

STATE OF FLORIDA  
DIVISION OF ADMINISTRATIVE HEARINGS

SOUTHERN BAPTIST HOSPITAL OF  
FLORIDA, INC., d/b/a WOLFSON  
CHILDREN'S HOSPITAL,

Petitioner,

vs.

Case No. 17-3200

DEPARTMENT OF HEALTH,

Respondent.

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RECOMMENDED ORDER

Pursuant to notice to all parties, a final hearing was held in this case before the Honorable R. Bruce McKibben, Administrative Law Judge, on September 19 and 29, 2017, in Tallahassee, Florida. The purpose of the final hearing was to conduct a de novo review of the evidence.

APPEARANCES

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STATEMENT OF THE ISSUE

The issue in this case is whether an application filed by Petitioner, Southern Baptist Hospital of Florida, Inc. d/b/a Wolfson Children's Hospital ("Wolfson"), to operate a pediatric trauma center should be approved.

PRELIMINARY STATEMENT

Wolfson filed its application on March 31, 2017. It was reviewed by Respondent, Department of Health ("DOH" or the "Department") to ascertain whether the application satisfied certain critical elements. Finding that the application did not satisfy those elements, even after the submission of additions and corrections, DOH denied the application. Wolfson timely filed a request for formal administrative hearing to contest the Department's decision.

At the final hearing, Wolfson called three witnesses: Michael Aubin, president of Wolfson, accepted as an expert in the administration of a children's hospital, including development and administration of pediatric trauma centers; Nicholas Dean Poulos, M.D., accepted as an expert in trauma services and quality of care; and Pamela Pieper, senior consultant, accepted as an expert in trauma program management. Wolfson's Exhibits 1 through 14 were admitted into evidence. The Department called one witness: Cindy Dick, assistant deputy secretary and interim director for emergency preparedness. The

Department's Exhibits 1 and 2 were admitted, along with Joint Exhibits 1 through 3.

A transcript of the final hearing was ordered. By rule, parties are allowed 10 days after filing of the transcript at DOAH to submit proposed recommended orders ("PROs"). The Transcript was filed on October 16, 2017; PROs were due on or before October 26, 2016. Each party timely filed its PRO and each was considered in the preparation of this Recommended Order.

#### FINDINGS OF FACT

The following findings of fact are derived from the stipulation of the parties, the admitted exhibits, and the testimony at final hearing.

1. DOH is the state agency responsible for, inter alia, the review and approval (or denial) of applications to operate trauma centers, including pediatric trauma centers. DOH denied the trauma center application filed by Wolfson, not due to an absence of need in the area, but due to Wolfson's failure to comply with some requirements set forth in the application.

2. Wolfson is a 216-bed not-for-profit children's hospital located in Jacksonville, Duval County, Florida. It is part of the Baptist Health organization and is one of three hospitals operated under that entity's license. Wolfson is located on the same campus as Baptist Medical Center - Jacksonville. The two hospitals share a pharmacy which is located in the children's

hospital and a laboratory located in the adult hospital, but no other services or staff.

3. Interestingly, Wolfson was developed by the sons of Morris Wolfson, a Jewish immigrant to the United States. One of Mr. Wolfson's children had died at an early age due to lack of access to health care services. Later in his life, after acquiring a small fortune from his business, Mr. Wolfson asked his five remaining sons to develop a children's hospital accessible to every child, regardless of race, creed, or religious affiliation. By 1951 the sons had raised over half a million dollars and were prepared to construct a hospital. They approached the Baptists, who agreed to build the children's hospital as part of their development of Baptist Hospital. In 1955, Mr. Wolfson's dream became a reality.

4. Wolfson provides a wide range of services to children, including but not limited to: two neonatal intensive care units; cardiac catheterization; open heart surgery; bone marrow transplants; and extracorporeal membrane oxygenation, a less complex bypass procedure.

5. There is an emergency department at Wolfson. It receives approximately 60,000 patients per year. Wolfson also operates three satellite emergency departments and has three mobile ICUs (known as "Kids Kare" mobile units).

