

STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

BERT FISH MEDICAL CENTER, INC.,)	
d/b/a BERT FISH MEDICAL CENTER,)	
)	
Petitioner,)	
)	
vs.)	Case No. 97-4290
)	
AGENCY FOR HEALTH)	
CARE ADMINISTRATION,)	
)	
Respondent.)	
_____)	

RECOMMENDED ORDER

A formal hearing was conducted in this case on December 16-19, 1997, in Tallahassee, Florida, before Suzanne F. Hood, a duly designated Administrative Law Judge with the Division of Administrative Hearings.

APPEARANCES

For Petitioner: R. Terry Rigsby, Esquire
Wendy A. Delvecchio, Esquire
Blank, Rigsby and Meenan, P.A.
204 South Monroe Street
Tallahassee, Florida 32301

For Respondent: Richard Patterson, Esquire
Agency for Health Care Administration
2727 Mahan Drive, Building 3, Suite 3431
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STATEMENT OF THE ISSUES

The issue is whether Respondent Agency for Health Care Administration properly denied Petitioner Bert Fish Medical Center, Inc.'s application for a certificate of need to establish an adult kidney transplant program at its existing hospital

located in Volusia County.

PRELIMINARY STATEMENT

On or about July 11, 1997, Respondent Agency for Health Care Administration (ACHA) notified Petitioner Bert Fish Medical Center, Inc. d/b/a as Bert Fish Medical Center (BFMC) that the agency intended to deny BFMC's application for a certificate of need (CON) to establish an adult kidney transplant program. ACHA published its decision preliminarily denying the application in the Florida Administrative Weekly, Vol. 23, No. 30, on July 25, 1997.

BFMC filed a Petition for Formal Administrative Hearing with AHCA on August 15, 1997. AHCA referred the petition to the Division of Administrative Hearings on September 10, 1997.

The parties filed a Response to Prehearing Order on October 2, 1997. A Notice of Hearing dated October 8, 1997, advised the parties that the formal hearing would commence on November 18-21, 1997.

AHCA filed a Motion for Continuance on October 30, 1997. An order dated October 31, 1997, rescheduled the case to be heard on December 15-18, 1997.

On November 5, 1997, BFMC filed a Motion to Modify Commencement Date of Final Hearing. An order dated November 6, 1997, rescheduled the case to be heard on December 16-19, 1997.

The parties filed a Joint Prehearing Stipulation on December 12, 1997.

When the hearing commenced on December 16, 1997, AHCA filed

a Motion to Hold Record Open for Late Filed Exhibit. That same day, BFMC filed a response in opposition to this motion.

During the hearing, Petitioner presented the testimony of 11 witnesses. Petitioner offered 12 exhibits which were accepted into evidence.

Respondent presented the testimony of four witnesses. Respondent offered seven exhibits which were received into evidence.

At the conclusion of the hearing, the undersigned denied AHCA's Motion to Hold Record Open for Late Filed Exhibit.

The first two volumes of the transcript were filed with the Division of Administrative Hearing on January 6, 1998. Volumes three through seven of the transcript were filed on January 14, 1997.

Petitioner filed a Motion to Exceed Page Limit on February 5, 1998. An order dated February 6, 1998, granted this motion.

Respondent filed a Motion for Extension of Time to file proposed recommended orders on February 10, 1998. An order dated February 12, 1998, granted this motion.

BFMC filed its Proposed Recommended Order on February 19, 1998. AHCA filed its Proposed Recommended Order on February 20, 1998.

FINDINGS OF FACT

I. THE APPLICANT

1. BFMC is a not-for-profit hospital located in New Smyrna Beach, Volusia County, Florida. The hospital is a 116-bed, Class 1, general acute-care hospital.

2. BFMC proposes to establish an adult kidney transplant program on its third floor next to the inpatient unit. The applicant will designate seven acute-care beds for use in the program. The hospital currently offers no other special programs or tertiary services.

3. BFMC is located in health planning District 4 which is comprised of seven counties.

4. BFMC is located in organ Transplant Service Area 3 which is comprised of ten counties located within the following four health planning districts: District 4, Volusia County; District 3, Lake County; District 7, Orange, Seminole, Osceola, and Brevard Counties; District 9, Indian River, St. Lucie, Martin, and Okeechobee Counties.

5. BFMC is a part of the Southeast Volusia Hospital District (SVHD) which encompasses southeastern Volusia County, including New Smyrna Beach, Edgewater, Oak Hill, and the unincorporated areas of south Volusia County. The legislature created the SVHD as a special taxing district to provide health care to all citizens without regard to their ability to pay.

