

THE STATE OF SOUTH CAROLINA
In the Court of Appeals

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APPEAL FROM THE ADMINISTRATIVE LAW COURT
Shirley C. Robinson, Administrative Law Judge

SC Court of Appeals

Appellate Case No. 2016-000190

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.

**RESPONDENT SOUTH CAROLINA DEPARTMENT
OF HEALTH AND ENVIRONMENTAL CONTROL'S
FINAL BRIEF**

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COUNTERSTATEMENT OF ISSUES PRESENTED

- I. WERE THE ADMINISTRATIVE LAW COURT'S (THE ALC) FINDINGS THAT BLESSED BIRTHS VIOLATED REGULATION 61-102 SECTIONS C.(3), D.(3)(B) AND -(F), AND D.(6)(D) SUPPORTED BY SUBSTANTIAL EVIDENCE?
- II. WERE THE ALC'S FINDINGS THAT BLESSED BIRTHS VIOLATED SECTIONS C.(3), D.(3)(B) AND -(F), AND D.(6)(D) AFFECTED BY AN ERROR OF LAW?

COUNTERSTATEMENT OF THE CASE

On February 13, 2015, Respondent South Carolina Department of Health and Environmental Control (the Department) mailed via certified mail, return receipt requested, an administrative order imposing a \$2,200.00 monetary penalty against Appellant Blessed Births, Inc. (Blessed Births), based upon six violations of *Standards for Licensing Birthing Centers for Deliveries by Midwives*, 8 S.C. Code Ann. Regs. 61-102 (2012). On February 23, 2015, Blessed Births filed a written request for final review with the Board of Health and Environmental Control (the Board). On March 18, 2015, the Board mailed notice of its decision not to conduct a final review conference and, on March 25, 2015, Blessed Births filed a Request for a Contested Case Hearing with the ALC.

A contested case hearing was held before the Honorable Shirley C. Robinson at the ALC on October 21, 2015. On January 7, 2016, the ALC filed its Final Decision and Order that upheld four of the six violations cited by the Department and imposed a \$700.00 monetary penalty. On February 1, 2016, Blessed Births served its Notice of Appeal on the Department.

COUNTERSTATEMENT OF FACTS

Blessed Births is the licensee of Blessed Births Family Wellness and Birth Center, a licensed birthing center in Greenville, South Carolina. (R. p. 7, lines 8-11; R. p. 197, line

19 – p. 198, line 15). The Department is the state agency responsible for administering the *Birthing Center Licensure Act*, S.C. Code Ann. Sections 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). (R. p. 7, lines 2-8).

In regulating birthing centers, the Department conducts unannounced inspections and investigations. (R. p. 38, line 17 – p. 40, line 14). On July 11, 2014, Department representatives attempted to conduct a routine inspection and complaint investigation of Blessed Births, but the facility was closed, and Blessed Births' administrator refused to come to the facility to allow the inspection. (R. p. 45, line 18 – p. 48, line 17). To ensure access on the next visit, Department representatives obtained an administrative search warrant. (R. p. 51, line 17 – p. 52, line 15). On July 16, 2014, the Department executed the warrant and conducted the routine inspection and complaint investigation. (R. p. 54, lines 3-10; App. pp. 11-19). Based upon observations made and evidence gathered, the Department issued reports of visit that described the cited violations of Regulation 61-102 and requested Blessed Births submit plans of corrections to the cited violations. (R. p. 57, line 1 – p. 58, line 8; R. p. 103, line 17 – p. 104, line 7; App. pp. 11-19).