6. Wolfson's service area is quite large, comprised of a triangle identified by the vertices of Savannah, Georgia - Dothan, Alabama - and Daytona Beach, Florida. About ninety percent of Wolfson's patients come from within that area.

7. There is not currently a pediatric trauma center in Jacksonville, which is located in Trauma Service Area ("TSA") 5. There are five counties in TSA 5: Duval, Baker, Clay, Nassau, and St. Johns. The closest pediatric trauma center to Jacksonville is located in Gainesville, Alachua County, Florida, some 60 miles away. There is a Level II trauma center located at UF Health Jacksonville, but it is not specifically for pediatrics. There are differences in the provision of care to pediatric patients versus adult trauma patients, including specialized equipment, age-appropriate drugs, and modified procedures.

8. Pediatric trauma patients from TSA 5 must be transported to UF Health Jacksonville or Shands in Gainesville. Some of those patients are designated as "trauma alert patients." Those are individuals identified by emergency medical services as requiring immediate, high-level treatment by skilled professionals. Not all trauma patients are trauma alert patients.

9. Once a pediatric trauma patient has been stabilized at UF Health Jacksonville or Shands, the patient can be transferred

to Wolfson for further treatment. Wolfson then undertakes the care needed by the patient. UF Health Jacksonville transfers about 20 to 30 pediatric trauma patients per month to Wolfson. Not all of those patients have previously been deemed trauma alert patients, but Wolfson has extensive experience treating patients with significant needs.

10. It is Wolfson's desire to operate its own pediatric trauma center, thereby obviating the need for a trauma patient to first go to UF Health Jacksonville or Shands before being transferred. There are times when a delay in transfer can have negative consequences for the patient. The number of such occurrences was not quantified by Wolfson, but Wolfson considers it a significant problem.

11. There is, by rule, a very precise process for a hospital to obtain verification as a trauma center. There are three stages to the process: provisional review, in-depth review, and site visit. Hospitals are given only one opportunity each year to apply for verification. In order to apply, a hospital must file a letter of intent ("LOI") between September 1 and October 1. On or before October 15, the Department sends an application package to each hospital which had timely submitted an LOI. After receiving the application package, a hospital has until April 1 of the following year to complete and submit the application. DOH must complete its

provisional review of the application and notify the applicant, by April 15, of any deficiencies which should be addressed. The hospital then has five business days to submit clarifying or corrective information. In accordance with this process, Wolfson timely filed its application to operate a pediatric trauma center.

12. By rule, the application must contain responses and support relating to nineteen "critical elements" related to trauma care. The Department then reviews the application to make sure that all minimum standards for approval have been met. An applicant is not required to necessarily satisfy each element or subpart of a standard in order for it to be approved by the Department. However, failure to comply with a critical element overall can result in denial of the application. The initial review of an application by the Department is extremely important because, if provisionally approved, the applicant can immediately commence operating as a trauma center.

13. In the present case, Wolfson's application was reviewed by two persons under contract with the Department: Dr. Robert Reed and Susan Cox, RN. The Department deems each of those persons to be an expert in the field of trauma care based on their background and training. The provisional review by the reviewers was for the purpose of determining whether the application was complete and whether the hospital satisfied the

critical elements required for a trauma center. After completion of their initial review, the reviewers sent a letter to Wolfson identifying certain deficiencies they had found in the application.

14. There were a number of deficiencies identified by Dr. Reed and Nurse Cox in Wolfson's application. However, the most important of those (and the ones at issue in this proceeding) were as follows: Standard II.B.1.b relates to trauma-related continuing medical education ("CME") requirements for emergency physicians; Standard XVII relates to required multidisciplinary conferences which must be held throughout the year; and Standard XVIII addresses Quality Management a/k/a Quality Improvement ("QI"), also referred to as Performance Improvement.

15. Wolfson was given an opportunity to address each of the stated deficiencies and did, in fact, submit some additional information. Despite the additional information, Wolfson's application was still deemed insufficient and was denied.

