

**STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT**

Lexington County Health Services District,)
 Inc., d/b/a Lexington Medical Center,)
)
 Petitioner,)
 vs.)
)
 South Carolina Department of Health and)
 Environmental Control; Sisters of Charity)
 Providence Hospital; and Palmetto Health)
 Alliance, Palmetto Health Richland,)
)
 Respondents.)

**FINAL ORDER AND DECISION
DOCKET NO. 04-ALJ-07-0365-CC**

APPEARANCES:

David B. Summer, Jr., Esquire
Faye A. Flowers, Esquire
For Petitioner Lexington Medical Center

Nancy S. Layman, Esquire
Ashley C. Biggers, Esquire
For Respondent South Carolina Department of
Health and Environmental Control

James G. Long, III, Esquire
Philip Wesley Jackson, II, Esquire
For Respondent Providence Hospital

M. Elizabeth Crum, Esquire
Ariail B. Kirk, Esquire
Pamela A. Baker, Esquire
For Respondent Palmetto Health Richland

STATEMENT OF THE CASE

The above-captioned matter comes before this Court upon the request of Petitioner Lexington County Health Services District, Inc., d/b/a Lexington Medical Center ("LMC"), for a contested case hearing to challenge the decision of Respondent South Carolina Department of Health and Environmental Control ("DHEC" or "Department") to deny its application for a Certificate of Need

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(CON) for the development of an open-heart surgery program and therapeutic cardiac catheterization program at its hospital in West Columbia, South Carolina. The Department denied LMC's CON application based upon its finding that the implementation of LMC's proposed cardiac program would result in an unnecessary duplication of such services in the Midlands and would have an undue adverse impact upon existing providers of cardiac services in the area. Two of those existing providers, Respondents Sisters of Charity Providence Hospital ("Providence") and Palmetto Health Alliance, Palmetto Health Richland ("Palmetto"), intervened in this matter in support of the Department's decision to deny LMC's CON application.

Prior to a hearing on the merits of this matter, the parties conducted extensive discovery, generating some 30,000 pages of documents and deposing over 40 individuals, and this Court heard a number of motions on discovery issues and other preliminary matters. After timely notice to the parties, a contested case hearing on the merits of this case was held from February 13, 2006, through March 10, 2006, for a total of sixteen days of trial. During the hearing, all four parties presented witnesses and offered exhibits in support of their respective positions. A total of twenty-two witnesses testified at the hearing, and the Court admitted seventy-seven exhibits into evidence, in addition to receiving two proffers of evidence. The following witnesses were designated as experts in the following areas of specialization: Dr. James Morris and Dr. Reid Tribble in the area of Cardiovascular and Open-Heart Surgery; Dr. Edward Leppard in the area of Cardiovascular Surgery; Dr. Leon Khoury, Dr. Stan Juk, Dr. Barry Feldman, and Dr. Myron Bell in the field of Cardiology; Dr. Richard Boyer in the area of Emergency Medicine; Richard Baehr and David Levitt in the field of Healthcare Planning and Finance; Martin Brown in the area of Healthcare Finance; and Joel Grice in the field of Healthcare Planning.

Having reviewed all of the documentary and testimonial evidence presented at the hearing, having considered the arguments of the parties made at the hearing and in their post-trial filings, and having followed the applicable law, I find that DHEC properly denied LMC's CON application for an open-heart surgery program at its West Columbia hospital because the implementation of the proposed program would conflict with the policies regarding the establishment of such programs set forth in the 2003 State Health Plan, would constitute an unnecessary duplication of cardiac services

in the Midlands, and would have a materially adverse impact upon existing open-heart surgery providers in the market.

FINDINGS OF FACT

Having carefully considered all testimony, exhibits, and arguments presented at the hearing of this matter, and taking into account the credibility and accuracy of the evidence, I make the following Findings of Fact by a preponderance of the evidence:

I. The Parties

1. Petitioner LMC is a not-for-profit, governmental incorporated health services district that operates a vertically integrated health care system primarily serving the citizens of Lexington County, South Carolina. This system consists of a 346-bed acute care hospital located in West Columbia, South Carolina, a 388-bed nursing home and Alzheimer center, 6 community medical centers providing urgent care services throughout Lexington County, and a network of 36 physician practices employing approximately 115 primary care and specialty physicians. In its CON application, LMC proposes to provide open-heart surgery and therapeutic cardiac catheterization services at its main hospital campus in West Columbia, which is located near the intersection of Interstate 26 and Highway 378.