6. The SVHD commissioners are appointed by the Governor. They also serve as the directors of BFMC.

7. East Volusia County is well developed, from Edgewater in the south, to the northern end of the county. Areas along the beaches, the Indian River, and the Halifax River are densely populated. Other areas of the county are less populated.

8. BFMC is located two blocks east of highway U.S. 1. State Road 44, a four-lane highway, connects New Smyrna Beach to Interstate 95. The applicant is located approximately 50 miles from Florida Hospital in Orlando, Florida. Florida Hospital-Orlando currently is the only adult kidney transplant center in Transplant Service Area 3.

9. BFMC offers the following inpatient and outpatient services: surgery (including a 14-bed intensive care unit for surgical and medical patients); medical and radiation oncology; cardiac catheterization; diabetic center; invasive radiology; MRI; CT scanning; and outpatient surgery. The hospital has an emergency room which is staffed on a 24-hour basis. BFMC operates a home health agency, a rehabilitation center, a diagnostic center, a primary care center and a clinic for the medically needy.

10. The medical staff at BFMC consists of 128 physicians. Eighty-two percent of the doctors are board-certified in their respective medical fields. The remaining 18 percent of doctors are board-eligible in a medical specialty.

11. The physicians at BFMC have medical specialties in the following areas: urology, nephrology, internal medicine, general surgery, vascular surgery, anesthesiology, cardiovascular surgery, transplant surgery, pain management, pathology, pulmonology, neurology, orthopedics, and orthopedic surgery.

12. The 260 member nursing staff at BFMC includes 172

licensed nurses. Eighty-seven percent of the nurses are registered nurses.

13. BFMC is a member of Halifax-Fish Community Health (Halifax-Fish), a partnership of the Halifax Hospital Medical Center (HHMC) and the SVHD. The goal of Halifax-Fish is to eliminate unnecessary duplication of services and to reduce health care costs.

14. The HHMC owns and operates Halifax Medical Center, a general acute-care hospital located in Daytona Beach. Halifax Medical Center operates the third busiest emergency center in the state. Halifax Medical Center provides the following services which are not available at BFMC: (a) an adult bone-marrow transplant program; (b) adult and adolescent inpatient psychiatric services; and (c) a neonatal intensive care unit.

15. The Halifax-Fish partnership provides the residents of eastern Volusia County with the following services: (a) two acute-care hospitals; (b) bone-marrow transplantation; (c) an HMO; (d) a PPO; (e) home health; (f) hospice; (g) long-term care; and (h) skilled nursing care.

16. Halifax Medical Center filed a letter of intent to establish an adult kidney transplant program in the same batching cycle as BFMC. Subsequently, Halifax Medical Center withdrew its letter and offered its support to BFMC's application.

17. The Organ Procurement and Transplant Network (OPTN) coordinates the listing of potential transplant recipients and

the distribution of donated organs on a local, regional, and national level. The United Network for Organ Sharing (UNOS) is the entity that operates OPTN.

18. UNOS has established standards for transplant surgeons, transplant physicians, and for certification of transplant centers. Most of the standards in AHCA's transplant rule, Rule 59C-1.044, Florida Administrative Code, are based on UNOS guidelines.

19. UNOS has approved BFMC's membership application. Membership in UNOS signifies that BFMC has met applicable federal guidelines for the establishment of a kidney transplant program. It also means that UNOS will permit BFMC to participate in the national organ sharing program pending state authorization.

20. There are six existing adult kidney transplant programs in Florida. These programs are located in the following districts and services areas: (a) Shands Hospital, District 3, Service Area 1; (b) Methodist Medical Center, District 4, Service Area 1; (c) Tampa General Hospital, District 6, Service Area 2; (d) Southwest Florida Regional Medical Center, District 8, Service Area 2; (e) Florida Hospital-Orlando, District 7, Service Area 3; and (f) Jackson Memorial Hospital, District 11, Service Area 4.

II. PREHEARING STIPULATION

21. The parties agree that BFMC timely filed its CON application, including the letter of intent, initial application, and response to omissions, with AHCA and the local health council. The initial CON application was filed on March 26, 1997. The response to omissions was filed on May 12, 1997.

22. The parties agree that BFMC's CON application meets the publication requirements of Section 408.039(2)(d), Florida Statutes (1995), and Rule 59C-1.008(1)(i), Florida Administrative Code.

23. The parties agree that BFMC's CON application meets the following requirements of Section 408.037, Florida Statutes:

(a) the application contains a certified copy of the resolution of its board of directors authorizing the filing of the CON application pursuant to Section 408.037(4), Florida Statutes;

(b) the application contains all of the minimum content items required by Section 408.037; and

(c) the application contains Schedules 1, 2, 3, 4, 6, 7, and 8 which are complete and reasonable and which properly document the required information.