The Department cited Blessed Births for violating Regulation 61-102 Section C.(3). (R. p. 59, lines 9-13; App. pp. 13). Section C.(3) provides:

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.*

(Emphasis added). On previous visits, Blessed Births' policy and procedures manual named the individual appointed to act in the absence of the administrator; however, the manual reviewed on July 16, 2014, had a blank in the spot that previously indicated the

individual who would act in the absence of the administrator. (R. p. 60, line 21 – p. 62, line 13; App. p. 23). When Blessed Births' administrator was asked for the person to act in her absence, she indicated she could not tell the Department inspector and needed to speak with her attorney. (R. p. 60, lines 12-16). Blessed Births submitted an August 18, 2014 letter responding to the Section C.(3) citation where it explained the person previously appointed to act in the absence of the administrator was no longer employed, and the new individual's name had not been inserted into the manual. (R. p. 62, line 24 – p. 64, line 22; App. p. 50). Blessed Births, however, did not indicate the new individual's name, and the manual attached to the letter did not name the new individual. (R. p. 64, lines 20-22; App. pp. 57). In a letter dated September 26, 2014, the Department requested the name of the new individual. (R. p. 66, lines 15-25; App. p. 63). Nearly three months after the July 16, 2014 visit, Blessed Births identified the individual appointed to act in the absence of the administrator in a letter dated October 14, 2014. (R. p. 67, line 3 – p. 68, line 4; App. p. 72). At trial, Blessed Births' administrator admitted to not having an individual appointed to act in her absence on July 16, 2014. (R. p. 200, line 24 – p. 201, line 5).

The Department also cited Blessed Births for violating Regulation 61-102 Section D.(3)(b). (R. p. 105, lines 4-7; App. p. 18). Section D.(3)(b) states, "There shall be policies and procedures addressing the receiving, transcribing, and implementing of orders for administration of drugs." Blessed Births' policy and procedure manual did not address the receiving, transcribing, and implementing of orders for administration of drugs. (R. p. 105, line 13 – p. 107, line 19; App. pp. 20-28). In its August 18, 2014 letter, Blessed Births explained that its manual remained unchanged since opening, but did not explain how or

where the manual addressed the receipt, transcription, and implementation of orders for administration of drugs. (R. p. 108, line 3 – p. 109, line 2; App. pp. 40 and 54-61). In a letter dated September 26, 2014, the Department asked Blessed Births to direct it to the applicable provisions of its manual that demonstrate compliance with Section D.(3)(b). (R. p. 109, line 3 – p. 110, line 12; App. p. 63). Blessed Births did not comply with the request. (R. p. 110, lines 13-22).

The Department additionally cited Blessed Births for violating Regulation 61-102 Section D.(3)(f). (R. p. 68, lines 5-9; App. p. 13). Section D.(3)(f) requires drugs and medications “be stored and secured in specifically designated cabinets, closets, drawers, or storerooms and made accessible only to authorized persons.” On the July 16, 2014 visit, the Department inspector observed on the table in the unlocked and opened hall birthing room three vials of Pitocin, an opened and expended single-use tube of Erythromycin ointment, and a bag of HeSpan intravenous fluids. (R. p. 68, lines 15-23; R. p. 71, line 21 – p. 73, line 17). The patient in labor and her family members were present in a separate birthing room. (R. p. 68, line 25 – p. 70, line 18; R. p. 210, lines 11-20). When asked about the unsecured medications, Blessed Births’ administrator indicated the medications were from a delivery that occurred the day before and she did not have a chance to clean them up. (R. p. 79, lines 12-20; R. p. 154, lines 19-21). In its August 18, 2014 letter, Blessed Births changed its position and indicated the medications were being used or were contemplated for use for the patient in labor. (R. p. 80, lines 10-25; App. pp. 50-51). While the patient was prescribed Pitocin, she was only prescribed two ampules, not three. (R. p. 82, line 23 – p. 83, line 5; App. p. 37). The patient was not prescribed HeSpan. (R. p. 83, lines 22-23; App. p. 37). Further, the Department inspector observed the opened and

expended single-use tube of Erythromycin ointment prior to the delivery of the newborn. (R. p. 78, line 19 – p. 79, line 11; R. p. 84, lines 1-5). Erythromycin is administered to newborns. (R. p. 72, lines 14-19).

Finally, the Department cited Blessed Births for violating Regulation 61-102 Section D.(6)(d). (R. p. 84, lines 6-10; App. p. 14). Section D.(6)(d) 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.