2. Respondent South Carolina Department of Health and Environmental Control is a state agency charged with, among other things, implementing South Carolina's Certificate of Need regulatory program, which includes licensing standards for the provision of open-heart surgery services and certain other cardiac care services.

3. Respondent Providence Hospital is a private charitable hospital that operates two hospital facilities in Columbia, including its main hospital and heart institute located on Forest Drive in downtown Columbia. Providence has provided open-heart surgery services since 1974 and is the second oldest open-heart surgery provider in South Carolina.

4. Respondent Palmetto Health Richland is a non-profit 579-bed general acute care hospital located in downtown Columbia near the intersection of Sunset Drive and South Carolina Route 277. Palmetto is the major teaching hospital in the Midlands and operates the area's only Level 1 trauma center. Palmetto has provided open-heart surgery services for twenty-five years and

has recently opened a "heart hospital" specifically dedicated to providing cardiac services.

II. Regulatory Background

A. Generally

5. This matter arises under South Carolina's comprehensive Certificate of Need (CON) regulatory program for health care facilities and services, which consists of the State Certification of Need and Health Facility Licensure Act found at S.C. Code Ann. §§ 44-7-110 to 44-7-370 (2002 & Supp. 2005), the accompanying CON regulations found at 24A S.C. Code Ann. Regs. 61-15 (Supp. 2005), and a State Health Plan which is revised at least biennially. The purpose of this regulatory scheme is to "promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services which will best serve public needs, and ensure that high quality services are provided in health facilities in this State." See S.C. Code Ann. § 44-7-120 (2002).

6. The primary vehicle by which this regulatory program is implemented and its stated goals achieved is the requirement that a health care facility apply for, and receive, a CON from DHEC prior to undertaking certain major projects or providing certain new services. See S.C. Code Ann. §§ 44-7-120, 44-7-160 (2002). In determining whether to grant or deny an application for a CON, the Department evaluates the proposed project under the review criteria found in the CON regulations and under the policies and standards set out in the State Health Plan. See S.C. Code Ann. § 44-7-210(C) (2002). The project review criteria set forth in Regulation 61-15 include thirty-three separate criteria that fall into five general categories: (1) criteria related to the need for the proposed project, (2) criteria related to the economic considerations of the project, (3) criteria related to the project's impact on the resources of the health care system, (4) criteria related to the suitability of the site of the project, and (5) criteria related to certain special considerations, such as the project's ability to serve medically underserved groups. See 24A S.C. Code Ann. Regs. 61-15, §§ 801, 802. As required by the CON Act, the State Health Plan contains the following statistics, standards, and findings with regard to the various facilities and services regulated by the CON Act:

- (1) an inventory of existing health care facilities, beds, specified health services, and equipment;
- (2) projections of need for additional health care facilities, beds, health services, and

equipment;

(3) standards for distribution of health care facilities, beds, specified health services, and equipment including scope of services to be provided, utilization, and occupancy rates, travel time, regionalization, other factors relating to proper placement of services, and proper planning of health care facilities; and

(4) a general statement as to the project review criteria considered most important in evaluating certificate of need applications for each type of facility, service, and equipment, including a finding as to whether the benefits of improved accessibility to each such type of facility, service, and equipment may outweigh the adverse affects caused by the duplication of any existing facility, service, or equipment.

S.C. Code Ann. § 44-7-180(B) (2002).

7. The 2003 State Health Plan was in effect at the time LMC filed its application for a CON to establish open-heart surgical services and therapeutic cardiac catheterization services and, therefore, the standards, findings, and policies set forth in the 2003 Plan are applicable to the review of LMC's CON application. See 24A S.C. Code Ann. Regs. 61-15, § 504. With regard to cardiovascular services, the 2003 State Health Plan sets forth separate definitions, standards, and review criteria for CONs for open-heart surgery and for cardiac catheterizations.

B. Standards and Definitions

8. Under the Plan, open-heart surgery is defined as "an operation performed on the heart or intrathoracic great vessels." See DHEC Ex. #2, at II-46. The most common open-heart surgery is coronary artery bypass grafting, or CABG, which is a highly invasive operation that entails harvesting a blood vessel from another area of the body and using it to bypass a blocked section of the coronary artery. These procedures are often done with the temporary use of a heart-lung bypass machine, although surgeons are increasingly performing CABGs while the patient's heart is still beating. Other open-heart surgeries include operations to repair congenital heart defects and surgeries to repair defects in the heart valves.