24. Other statutory and rule review criteria are addressed below.

III. CERTIFICATE OF NEED REVIEW CRITERIA

(A) Need in Relation to State and District Health Plans: Section 408.035(1)(a), Florida Statutes.

25. There is no published fixed need pool applicable here. Nevertheless, BFMC must show that its service area needs an additional adult kidney transplant program. The demonstration of need requires consideration of the following state and local health plan preferences.

(a) State Health Plan

26. The state health plan has eight preferences which apply

to all proposed transplant programs.

27. The parties agree that BFMC's application complies with Preference 1. That preference requires the applicant to make a commitment to accept patients for organ transplants regardless of their ability to pay.

28. Preference 2 favors applicants with a history of providing a disproportionate share of charity care and Medicaid patient days. BFMC is entitled to partial credit for this preference because it provides a high percentage of charity care. However, BFMC does not meet the Medicaid disproportionate share criteria.

29. Preference 3 favors applicants with other existing organ transplantation programs. As the sole applicant, BFMC does not meet this criteria. However, BFMC's partner in the Halifax-Fish partnership, Halifax Medical Center, has a bone-marrow transplant program.

30. Preference 4 favors teaching hospitals for the establishment of any organ transplantation program. BFMC does not meet this criteria because it is not a teaching hospital. However, Rule 59C-1.044, Florida Administrative Code, specifically excludes kidney transplant programs from the type of transplant programs which are restricted to teaching hospitals.

31. Preference 5 favors applicants that are members of UNOS. The parties agree that BFMC meets this preference.

32. The parties agree that BFMC meets the requirements of Preference 6. That preference favors an applicant that can

demonstrate successful implementation of the Uniform Anatomical Gift Act.

33. BFMC is not a teaching hospital. Therefore, it cannot receive credit for Preference 7. That preference favors teaching hospitals that document the establishment of a residence program related to the proposed organ transplantation program.

34. Preference 8 favors facilities approved by the National Institute of Health (NIH) and Medicare for the establishment of additional transplant programs. BFMC does not meet the requirements of this preference because it is not an NIH approved facility or a Medicare designated center. Additionally, BFMC is seeking to establish an initial program, not an additional transplant program.

35. As to state health plan preferences that apply to transplant programs, BFMC meets the requirements of at least three preferences and partially meets the requirements of at least two other preferences.

(b) Local Health Plan

36. District 4 has eight local health plan preferences. Only six of these preferences are applicable here. The parties agree that Preference 5 and Preference 6 do not apply to BFMC's proposed project.

37. Preference 1 favors applications for transplant centers to be located in a major metropolitan area. This preference defines "major metropolitan area" as a county with a population

of 250,000 or more. BFMC meets this requirement because Volusia County's population exceeds 250,000.

38. Preference 2 favors applicants who document that they have written relationships with a broad spectrum of other health care providers for patient transfer, tissue procurement, and/or joint venture with regard to the proposed service. BFMC meets the requirement of this preference. BFMC has agreements for transfer with nursing homes for the transfer of patients and emergency services. It has an agreement with a UNOS-designated organ procurement organization. The hospital has an agreement for laboratory services. BFMC and Halifax Medical Center provide an integrated health care system through the Halifax-Fish partnership. The partnership helps ensure continuity of care and non-duplication of costly services.

39. BFMC does not meet the requirements of Preference 3. It is not recognized as a stand alone regional or national referral center. It does not have its own regional or national clientele.

40. Preference 4 favors applicants that play a significant role in regional or national efforts such as comprehensive cancer centers designated by the National Cancer Institute. Pursuant to Preference 4, an applicant plays a "significant role" if it serves as the contracting agency for government medical research grants or if it has a formal affiliation with the lead agency and engages in active medical research with the lead agency. BFMC deserves partial credit for this preference based on its affiliation with Halifax Medical Center which participates

actively in cancer research and operates a bone-marrow

transplantation program. In cooperation with Halifax Medical Center, BFMC operates an Oncology Center which is dedicated to the outpatient treatment and management of a variety of cancers.

41. The parties agree that BFMC meets the requirements of Preference 7. BFMC has submitted a plan to increase local organ donations.

42. Preference 8 favors applicants who formally commit to a program of charity care, with the commitment spelled out in their CON application. BFMC's application meets this preference. SVHD's mission is to provide medical services to residents without regard to their ability to pay. BFMC's application is conditioned on the provision of 4 percent charity care, which equates to one person in each of the first two years of operation.

43. Of the six applicable local health plan preferences from District 4, BFMC meets the requirements of four preferences in full and one preference in part.

44. BFMC's application did not address the local health plan preferences for transplant programs in Districts 3, 7 and 9.