(Emphasis added). Blessed Births admitted to not having two staff members of the clinical staff or one member of the clinical staff and a registered nurse present during the patient's delivery on July 16, 2014. (R. p. 93, lines 4-13; App. p. 75). Blessed Births' administrator was the only facility staff member present during the patient's delivery. (R. p. 90, line 20 – p. 91, line 2). Blessed Births' administrator attempted to find a second clinical staff member or registered nurse, but was unsuccessful. (R. p. 91, line 19 – p. 92, line 2; R. p. 214, line 21 – p. 215, line 10; App. p. 51).

The Department issued its administrative order on February 13, 2015, which included the above-described cited violations and two other cited violations. (R. p. 189, line 12 – p. 193, line 25; App. pp. 1-10). The ALC agreed with the Department regarding the above-described citations and imposed a \$700.00 monetary penalty. (R. p. 255). The ALC disagreed with the Department with regards to the remaining two citations (Sections D.(3)(c) and F.(5)(a)) that served as grounds for the Department's administrative order. (R. pp. 252-255).

STANDARD OF REVIEW

This appeal is governed by the South Carolina Administrative Procedures Act (the APA), S.C. Code Ann. Sections 1-23-310 *et seq.* (2005 and Supp. 2015). *See Murphy v. S.C. Dep't of Health & Envtl. Control*, 396 S.C. 633, 639, 723 S.E.2d 191, 194 (2012). Pursuant to the APA, an appellate court may only reverse or modify a final decision of the ALC if the petitioner's substantive rights have been prejudiced because the ALC's decision is:

- (a) in violation of constitutional or statutory provisions;
- (b) in excess of the statutory authority of the agency;
- (c) made upon unlawful procedure;
- (d) affected by other error of law;
- (e) clearly erroneous in view of the reliable, probative and substantial evidence on the whole record; or
- (f) arbitrary or capricious or characterized by abuse of discretion or clearly unwarranted exercise of discretion.

S.C. Code Ann. § 1-23-610(B) (Supp. 2015).

ARGUMENT

I. SUBSTANTIAL EVIDENCE IN THE RECORD SUPPORTS THE ALC'S FINDINGS THAT BLESSED BIRTHS VIOLATED SECTIONS C.(3), D.(3)(B) AND -(F), AND D.(6)(D).

In its brief, Blessed Births cites bits and pieces of the record supporting its side of the facts and characterizes the Department's inspection and enforcement practices as petty and unfair. The record in this matter is replete with evidence supporting the findings of the Department and the ALC that Blessed Births violated Regulation 61-102 Sections C.(3), D.(3)(b) and -(f), and D.(6)(d).

The ALC is the sole finder of fact in contested cases pursuant to the APA, and an appellate court's review is limited to determining whether the findings were supported by substantial evidence or were controlled by an error of law. *Mauil v. S.C. Dep't of Health*

& Envtl. Control, 411 S.C. 349, 358, 768 S.E.2d 402, 407 (Ct. App. 2015). Further, the appellate court may not substitute its judgment for that of the ALC as to the weight of the evidence on questions of fact unless the findings are clearly erroneous in view of the reliable, probative, and substantial evidence in the record. *Bailey v. S.C. Dep't of Health & Envtl. Control*, 388 S.C. 1, 5, 693 S.E.2d 426, 429 (Ct. App. 2010). "Substantial evidence is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *S.C. Dep't of Mental Retardation v. Glenn*, 291 S.C. 279, 281, 353 S.E.2d 284, 286 (1987). It "is not a mere scintilla of evidence, but evidence which, considering the record as a whole, would allow reasonable minds to reach the conclusion the agency reached." *Converse Power Corp. v. S.C. Dep't of Health & Envtl. Control*, 350 S.C. 39, 46, 564 S.E.2d 341, 345 (Ct. App. 2002).

