patient I.M., comforting her.

11. Ms. Leland also admits that no other clinical staff member was in the facility with her during Patient I.M.'s delivery. She explained that she attempted to call another midwife to assist with the delivery but that Ms. Hatcher said the other midwife would not be allowed to assist because she was not an employee of the birthing center. Ms. Leland testified that she tried to use her "call system" to have someone come in to assist with Patient I.M.'s delivery but Ms. Hatcher interfered with her efforts and insisted on conducting the inspection. Patient I.M. delivered her baby before a second staff member could arrive.

12. Lastly, Ms. Leland testified that the birthing center has two bathrooms that are utilized by patients and their guests. One bathroom is within the larger birthing room in the back of the facility, where Patient I.M. was laboring. The second bathroom is off the main hall. Ms. Leland explained that urine samples from patients who were seen the day before were left in the hall bathroom overnight. She stated the samples were saved because her testing strips did not appear to be functioning properly, and she planned to retest the samples for accuracy. The retesting was delayed when Patient I.M. went into labor, and there was another bathroom available for the patient and her family to use. Ms. Leland stated she eventually retested the urine samples. Other

than the urine sample cups, the bathrooms and other parts of the facility were clean and sanitary at the time of the inspection.

13. Dr. Warren Keith Stafford, a medical practitioner in Greer, South Carolina, also testified during the hearing. Dr. Stafford is the owner and primary physician at Cornerstone Family Medicine, the medical consultant for Blessed Birth. As part of the consultative services, Dr. Stafford meets with each patient, evaluates the overall health of the mother and baby, and prescribes medications needed for the patient during the pregnancy and labor. Ms. Leland also contacts him when something unusual arises during a patient's pregnancy. According to Dr. Stafford, there are four standard prescription medicines that are given to every patient, vitamin K for the baby, Erythromycin eye drops which is applied to the baby immediately after birth, and two others that are given to the mother to prevent, or in case of, complications. Dr. Stafford described the process used to issue written prescriptions to Respondent's patients.

14. Gwendolyn Thompson, Chief of the Department's Bureau of Health Facility Licensing, explained how the Department determined the amount of the monetary penalty assessed against Respondent. According to Ms. Thompson, factors considered in determining the penalty include potential impact on health, safety or welfare, efforts by the facility to correct conditions, history of compliance and other pertinent conditions. In this instance, the Respondent was cited with violating six provisions of Regulation 61-102. Specifically, Respondent was cited for violating subsections C.(3) and F.5(a), both of which are categorized as Class II violations; and for four Class I violations under subsections D.(3)(b), D.(3)(c), D.(3)(f), and D.(6)(d). S.C. Code Ann. Reg. 61-102 (2012). Class I violations and are the most severe. According to the monetary penalty guide shown in regulation 61-102's penalty provision, monetary penalties can range from $200 to $5000 for Class I violations, and from $100 to $5000 for Class II violations. In Respondent's case, the Department concluded that $2,200 was an appropriate monetary penalty for the violations found during the July 16, 2014 inspection.

LAW

Based upon the foregoing Findings of Fact, the Court concludes the following as a matter of law:

Jurisdiction.

Jurisdiction over this case is vested with the South Carolina Administrative Law Court pursuant to sections 1-23-310 et seq. of the South Carolina Code (2005 & Supp. 2014), section 1-

23-600(B) of the South Carolina Code (Supp. 2014), and section 44-89-90 of the South Carolina Code (2002).

The weight and credibility assigned to evidence presented at the hearing of a matter is within the province of the trier of fact. See S.C. Cable Television Ass'n v. S. Bell Tel. & Tel. Co., 308 S.C. 216, 222, 417 S.E.2d 586, 589 (1992). Furthermore, a trial judge who observes a witness is in the best position to judge the witness's demeanor and veracity and to evaluate the credibility of his testimony. See, e.g., Woodall v. Woodall, 322 S.C. 7, 10, 471 S.E.2d 154, 157 (1996); Wallace v. Milliken & Co., 300 S.C. 553, 556, 389 S.E.2d 448, 450 (Ct. App. 1990). The standard of proof in administrative proceedings is a preponderance of the evidence unless otherwise specified. Anonymous v. State Bd. of Med. Exam'rs, 329 S.C. 371, 375, 496 S.E.2d 17, 19 (1988).