45. AHCA sent an application packet to BFMC which indicated that District 4 was the applicable health planning district for BFMC's application. The application packet included a copy of the District 4 preferences. AHCA's omissions letter did not inform BFMC that it should address all local health plans for each district in Transplant Service Area 3.

46. District 3 has one CON preference for transplantation programs. This preference favors programs at teaching hospitals. Shands Hospital, a teaching hospital in Gainesville, Florida, is located in District 3. BFMC does not meet this criteria.

47. District 7 has two local preferences which address organ transplantation in general. The first favors applicants with residency programs. BFMC is not entitled to this preference.

48. The second preference from District 7 favors applicants that agree to provide charity care. This preference requires the applicant to provide data detailing, by county and payor source, the admissions to the facility for the last year, and copies of any letters of support from referral facilities indicating their past good experiences in placing patients in need in the applicant's facility. BFMC is entitled to partial credit for this preference based on its commitment to provide charity care.

49. District 9 does not have any local health plan preferences which apply to BFMC's application.

(B) Need in Relation to Rule Criteria: Rule 59C-1.044, Florida Administrative Code.

50. The parties stipulated that BFMC's application met the threshold need determination set forth in Rule 59C-1.044(8), Florida Administrative Code. This rule requires each existing kidney transplant program in the transplant service area to have performed a minimum of 30 transplants in the most recent calendar year. Additionally, the applicant must document that it will

perform a minimum of 15 transplants within two years of operation.

51. The only hospital currently providing adult kidney transplant services in Transplant Service Area 3, Florida Hospital-Orlando, performed in excess of 100 transplants in the most recent calendar year.

52. BFMC projects that it will perform 19 kidney transplants in its first year of operation, and 25 transplants in its second year of operation. BFMC based these projections on the number of persons on dialysis in Transplant Service Area 3.

53. Nationally, about 50 percent of the persons on dialysis might be candidates for a kidney transplant. For persons below the age of 65, approximately 75 percent of the persons on dialysis could be candidates for a kidney transplant.

54. In Transplant Service Area 3, there are about 2,161 persons on dialysis. Approximately 40 percent of those persons are not suitable for transplantation. Therefore, only 1,297 persons may be candidates for transplantation.

55. Of the 1,297 persons that might be suitable for transplantation, only nine or ten percent will actually be willing to undergo a transplant. The number of persons willing to be listed as a candidate for a transplant is expected to increase by 12 percent annually.

56. BFMC's projections have been adjusted for the relatively small number of pediatric cases in the transplant

service area. The projections also consider the number of procedures performed by Florida Hospital-Orlando. The projections are reasonable based on the number of persons on dialysis in the transplant service area.

57. On a statewide basis, there is a positive correlation between the number of available transplant centers, the number of people on the kidney transplant waiting list, and the number of transplants performed.

58. Statistics from the Health Care Financing Administration (HCFA) indicate that, on a statewide basis, a greater number of transplant centers will result in a larger number of dialysis patients on the kidney transplant waiting list, and a larger number of transplants performed. Currently, Florida's percentage of transplant centers, compared to the total dialysis population, is significantly less than this same percentage for other states with similar numbers of persons on dialysis. Florida also lags behind other states with similar dialysis populations in the percentage of people on the transplant list and the number of transplants per the dialysis population.

59. Volusia County is the appropriate location for an additional adult kidney transplant program within the ten-county area that comprises Transplant Service Area 3. Volusia County is second only to Orange County in the number of persons afflicted with one or more of the diseases which cause renal failure.

Brevard County, which is located immediately adjacent to south Volusia County, is third. Together, Volusia County and Brevard County have more people on dialysis than Orange County.

(C) The Availability, Quality of Care, Efficiency, Appropriateness, Extent of Utilization, and Adequacy of Like and Existing Health Care Services in the Service District: Section 408.035(1)(b), Florida Statutes.

60. There is no evidence that any patient on the UNOS waiting list has ever been turned away from a kidney transplant center in Florida.

61. The kidney transplant program at Florida Hospital-Orlando has been in existence for 25 years. It performs four times the minimum number of transplants necessary before a new program may be considered in the service area.

62. Despite its significant growth in the past few years, there is no evidence that Florida Hospital-Orlando is operating inefficiently. It has not reached its capacity for performing kidney transplants. Nevertheless, a new kidney transplant program at BFMC would improve access for patients who otherwise would not seek placement on the transplant waiting list.

63. Patients that are appropriate candidates for placement on the kidney transplant waiting list often refuse that opportunity due to the distance from their home to the transplant center. They are not willing to travel very far from home for evaluation, for surgery, and for maintenance and follow-up after surgery. Kidney transplant patients require lifetime monitoring of immunosuppressants as well as continued treatment for the underlying disease. These patients are more willing to be placed on the waiting list and to consider a transplant, as an alternative to continued costly dialysis, if the transplant

facility is close to their family and home.