9. The Plan sets the capacity of an open-heart surgery program at 500 open-heart procedures per year for each open-heart operating room, and defines the service area for open-heart surgery services as the area within a 60-minute one-way automobile drive of the facility. See DHEC Ex. #2, at II-48. The Plan further emphasizes that an open-heart surgery program should perform a minimum of 200 open-heart surgeries per unit each year to maintain its proficiency, and that

improved results in the quality of care are found when a program performs at least 350 open-heart surgeries per unit annually. See DHEC Ex. #2, at II-35, II-36.

10. A cardiac catheterization is an invasive medical procedure performed within a cardiac catheterization laboratory, also known as a “cath lab,” during which a thin, flexible catheter is inserted into a blood vessel as a diagnostic or therapeutic tool for heart and circulatory conditions. See DHEC Ex. #2, at II-37. Diagnostic catheterizations involve the use of a catheter to inject dye in the blood vessel to determine the amount of blockage in an artery; the most common therapeutic catheterizations, also known as angioplasties, involve the use of an inflatable balloon to unblock a clogged artery, often with the insertion of a stent into the artery to keep the artery open. That is, as their names imply, diagnostic catheterizations simply diagnose the extent of blockage in an artery, while therapeutic catheterizations actually treat the blockage itself.

11. The 2003 State Health Plan sets out different standards for CON approval of diagnostic cath labs and “comprehensive” cath labs that perform both diagnostic and therapeutic catheterizations. See DHEC Ex. #2, at II-38 to II-41. For example, the service area for a diagnostic cath lab is the area within a 45-minute one-way automobile drive of the lab, while the service area for a comprehensive cath lab reaches to a 60-minute one-way drive from the lab. Further, given the risks associated with therapeutic cardiac catheterization, comprehensive cath labs may only be located in hospitals that provide open-heart surgery services, whereas diagnostic cath labs may be located in facilities that do not offer open-heart surgery services. The capacity of a cath lab is also weighted according to the type of catheterization performed; specifically, under the 2003 State Health Plan, the capacity of a cath lab is defined to be 1,200 procedures annually, with diagnostic catheterizations each counting as one procedure and therapeutic catheterizations each counting as two procedures toward the total.

III. Application Process

12. On April 21, 2004, Petitioner LMC submitted an application to the Department for a CON for the development of a comprehensive cardiac program at its West Columbia hospital, to include both open-heart surgical capabilities and therapeutic cardiac catheterization capabilities. Specifically, LMC proposed the addition of two dedicated open-heart surgery suites—one of which

would be designated as a “back-up” surgery suite—and a second cardiac catheterization laboratory to complement its existing diagnostic catheterization laboratory. As part of the project, LMC would also develop additional services to support the proposed open-heart surgery program, including the creation of a separate, dedicated intensive care unit for cardiac patients. If approved, the proposed project would authorize LMC to perform open-heart surgery and provide comprehensive cardiac catheterization services.

13. By a letter dated May 21, 2004, the Department deemed LMC’s CON application to be complete and set forth the most relevant project review criteria for the evaluation of LMC’s application. These criteria, ranked in order of their importance, were as follows:

1. Compliance with the Need as outlined in the 2003 South Carolina Health Plan-1
2. Community Need Documentation-2a, 2b, 2c, 2e
Distribution (Accessibility)-3a, 3b, 3c, 3d, 3e, 3f, 3g, 3h
Adverse Effects on Other Facilities-23a, 23b
3. Projected Revenues-6a, 6b, 6c
Projected Expenses-7
Financial Feasibility-15
Cost Containment-16c
4. Staff Resources-20a, 20b
5. Acceptability-4a, 4b

DHEC Ex. #1, at 524.

14. On August 10, 2004, the Department held a project review meeting concerning LMC’s CON application. At the meeting, presentations were made by LMC in support of the project and by Providence and Palmetto in opposition to the proposed project.