16. The Department now concedes that the CME standard was satisfied in Wolfson's application. The same is true for the standard relating to multidisciplinary conferences.

17. The QI standard (Standard XVIII), however, remains in dispute. DOH contends that the information submitted by Wolfson in its initial application and deficiency response falls short



of proving compliance with this critical element. The QI standard requires a system of procedures and protocols that will promote performance improvement while maintaining patient safety. The goal is to establish processes to ensure a hospital is continually improving the quality of care provided. The subparts of the QI standard require detailed demonstrations of various processes, including:

A.2 - A clearly defined performance improvement program for the trauma population;

B.1 - Review of all trauma patient records from five specified categories;

B.2 - Monitoring of six indicators relevant to the respective facility (which are in addition to four state-mandated indicators);

B.3 - Review of cases relevant to the six indicators by the trauma medical director ("TMD") and trauma program director ("TPD"), to decide whether the cases should be referred to the quality management committee ("QMC").

B.5 - Evaluation by QMC of the effectiveness of action taken to ensure problem resolution;

G - Preparation and submittal of a quarterly report showing which cases have been selected for corrective action; and

H - Maintenance of an in-hospital trauma registry with information on patients being treated.

18. The gist of Wolfson's QI program is set forth on a flow chart contained in the application. That chart is

entitled, "Trauma PI Process: Levels of Review." Though not explained at final hearing, the "PI" in the chart is presumably "Performance Improvement." The flow chart indicates there to be a primary (daily) review, a secondary (weekly) review, and a tertiary (monthly) review involving certain designated persons. In each of the "boxes" for the respective reviews, there is a stated purpose for the review. For the primary review, the purpose is stated as: Identification of opportunities for Improvement/Validation. The secondary review's purpose is: Adverse Event/Audit Filter Review. And the purpose of the tertiary review is: Peer Review/Accountability Determination, Loop Closure Plan, Trended Data Review.

19. Phases of care identified in the flow chart are: Pre-hospital, Resuscitation, Inpatient Care Review, and Readmission Review. There is a list of "actions" in the flow chart: Education; Counseling; Trend Report; Guidance/Policy/Protocol Development; and Hospital PI Project. From that list, there is an arrow pointing back toward the primary review box.

20. There is no narrative in the flow chart to explain how the various boxes interconnect or how the information therein ties to the requirements as outlined in the application form. Wolfson asserts that all relevant information is contained in the flow chart, whether in narrative form or not. There is also additional information in the application, attached as a "Scope

of Services" addendum, which further elucidates what is found in the flow chart. The Department deems the flow chart and scope of services information insufficient for determining whether the proposal satisfies the critical elements.

21. Wolfson says the flow chart is a "clearly defined performance improvement program." It is, in fact, only an outline of a clearly defined program. The testimony provided at final hearing by Wolfson's TPM explained how that outline would work to improve performance. With that explanation, the flow chart/scope of service information minimally satisfies this critical element of the application.

22. Wolfson maintains that the information provided supports the requirement for review of all records from five specified categories, i.e., all trauma alert cases, critical or ICU admissions, operating room admissions for traumatic injury, critical trauma transfers, and in-hospital deaths. Upon review of the flow chart there is insufficient evidence concerning those five areas. However, the scope of information addendum at least minimally refers to those areas as part of the review process.

23. The flow chart/scope of service information addresses the four state-required indicators. The other six indicators required in the application are listed as "to be determined by the [Quality Management] committee." Wolfson points out that in

the minutes from a QMC meeting in February (which was included in the application), nine additional indicators are listed. So, although not easily found, the application does provide sufficient response to the required element.

24. The application is also supposed to identify cases relevant to the six selected indicators in order to determine whether any of those cases should be referred to the QMC. The determination to refer cases is followed up by an evaluation of the effectiveness of actions taken by the committee. The flow chart can be interpreted to address this requirement, but it is fairly nebulous. The scope of services information provides some additional support, but only in general terms.