64. There is no evidence that BFMC's proposed program will adversely impact any other existing provider of kidney transplants.

65. No provider of transplant services intervened in this proceeding to challenge BFMC's program. On the other hand, BFMC received support for its proposed program from numerous hospitals through out the transplant service area and in the adjacent transplant service area.

66. An additional kidney transplant program will lead to a potential increase in the number of available donors. It will improve accessibility and availability of kidney transplant services, as well as the efficiency, appropriateness, and adequacy of the service in Transplant Service Area 3.

(D) The Ability of the Applicant to Provide Quality of Care and the Applicant's Record of Providing Quality of Care: Section 408.035(1)(c), Florida Statutes.

67. The parties agree that BFMC's has a record of providing quality of care. BFMC's application demonstrates that it has the ability to provide quality of care for the proposed kidney transplant program.

68. BFMC is accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The mechanisms for identifying and correcting potential problems are already in place at BFMC.

69. BFMC's nursing staff has the necessary training and

experience to deliver quality care to kidney transplant patients.

70. BFMC is not a teaching or research hospital. Apart from its association with Halifax Medical Center, BFMC does not offer any tertiary services. However, the statutory and rule criteria do not require BFMC to be a teaching or research hospital in order to receive a CON for an adult kidney transplant program.

71. BFMC is a "small" hospital. Nevertheless, it offers the essential services for a kidney transplant program. For example, BFMC performs cardiac catheterization which is required in a small percentage of kidney transplant cases.

72. BFMC is already performing procedures which are more complex than kidney transplants. In addition to major cardiovascular procedures with cardiac cath, BFMC performs the following procedures: (a) stomach, esophageal and duodenal procedures greater than age 17 with cardiac cath; and (b) tracheostomy, except for mouth, larynx or pharynx disorder.

73. Of all the transplant procedures, kidney carries the lowest DRG (diagnosis related group) weight. The DRG weight is an indication of the complexity and resource utilization of a procedure.

(E) The Availability and Adequacy of Other Health Care Facilities and Services in the District Which May Serve as Alternatives for the Services to be Provided by the Applicant: Section 408.035(1)(d), Florida Statutes.

74. The parties agree that a patient in need of kidney transplant services has no acceptable alternative for long-term treatment.

75. Dialysis is an interim outpatient alternative for patients who are candidates for a kidney transplant. Dialysis has higher long-term costs than transplantation. It is not the preferred treatment.

76. A kidney transplant eliminates a patient's dependence on dialysis. It encourages personal and health care independence. A successful transplant greatly improves a patient's quality of life.

77. BFMC's proposed program will lead to an increased awareness of the need for organ donors. The proposed project will result in the addition of persons on the transplant waiting list, the increased availability of organs for transplantation, and a growth in the number of transplants performed. An additional adult kidney transplant program in Transplant Service Area 3 will have a minor short-term impact, if any, on the kidney transplant program at Florida Hospital-Orlando.

(F) Probable Economies and Improvements in Service That May be Derived from Operation of Joint, Cooperative, or Shared Health Care Resources: Section 408.035 (1)(e), Florida Statutes.

78. The parties stipulated that this provision does not apply to BFMC's proposed project.

(G) Need in the Service District for Special Equipment and Services Which are Not Reasonably and Economically Accessible in Adjoining Areas: Section 408.035 (1)(f), Florida Statutes.

79. As discussed above, BFMC is located appropriately for the establishment of an additional adult kidney transplant program in Transplant Service Area 3. The proposed project is

needed to improve access to the service.

(H) Need for Research and Educational Facilities, Health Care Practitioners, and Doctors of Osteopathy and Medicine at the Student, Internship, and Residency Training Levels: Section 408.035(1)(g), Florida Statutes.

80. BFMC's proposed project will provide educational opportunities for the general public as well as medical professionals, residents, and students. If the project is approved, family practice residents from Halifax Medical Center will rotate through the program. Nursing students and allied technical support students, such as physical therapists, will receive training in the program.

(I) Availability of Resources Including Manpower, Management Personnel, and Funds for Project Accomplishment and Operation; Effects the Project Will Have on Needs of Health Professional Training Programs in the District: Section 408.035(1)(h), Florida Statutes.

81. AHCA stipulated that BFMC has the necessary resources to establish and operate the proposed project. These resources include health manpower, management personnel, and funds for project accomplishment and operation. BFMC is willing to condition approval of its CON application on the performance of a study that would be defined by AHCA for the benefit of health care in the state.

(J) Immediate and Long-term Financial Feasibility of the Proposal: Section 408.035(1)(i), Florida Statutes.