Administrator's Alternate.

Respondent was cited by the Department for violating subsection C.(3) of regulation 61-102. Subsection C.(3) provides, in pertinent part:

> 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... *An individual shall be appointed to act in the absence of the administrator.*

S.C. Code Ann. Reg. 61-102 C.(3) (2012) (emphasis added).

Ms. Leland admits that the birthing center's Policy and Procedures Manual failed to identify the name of an individual who would act in the absence of the administrator. Respondent did provide the name of an individual who would serve as the administrator's alternate to the Department on October 14, 2014. Although Respondent remedied the problem following the inspection, the violation existed at the time of the inspection, and the Department was correct in citing Respondent with the violation.

Pharmaceutical Services.

The Department also cited Respondent for noncompliance with subsections D.(3)(b), D.(3)(c) and D.(3)(f) of regulation 61-102. These subsections each address pharmaceutical services provided by birthing centers. Subsection D.(3)(b) states "there shall be policies and procedures addressing the receiving, transcribing, and implementing of orders for administration of drugs." S.C. Code Ann. Reg. 61-102 D.(3)(b) (2012). Ms. Leland testified that the birthing center's policy manual has remained the same since Respondent originally applied for a birthing

center license with the Department fifteen years ago. Ms. Leland asserts that because the manual has not changed and the Department failed to identify a problem with the birthing center's medication policy during previous inspections it should be precluded from doing so now. The Court rejects this argument. Respondent also contends that the regulation does not specify what wording birthing centers are required to use in their policy manuals relative to the administration of drugs, and the topic was adequately addressed in its policy manual. After carefully reviewing the relevant section of Respondent's policy manual, this Court agrees with the Department that at the time of the inspection the Respondent's manual did not address the receiving, transcribing and implementing of orders for the administration of drugs. The Court notes that subsequent to being cited, Respondent amended its policy manual to include specific language addressing the administration of drugs.

Respondent was also cited for violating subsection D.(3)(c) which provides that "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." S.C. Code Ann. Reg. 61-102 D.(3)(c) (2012). As part of the July 16, 2014 inspection, Ms. Hatcher reviewed Patient K.D.'s medical file. Following the review, Ms. Hatcher determined that the birthing center administered Patient K.D. more medication than had been prescribed for her. Specifically, the file reflected that Patient K.D. was administered 3 mL Pitocin IM on May 28, 2014 while Respondent had a prescription or order for 2 mL Pitocin IM. Ms. Leland testified that the birthing center maintains some medications which are not prescribed for specific patients but are kept at the facility for emergencies, however, these medications are prescribed by Dr. Stafford, the birthing center's consulting physician. In Patient K.D.'s case, according to Ms. Leland, 1 mL Pitocin IM was administered as a life-saving measure and she did not provide the prescription or order to the Department because it was not requested. The Court finds Ms. Leland's testimony to be credible.

The Department also determined that Respondent violated subsection D.(3)(f) of Regulation 61-102, which states that "drugs, medications, and chemicals shall be stored and secured in specifically designated cabinets, closets, drawers, or storerooms and made accessible only to authorized persons." S.C. Code Ann. Reg. 61-102 D.(3)(f) (2012). Ms. Hatcher testified that during the July 16, 2014 inspection, she observed medications exposed and lying on a table in the hall birthing room. The door to the room was not locked or closed and some of the medication

had been previously opened and used. Medications observed by Ms. Hatcher included three unopened vials of Pitocin, Hespan, and Erythromycin ointment. The Hespan and Erythromycin appeared to have been previously used. Respondent's attorney explained in correspondence to the Department that the medications were for the patient that was in labor at the time of the inspection. However, Ms. Hatcher stated that the opened Erythromycin ointment, which is used for newborns, was observed prior to the delivery, and no prescription or order for Hespan was in the patient's file. Based on this testimony, the D.(3)(f) violation is sustained.

Clinical Staff.

On the day of the inspection, Ms. Hatcher arrived at the birthing center and found Ms. Leland caring for a patient in active labor. Ms. Hatcher testified that she was at the birthing center up to the time of the patient's delivery, and that Ms. Leland was the only clinical staff member present during the delivery. Based upon her observations, Ms. Hatcher cited the birthing center for non-compliance with subsection D.(6)(d) of regulation 61-102 which states "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." Ms. Leland admits that she was unable to secure a second clinical staff member during her patient's delivery. Therefore, the Department correctly cited Respondent for this violation.