15. Based upon LMC’s CON application and the information collected during the project review process, the Department issued a decision denying LMC’s application on October 22, 2004. In the decision, the Department concluded that, while LMC’s project met the technical standards for adult open-heart surgical services set forth in the 2003 State Health Plan, the project was ultimately inconsistent with Sections 802(3)(a), 802(3)(b), and 802(23)(a) of Regulation 61-15, which address

the unnecessary duplication of health care services and the adverse impact of proposed services upon existing providers. In particular, the Department found that

this proposal would unnecessarily duplicate existing open-heart surgical services performed at Palmetto Health Richland Memorial Hospital and Providence Hospital because their services are geographically accessible to Lexington Medical Center's target population. Such duplication of services is not justifiable due to the reduction in the growth of open-heart surgical services that is occurring at this time. As a result, the proposed project would have an adverse impact on the current and projected use rates of these existing open-heart surgery providers. In addition, as documented in the 2003 State Health Plan, the State Health Planning Committee, recognizing the important correlation between volume and proficiency, further acknowledges that the number of open-heart surgery cases is decreasing and that maintaining volume in programs is very important to the provision of quality care to the community.

DHEC Ex. #1, at 846.

16. Petitioner LMC timely requested a contested case hearing before this Court to challenge the Department's denial of its CON application. Respondents Providence and Palmetto were subsequently granted leave to intervene in this matter in opposition to Petitioner's CON application.

IV. Availability and Use of Open-Heart Surgery Services in the Midlands

A. Generally

17. There are three existing open-heart surgery programs within LMC's service area—that is, within a 60-minute one-way drive of LMC. These programs are located at Providence Hospital and Palmetto Health Richland Hospital in downtown Columbia and Aiken Regional Medical Center in Aiken, South Carolina. While there are three open-heart surgery providers within LMC's service area, there are no open-heart surgery programs located within the boundaries of Lexington County.

18. Providence Hospital currently has four open-heart surgery suites. With a stated capacity of 500 open-heart procedures per year for each operating room, Providence has a total annual capacity of 2,000 open-heart surgeries at the hospital. In fiscal year 2005, Providence performed 939 open-heart surgeries, leaving the hospital with an excess capacity of 1,061 heart surgeries, or over 50% excess capacity, for the year.

19. Palmetto Health Richland Hospital has two open-heart surgery units, for an annual capacity of 1,000 open-heart procedures at the hospital. In fiscal year 2005, Palmetto performed 410 open-heart surgeries at its hospital. Therefore, for 2005, Palmetto had an excess capacity of 590 open-heart surgeries, or 59% excess capacity.

20. Aiken Regional Medical Center is likewise well below its capacity for open-heart surgeries. With one open-heart surgical suite, Aiken Regional Medical Center has the capacity to perform 500 open-heart surgeries per year. However, in fiscal year 2004, Aiken only performed 107 open-heart surgical procedures, leaving the hospital with an excess capacity of 383 surgeries, or 78% excess capacity. In fact, this excess capacity for open-heart surgeries exists statewide, with few, if any, of South Carolina's open-heart surgery providers utilizing more than 50% of their capacity to perform open-heart surgeries in recent years.

21. Much of this excess capacity is the result of a state and national trend away from open-heart surgery toward other treatments for coronary artery disease, including the use of therapeutic catheterization to place stents in blocked vessels. During the 1980s and 1990s, both the number of open-heart surgeries performed and the use rate for such surgeries increased dramatically in South Carolina, leading to a proliferation of open-heart surgery programs in the state. However, with developments in the use of therapeutic catheterization to treat heart problems in the late 1990s and early 2000s, and, in particular, with the development of the drug-eluting stent to open blocked vessels in 2003, the number of open-heart surgeries performed in South Carolina has declined dramatically since the year 2000, reflecting a similar trend throughout the nation.

22. After peaking at 6,473 surgeries in 2000, the number of open-heart surgeries performed in South Carolina has steadily declined, falling to 5,850 surgeries in 2004 despite an increase in the state's population during that time. Accordingly, the use rate for open-heart surgery in South Carolina has also shown a dramatic decline in the past several years, dropping from 164 surgeries per 100,000 residents in 2000 to 139 surgeries per 100,000 residents in 2004.

23. These statewide numbers are reflected in the data for the open-heart surgeries performed at Providence and Palmetto. The volume of open-heart surgeries performed at Providence has declined from a peak of around 1,100 surgeries per year in 1998 and 1999 to the 939 surgeries