82. The parties have stipulated that BFMC's proposed project is financially feasible, immediately and in the long-term.

(K) Special Needs of Health Maintenance Organizations: Section 408.035(1)(j), Florida Statutes.

83. The parties agree that this criteria does not apply to BFMC's CON application.

(L) Needs and Circumstances of Those Entities Which Provide a Substantial Portion of Their Services or Resources, or Both, to Individuals Not Residing in the District: Section 408.035(1)(k), Florida Statutes.

84. BFMC has not provided evidence that it currently provides a substantial portion of its services or resources to individuals residing outside of its health planning district, District 4. However, BFMC proposes to serve the ten-county area comprising Transplant Service Area 3. This service area includes portions of health planning Districts 3, 4, 7, and 9.

(M) Probable Impact of the Proposed Project on the Cost of Providing Health Services Proposed by the Applicant: Section 408.035(1)(l), Florida Statutes.

85. The parties stipulated that BFMC's application demonstrates compliance with this criteria.

(N) Costs and Methods of the Proposed Construction and the Availability of Alternative, Less Costly, or More Effective Methods of Construction: Section 408.035(1)(m), Florida Statutes.

86. The parties stipulated that BFMS's application demonstrates compliance with this criteria.

(O) The Applicant's Past and Proposed Provision of Health Care Services to Medicaid Patients and the Medically Indigent: Section 408.035(1)(n), Florida Statutes.

87. The parties stipulated that BFMS's application demonstrates compliance with this criteria.

(P) The Applicant's Past and Proposed Provision of Services Which Promote a Continuum of Care in a Multilevel Health Care System: Section 408.035(1)(o), Florida Statutes.

88. Halifax-Fish is a multilevel health care system. As discussed above, it provides a continuum of care through the services of a HMO, PPO, home health agencies, tertiary care (NICU

and bone-marrow transplant), adult and adolescent psychiatric beds, skilled nursing beds, hospice, and long-term care.

(Q) Whether Less Costly, More Efficient, or More Appropriate Alternatives to the Proposed Inpatient Services are Available: Section 408.035(2)(a), Florida Statutes.

89. Less costly, more efficient, or more appropriate alternatives to BFMC's proposed project are not available. Expanding the existing program at Florida Hospital-Orlando would not improve access for patients who are unwilling to travel to Orlando for evaluation, surgery, and follow-up services. BFMC has the necessary staff and facilities to establish a successful kidney transplant program. The applicant's utilization projection is reasonable.

(R) Whether the Existing Facilities Providing Similar Inpatient Services Are Being Used in an Appropriate and Efficient Manner: Section 408.035(2)(b), Florida Statutes.

90. Florida Hospital-Orlando is being used in an appropriate and efficient manner. Florida Hospital-Orlando draws patients primarily from Orange County, certain other counties in the transplant service area, and out-of-state. It does not attract a large percentage of transplant patients from Volusia County. Florida Hospital-Orlando's patient origin for kidney transplants indicates that there is an existing geographic barrier to service for residents in the service area.

(S) That Patients Will Experience Serious Problems in Obtaining Inpatient Care of the Type Proposed, in the Absence of the Proposed New Service: Section 408.035(2)(d), Florida Statutes.

91. As discussed above, many persons now on dialysis, who

are potential candidates for transplant, do not seek a transplant because they do not have access to a program close to their home. BFMC's proposed project will make it possible for these people in Service Area 3 to obtain a transplant in or nearer to their community. The project will definitely improve access to the proposed service for handicapped and minority persons who find it especially difficult to travel. BFMC has a history of providing services to the chronically underserved.

IV. RULE CRITERIA

92. Rule 59C-1.044(3)(c), Florida Administrative Code, requires an age-appropriate (adult or pediatric) intensive care unit which includes facilities for prolonged reverse isolation. The applicant's proposal meets this requirement. Additionally, AHCA stipulated that BFMC's application meets all architectural and construction requirements.

93. BFMC has demonstrated compliance with Rule 59C-1.044(4)(f), Florida Administrative Code. The proposed program includes nutritionists with expertise in the nutritional needs of transplant patients. Ms. Jayne Meade is a dietitian with experience in working with renal patients. Through the partnership with Halifax Medical Center, Ms. Kim Koeving will act as a consultant renal dietitian. Based on Ms. Meade's experience, supplemented by the expertise of Ms. Koeving, BFMC complies with this criteria. Furthermore, AHCA stipulated that BFMC's CON application met the specific criteria of

Rule 59C-1.044(8)(a)3, Florida Administrative Code, which requires the applicant to demonstrate the availability of ancillary services, including post transplantation nutritional services.