Housekeeping.

Finally, the Department found that the birthing center violated subsection F.(5)(a) of regulation 61-102 by failing to maintain a clean and sanitary bathroom, free from odors and waste. Subsection F.(5)(a) reads:

> 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.

S.C. Code Ann. Reg. 61-102 (2012). Non-compliance with this subsection is a Class II violation.

When Ms. Hatcher inspected the facility's hall bathroom she found styrofoam cups containing urine samples. Some of the cups were labeled with patient names, dates and times, and Ms. Hatcher testified the urine samples emitted a "putrid odor." The Department cited Respondent for violation of subsection F.(5)(a). Ms. Leland explained that the urine samples were left in the

bathroom from the previous day because she intended to retest them for accuracy and had not had the opportunity to do so. The Court notes that other than the odor from the cups containing the urine samples, Ms. Hatcher did not testify, or include in her report, other observations that the bathroom was otherwise unclean or unsanitary. Given Ms. Leland's explanation for leaving the urine samples in the bathroom, and the fact that another bathroom was available to be used by the patient and her family, I find no violation in this instance.

Violation Classification Schedule and Penalties.

Subsection A.(3) of regulation 61-102 distinguishes between Class I and Class II violations:

> Class I violations are those which the Department determines present an imminent danger to the patients or other occupants of the facility or a substantial probability that death or serious physical harm could result therefrom... Class II violations are those, other than Class I violations, which the Department determines have a direct or immediate relationship to the health, safety or security of the facility's patients or other occupants.

S.C. Code Ann. Reg. 61-102 A.(3)(a) and (b) (2012).

This subsection also outlines the penalties associated with committing Class I and Class II violations. Specifically, "the Department may deny, suspend, or revoke licenses or assess a monetary penalty for violations of provisions of law or departmental regulations. The Department shall exercise discretion in arriving at its decision to take any of these actions." S.C. Code Ann. Reg. 61-102 A.(3)(e) (2012). In determining the penalty to apply, the Department considers: the specific conditions and their impact or potential impact on health, safety or welfare; efforts by the facility to correct; overall conditions; history of compliance; and any other pertinent conditions. Id.

A first offense Class I violation may be assessed a monetary penalty between two hundred dollars ($200.00) and one thousand dollars ($1,000.00), and a first offense Class II violation may be assessed a monetary penalty between one hundred dollars ($100.00) and five hundred dollars ($500.00). Respondent was cited by the Department for the commission of four (4) Class I violations and two (2) Class II violations, and assessed a monetary penalty totaling two thousand two hundred dollars ($2,200.00).

VIOLATIONS

I find that the credible evidence and testimony in this case supports a finding that Respondent committed three Class I violations. Specifically, on the date of the inspection, Respondent's policy and procedures manual did not address the receiving, transcribing, and implementing of orders for the administration of drugs, a violation of section D.(3)(b); Respondent violated section D.(3)(f) by failing to ensure that drugs and medications were stored and secured; and Respondent violated section D.(6)(d) by failing to ensure that two members of the clinical staff or one member and a registered nurse were present during a mother's delivery.

This Court also finds that Respondent committed one Class II violation. Specifically, Respondent violated section C.(3) by failing to have an individual appointed to act in the absence of the facility's administrator.

Because these are all first violations, and also considering the mitigating testimony, I find that a monetary penalty of $200 for each of the three Class I violations is appropriate, and a monetary penalty of $100 for the Class II violation is appropriate.

ORDER

Based upon the foregoing, it is hereby ordered that Respondent shall be assessed a monetary penalty of seven hundred dollars ($700.00) for violating subsections C.(3), D.(3)(b) and (f), and D.(6)(d) of regulation 61-102 of the South Carolina Code of Regulations (2012). This penalty must be paid to the Department within thirty (30) days from the date of this order.

AND IT IS SO ORDERED.

SHIRLEY C. ROBINSON
South Carolina Administrative Law Judge

January 7, 2016
Columbia, South Carolina

[illegible] ... the United States mail, postage paid, or in the interagency mail service addressed to the party(ies) or their attorney(s).
This 7 day of January 2016
By [illegible]