As explained in greater detail in the above counterstatement of the facts, the ALC's findings that Blessed Births violated Regulation 61-102 Sections C.(3), D.(3)(b) and -(f), and D.(6)(d) are supported by substantial evidence when considering the record as a whole. Regarding Section C.(3), Blessed Births' administrator admitted at trial to not having an individual to act in her absence as of July 16, 2014. (R. p. 200, line 24 – p. 201, line 5). Regarding Section D.(3)(b), Blessed Births' policies and procedure manual, which was admitted into evidence, simply fails to address the receipt, transcription, and implementation of orders for administration of drugs. (R. p. 105, line 13 – p. 107, line 19; App. pp. 20-28). Regarding Section D.(3)(f), the Department inspector observed medications unsecured and accessible in a birthing room not currently being utilized by Blessed Births. (R. p. 68, line 16 – p. 71, line 20). After initially indicating the medications were from a previous delivery, Blessed Births contended the medications were for the

patient in labor on July 16, 2014. (R. p. 79, line 12 – p. 80, line 25; R. p. 154, lines 19-21; App. pp. 50-51). However, the observed medications did not correspond to the medications prescribed to that patient and the timing of that patient’s delivery. (R. p. 82, line 23 – p. 84, line 5; App. p. 37). Finally, regarding Section D.(6)(d), Blessed Births’ administrator attempted, but was unsuccessful in obtaining the presence of a second clinical staff member or registered nurse for the patient’s delivery. (R. p. 90, line 20 – p. 92, line 2; R. p. 214, line 21 – p. 215, line 10; App. p. 75). When considering the record, reasonable minds would support the ALC’s conclusions that Blessed Births violated Sections C.(3), D.(3)(b) and –(f), and D.(6)(d).

II. THE ALC’S FINDINGS THAT BLESSED BIRTHS VIOLATED SECTIONS C.(3), D.(3)(B) AND –(F), AND D.(6)(D) ARE NOT AFFECTED BY ANY ERROR OF LAW.

a. The Department was not estopped from citing Blessed Births with violating Section D.(3)(b).

Blessed Births argues the Department is estopped from citing a violation of Section D.(3)(b) based upon the Department’s failure to cite Blessed Births on previous inspections. (Appellant’s Br. p. 5). “To prove estoppel against the government, the relying party must prove: (1) the lack of knowledge and of the means of knowledge of the truth of the facts in question; (2) justifiable reliance upon the government’s conduct; and (3) a prejudicial change in position.” *S.C. Dep’t of Transp. v. Horry Cty.*, 391 S.C. 76, 83, 705 S.E.2d 21, 25 (2011). “As a general rule, estoppel does not lie against the government to prevent the due exercise of its police power or to thwart the application of public policy.” *Id.* Further, the government cannot be estopped by the unauthorized or erroneous conduct or statements of its officers or agents which have been relied on by a third party to his

detriment. *S.C. Coastal Council v. Vogel*, 292 S.C. 449, 453, 357 S.E.2d 187, 189 (Ct. App. 1987). Blessed Births failed to carry its burden of proving estoppel.

Notably, there is no evidence in the record indicating a Department representative, whether authorized or unauthorized, affirmatively approved the contents of Blessed Births' policy and procedure manual. The Department simply had not cited Blessed Births for violating Section D.(3)(b) before the July 16, 2014 visit. At all times, Blessed Births was aware of the requirements of Section D.(3)(b) and the contents, or lack thereof, of its manual.

Even if there was some form of Departmental approval of its manual, Blessed Births would not be reasonable in relying upon the erroneous approval. *See Vogel*, 292 S.C. 449 (where the Court of Appeals found the Coastal Council was not estopped from requiring removal of a deck due to a Council planner's alleged representation to landowners that a permit was unnecessary, where the planner had no authority to make the alleged representation and where the alleged statement was erroneous). As explained in the Final Decision and Order, the manual simply does not contain the contents required by Section D.(3)(b). (R. p. 252). Under Blessed Births' line of reasoning, the Department would be precluded from citing it for noncompliance on issues that the Department had already inspected, regardless of whether the Department was mistaken in failing to initially cite. This is unreasonable. Estoppel does not apply to prevent the Department from citing Blessed Births for violating Section D.(3)(b), a function of the Department's police power of protecting and promoting public health and safety.

b. The Department's and the ALC's interpretations of Section D.(3)(f) are reasonable and not affected by an error of law.