94. BFMC also demonstrated compliance with Rule 59C-1.044(4)(g), Florida Administrative Code. That rule requires the proposed program to include respiratory therapists with expertise in the needs of transplant patients. BFMC has at least four respiratory therapists with expertise in the needs of transplant patients. Two of the therapists are on duty at all times.

95. As to Rule 59C-1.044(8)(a)2., Florida Administrative Code, BFMC has demonstrated that outpatient services for the proposed program are available. These services include renal dialysis and ambulatory renal clinic services. BFMC meets this requirement through an agreement with Southeast Acute Care Services.

96. As to Rule 59C-1.044(8)(b)3., Florida Administrative Code, BFMC's transplant team includes physicians who are board-certified or board-eligible in the areas of anesthesiology, nephrology, and psychiatry. There is no board certification for vascular surgery. Dr. Morris, the transplant surgeon, is board-certified in general surgery with a certificate in transplant surgery. Dr. Morris practices general, vascular, and thoracic surgery. Dr. Toub, the back-up transplant surgeon, is board-certified in surgery. Dr. Toub practices general, vascular and

non-cardiac thoracic surgery. He also has experience in kidney transplantation.

97. BFMC's program will have two transplant physicians. Dr. Chattopadhyay is board certified in internal medicine and nephrology. Dr. Latif is certified in internal medicine and board eligible in nephrology, awaiting the results of his boards.

98. The proposed project will have a board certified urologist, Dr. Green, on the team.

99. As to Rule 59C-1.044(8)(b)4., Florida Administrative Code, BFMC's application demonstrates that it includes a renal dietitian on its own staff as well as on the staff at Halifax Medical Center. Additionally, the team will include an experienced nephrology nurse, Valerie Holley, R.N. Ms. Holley has extensive experience with patients who have chronic renal failure.

100. As to Rule 59C-1.044(8)(b)6., Florida Administrative Code, BFMC demonstrated that Dr. Gramer is an anesthesiologist with experience in both kidney and heart transplants.

101. As to Rule 59C-1.044(8)(d)3., Florida Administrative Code, BFMC submitted data and information indicating a projected utilization of 19 transplants in the first year of operation, and 25 transplants in the second year of operation. These projections appear to be reasonable and achievable. They are based on a reasonable calculation of the percentage of persons currently on dialysis in the transplant service area who are

potential candidates for transplantation.

102. Despite the requirement of AHCA's rule, there is no evidence of a state or national standard which can serve as "commonly accepted criteria" for determining the number of dialysis patients who are potential kidney transplant recipients.

103. BFMC's CON application demonstrates compliance with all other applicable rule criteria.

CONCLUSIONS OF LAW

104. The Division of Administrative Hearing has jurisdiction over the parties and the subject matter of this proceeding pursuant to Sections 120.569 and 120.57(1), Florida Statutes.

105. An applicant has the burden of establishing its entitlement to a CON for an adult kidney transplant program. Boca Raton Artificial Kidney Center, Inc. v. Department of Health and Rehabilitative Services, 475 So. 2d 260 (Fla. 1st DCA 1985).

106. Balanced consideration of all applicable statutory and rule criteria demonstrates that BFMC has met its burden in this case.

(A) State and Local Health Plans

107. BFMC's application is consistent with a significant number of the District 4 health plan recommendations and the state health plan preferences.

108. BFMC's argument that the 1993 State Health Plan does not apply to its application is not persuasive. In 1997, the Legislature deleted the criteria in Section 408.035(1)(a), Florida Statutes, regarding need in relation to the applicable state health plan. However, Section 408.035(1)(a), Florida Statutes (1997), does not apply to CON applications filed prior to July 1, 1997. Ch. 97-270, Sections 2, 14, and 15, Laws of Fla. Any evaluation of a CON application filed prior to that date must consider state health plan preferences as a statutory

requirement. BFMC filed its application on March 26, 1997. The 1993 State Health Plan was still in effect at that time.

109. Of the eight state health plan preferences that apply to all proposed transplant programs, BFMC demonstrated full compliance with three preferences and partial compliance with at least two other preferences.

110. District 4 has six local health plan preferences which apply here. BFMC demonstrated full compliance with four of these preferences and partial compliance with one additional preference.

111. Local health plan preferences for Districts 3, 7, and 9 are not applicable here. The plain language of Section 408.035(1)(a), Florida Statutes, as well as the specific rule provisions governing transplantation services, demonstrate that BFMC only has to comply with District 4 health plan allocation factors.

(1) The agency shall determine the reviewability of applications and shall review applications for certificate-of-need determinations for health care facilities and services, hospices, and health maintenance organization in context with the following criteria:

(a) The need for the health care facilities and services and hospices being proposed in relation to the applicable district plan and state health plan, except in emergency circumstances which pose a threat to the public health.