25. The required quarterly reports are supposed to show which cases have been selected for corrective action by the committee. Wolfson asserts that it cannot submit any such reports until it is operating as a pediatric trauma center, i.e., until it actually has patient cases to report. That position is plausible. The Department did not provide any evidence as to how other applicants satisfied this requirement, so Wolfson's position cannot be measured against other providers.<sup>1/</sup>

26. The same is true as to the requirement for an in-hospital registry of information concerning patients who are being treated. Wolfson has purchased the software needed to

commence its registry once patients are being admitted, but it cannot do so at this time, again because it has no such patients.

27. All things considered, Wolfson's application was not a superlative response to the question of its abilities, but it at least minimally met the requirements for approval of a provisional license. Considering, de novo, all of the evidence concerning Wolfson's proposed trauma center operations, the application is complete.

28. Wolfson provided extensive testimony and evidence as to the need for a pediatric trauma center in the service area and its willingness and ability to meet that need. There is no doubt that, if approved, the pediatric trauma center would be beneficial to the area. However, need was not an issue in the proceeding.

#### CONCLUSIONS OF LAW

29. The Division of Administrative Hearings has jurisdiction over the parties to and the subject matter of this proceeding. §§ 120.569, 120.57(1), and 395.4025(7), Fla. Stat. Unless specifically stated otherwise herein, all references to Florida Statutes are to the 2017 version.

30. Wolfson, as the party asserting the affirmative of the issue, has the burden of proving whether it substantially complied with all of the critical elements of the application,

and that its application should be approved. Fla. Dep't of Transp. v. J.W.C. Co., 396, So. 2d 778, 787 (Fla. 1st DCA 1981). Findings of fact are to be based on the preponderance of evidence standard. § 120.57(1)(j), Fla. Stat.

31. Pursuant to section 120.57(1)(k), this is a de novo proceeding. As such, the hearing is for the purpose of formulating agency action rather than reviewing what the agency has already decided. Boca Raton Artificial Kidney Ctr., Inc. v. Dep't of HRS, 475 So. 2d 260, 262 (Fla. 1st DCA 1985).

32. This case addresses whether Wolfson's application to operate a provisional pediatric trauma center should be approved, i.e., whether Wolfson has met the critical elements required for a trauma center. Wolfson must therefore show that its application is in substantial compliance with the requirements of section 395.4025. Substantial compliance is important because, if the application is deemed so, Wolfson may immediately engage in treatment of trauma patients.

33. Neither the trauma rules nor the statutes define "substantial compliance" in the context of trauma center applications. The plain meaning of the words is that Wolfson's responses to the application questions amply covered the information requested. As shown above, while the responses were in some cases minimal and elusive, Wolfson was substantially in compliance with all elements.

RECOMMENDATION

Based on the foregoing Findings of Fact and Conclusions of Law, it is RECOMMENDED that Respondent, Department of Health, enter a Final Order approving the pediatric trauma center application filed by Petitioner, Southern Baptist Hospital of Florida, Inc. d/b/a Wolfson Children's Hospital.

DONE AND ENTERED this 14th day of November, 2017, in Tallahassee, Leon County, Florida.



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R. BRUCE MCKIBBEN  
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Filed with the Clerk of the  
Division of Administrative Hearings  
this 14th day of November, 2017.

ENDNOTE

<sup>1/</sup> In fact, the Agency provided no direct evidence concerning how the hired consultants reviewed Wolfson's application, how much time they spent, how in-depth their review was, or whether they even reviewed the entire application. Rather, Ms. Dick formulated her position on the application solely upon what she had been provided by the consultants. While her testimony was given due consideration based on her current position and past experience, it was insufficient to rebut Wolfson's statements concerning the application content.

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NOTICE OF RIGHT TO SUBMIT EXCEPTIONS

All parties have the right to submit written exceptions within 15 days from the date of this Recommended Order. Any exceptions to this Recommended Order should be filed with the agency that will issue the Final Order in this case.