Blessed Births argues, "It is beyond pale to interpret [Section D.(3)(f)] as requiring that the drugs and medications necessary for the delivery of the child and the safety of the mother and child remain secured while the [patient] procedure is ongoing." (Appellant's Br. p. 6). The Department agrees and the ALC's findings are in accordance with this interpretation of Section D.(3)(f). Medications for patients in labor certainly must be readily accessible. The record, however, indicates the observed medications were not being used or contemplated for use by Blessed Births for the patient in labor.

The observed medications were in a separate unlocked birthing room from where the patient in labor was being treated. (R. p. 68, line 18 – p. 70, line 18; R. p. 71, line 5 – p. 72, line 5). Blessed Births' administrator initially explained to the Department representative that the medications were from a previous delivery and she did not have the opportunity to clean them up. (R. p. 79, lines 12-20; R. p. 154, lines 19-21). The patient in labor did not have prescriptions for all of the observed medications. (R. p. 82, line 23 – p. 83, line 5; App. p. 37). Finally, the Department inspector observed the opened and expended single-use tube of Erythromycin ointment, which is administered to a newborn, prior to delivery of the newborn. (R. p. 78, line 19 – p. 79, line 11; R. p. 84, lines 1-5). Substantial evidence in the record establishes that the medications were not being used for the patient in labor and, thus, needed to be "stored and secured in specifically designated cabinets, closets, drawers, or storerooms and made accessible only to authorized persons", as required by Section D.(3)(f). Blessed Births failed to properly store and secure the medications.

- c. The Department inspector does not constitute a member of the clinical staff or a registered nurse for purposes of determining compliance with Section D.(6)(d).**

Blessed Births argues it was in compliance with Section D.(6)(d) because its administrator and the Department inspector, a registered nurse, were present during the patient's July 16, 2014 delivery. (Appellant's Br. p. 7). This interpretation is in conflict with the personnel requirements for licensed birthing centers and overlooks the intent of Section D.(6)(d).

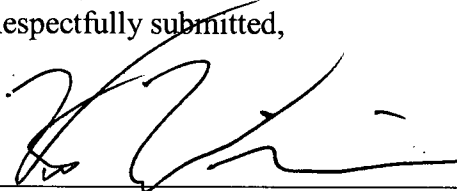
Regulation 61-102 Section C.(5) includes a number of personnel requirements for birthing centers. "Clinical staff" is defined to mean "physicians, certified nurse midwives and lay midwives appointed by the governing authority to practice within the birthing center and governed by rules approved by the governing body." 8 S.C. Code Ann. Regs. 61-102 § A.(1)(f). "Personnel" is defined to mean "individual(s) in training and/or employed by the birthing center." *Id.* § A.(1)(n). The Department inspector was not a member of Blessed Births' "clinical staff" or "personnel." The Department inspector was at Blessed Births in her capacity as an inspector, not a Blessed Births caregiver.

The second caregiver requirement of Section D.(6)(d) seeks to ensure birthing center patients receive adequate care and treatment from two capable caregivers. Should a center encounter an emergency or unexpected event, two caregivers should be able to more appropriately respond and provide care to the patient than only one. The technical application of Section D.(6)(d) advocated for by Blessed Births should not be upheld by the Court. Blessed Births failed to procure an appropriate second person to attend the patient's delivery and, thus, violated Section D.(6)(d).

CONCLUSION

For the foregoing reasons, the Department respectfully requests that the Court of Appeals affirm the ALC's January 7, 2016 Final Decision and Order.

Respectfully submitted,



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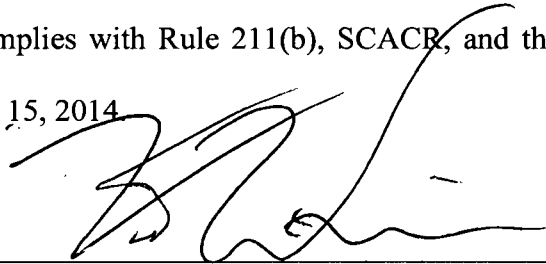
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Blessed Births, Inc., d/b/a Blessed Births
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Appellant.

CERTIFICATE OF COUNSEL

The undersigned certifies that the final Brief of Respondent South Carolina Department of Health and Environmental Control complies with Rule 211(b), SCACR, and the South Carolina Supreme Court Order of April 15, 2014.



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