Section 408.035(1)(a), Florida Statutes. (Emphasis Added.)

112. Section 408.032(5), Florida Statutes, defines

"district" as "a health service planning district composed of the following counties: . . . District 4.--Baker, Nassau, Duval, Clay, St. Johns, Flagler, and Volusia Counties."

113. Rule 59C-1.044, Florida Administrative Code, establishes four transplant service planning areas, each of which is comprised of two or more health service planning districts, in addition to one or more selected counties from other districts. There is no transplant service area health plan. Likewise, there is no specific rule provision requiring a transplant applicant to demonstrate compliance with local health plan allocation factors for the applicable service in each district within the transplant service planning area.

(B) Statutory and Rule Criteria

114. AHCA stipulated that BFMC met a significant number of the applicable statutory and rule criteria. BFMC demonstrated compliance with the remaining criteria at final hearing.

115. The greater weight of the evidence indicates that the proposed project is capable of meeting its projected number of transplant cases during its first two years of operation, is financially feasible in the immediate and long-term, and will improve access to quality renal transplantation services in an underserved area of the state.

116. The proposed program has already been accepted for membership in UNOS. This membership indicates that BFMC's kidney transplant program meets all of the national standards. It is

capable of being implemented upon receipt of state approval.

117. BFMC presented persuasive evidence of need for the proposed program according to the applicable statutes and administrative rules. Independent data showed that Florida lags behind states with similar dialysis populations with regard to the number of transplantation programs per dialysis population. BFMC demonstrated that Florida transplants fewer kidneys than would be expected given the number of people on dialysis and the number of available kidneys.

118. Expanding the capacity for kidney transplants at Florida Hospital-Orlando will not improve access for patients who would rather remain on dialysis, at a higher cost to the health care system, than seek a transplant at a facility located fifty miles from their home and family.

(C) Need Analysis

119. BFMC has demonstrated compliance with Rule 59C-1.044(8)(d), Florida Administrative Code. Florida Hospital-Orlando performed in excess of 100 kidney transplants in the most recent calendar year preceding BFMC's application. The rule only required the existing kidney transplant program to perform 30 transplants before a new program could be considered.

120. Additionally, BFMC's application demonstrates that its projected number of transplants will exceed the minimum number of 15 transplants per year for the first two years of the program. The greater weight of the evidence indicates that BFMC's

projections are reasonable and achievable based on a percentage of the number of persons on dialysis who would likely seek out transplantation, as well as the increase in donations which typically occurs with the establishment of a new program.

(D) Tertiary Services

121. There is no statutory or rule requirement that a kidney transplant program be located in a hospital that has a certain number of inpatient beds, or which offers a "tertiary" service. While most other transplant programs are required to be located in teaching hospitals and/or hospitals with research affiliations, there is no such requirement applicable to kidney transplantation. See Rule 59C-1.044, Florida Administrative Code.

122. There is no evidence that kidney transplantation requires the support of another tertiary service. A successful kidney transplantation program depends on the medical team, the availability of needed services, and the level of quality of care. BFMC has demonstrated that it meets all of these criteria.

123. The purpose of limiting tertiary services to a few providers is to "ensure the quality, availability and cost-effectiveness of such service." Section 408.032(19), Florida Statutes. This statute was not intended to prohibit the establishment of needed services. The tertiary nature of kidney transplant has not prevented AHCA from approving second programs in three of the four transplant service areas in the state.

124. Of the six existing adult kidney transplantation programs in Florida, one-half are not located in teaching or research hospitals.

125. BFMC has demonstrated that its program will be

operated by a team of qualified specialists with demonstrated expertise in kidney transplantation, that it will be staffed by qualified and experienced medical and ancillary staff, and that it will be housed in state-of-the-art facilities which meet each requirement for establishing an adult kidney transplantation program.

126. BFMC is already performing complex procedures carrying much higher DRG weights, signifying higher complexity and use of resources, than that established for kidney transplantation. Of all the transplant procedures, kidney transplantation carries the lowest DRG weight.

127. A new program at BFMC will address the need for an additional transplant program in the state, and particularly in transplant service area 3. The program is ready for implementation upon state approval. The Halifax-Fish partnership provides that ability to link the services at BFMC with all of the medical specialties and support available at Halifax Medical Center.

RECOMMENDATION

Based on the forgoing Findings of Fact and Conclusions of Law, it is recommended that AHCA enter a Final Order granting BFMC's CON application No. 8724 for an adult kidney transplantation program.

DONE AND ORDERED this 12th day of March, 1998, in
Tallahassee, Leon County, Florida.

SUZANNE F. HOOD
Administrative Law Judge
Division of Administrative Hearings
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Filed with the Clerk of the
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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.