

STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

BAYFRONT MEDICAL CENTER,)
)
Petitioner,)
)
vs.) CASE NO. 87-2029
)
DEPARTMENT OF HEALTH AND)
REHABILITATIVE SERVICES,)
)
Respondent.)
_____)

RECOMMENDED ORDER

Pursuant to notice, an administrative hearing was held before Diane D. Tremor, Hearing Officer with the Division of Administrative Hearings, on January 6 and 7, 1988, in St. Petersburg, Florida. The issue for determination in this proceeding is whether St. Anthony's Hospital is entitled to a Certification of Need to establish radiation therapy services.

APPEARANCES

For Petitioner, Kenneth F. Hoffman, Esquire
Bayfront: Oertel and Hoffman, P.A.
Post Office Box 6507
Tallahassee, Florida 32314-6507

For Respondent, Leslie Mendelson, Esquire
HRS: Assistant General Counsel
Ft. Knox Executive Center
2727 Mahan Drive, Suite 309
Tallahassee, Florida 32308

For Respondent, Ivan Wood and Judith S. Marber, Esquire
St. Anthony's: Four Houston Center
1221 Lamar, Suite 1400
Houston, Texas 77010-3015

INTRODUCTION

In support of its application for a Certificate of Need to establish a radiation therapy center, St. Anthony's Hospital presented the testimony of Daniel T. McMurray and Joseph P. Daniel, III, both of whom were accepted as expert witnesses in the field of hospital administration; Philip T. Lancaster, Jr., accepted as an expert witness in hospital finance; and Thomas J. Konrad, accepted as an expert witness in health planning. St. Anthony's Exhibits 1 and 2 were received into evidence.

Bayfront Medical Center presented the testimony of Garry M. Walsh, accepted as an expert witness concerning the management of a radiation oncology center, including staffing and equipment planning, radiation docimetrist and radiation

therapy technology; Maria N. Sheats; Teresa Maria Stroup; Robert Joseph Miller; Christopher McConnell; Michael C. Carroll, accepted as an expert in health planning; and Rufus Harris, accepted as an expert in accounting and financial feasibility analysis. Bayfront's Exhibits 1 through 6A-K were received into evidence.

The Department of Health and Rehabilitative Services (HRS) presented, by way of deposition, the testimony of Reid S. Jaffe, accepted as an expert in health planning. HRS's Exhibits 1 through 3 were received into evidence.

Subsequent to the hearing, all parties submitted proposed findings of fact and proposed conclusions of law. To the extent that the parties' proposed findings of fact are not included in this Recommended Order, they are rejected for the reasons set forth in the appendix hereto.

FINDINGS OF FACT

1. St. Anthony's Hospital (St. Anthony) is a 434-bed nonprofit hospital located in St. Petersburg, Florida, sponsored by the Franciscan Sisters of Allegheny. It provides a full range of services, including a surgical program, a medical program, and departments of radiology, nuclear medicine and pathology. It has an established cancer treatment program which provides interrelated services such as medical and surgical oncology, tumor registry, pharmacology, pathology, an oncology committee and tumor board, social work and a pastoral care department. Radiation therapy is the only major element of cancer treatment which St. Anthony currently lacks.

2. St. Anthony now proposes to construct, equip and operate a radiation therapy center in a separate facility located on its campus, but not physically connected to its existing hospital. It is anticipated that at least ninety% (90%) of all patients to be treated will be outpatients. It is contemplated that a separate facility will maximize ease of access for outpatients, help the patient's psychological status by removing the necessity to return to the hospital for radiation treatment services and reduce the disruption caused by construction inside the existing hospital facility.

3. The proposed radiation therapy building will house two treatment suites, a simulator, conference rooms, examination rooms, dosimetry rooms, waiting areas and office space. The separate facility will contain 6,315 square feet and will include a 4 MV linear accelerator and a 6 MV/18MV dual linear accelerator. The estimated total project cost is \$4,191,000.

4. St. Anthony's service area contains a considerably higher than average percentage of elderly and Medicare-eligible population. Approximately 30% of the population of South Pinellas is 65 years and older, as compared to about an 18 to 20% statewide average. Approximately 70% of St. Anthony's patient load is Medicare-eligible. As the population increases, and particularly the elderly population, the incidence of cancer will likewise increase.

5. Utilizing ICD-9-CM data, a universally accepted method of classifying patients relative to their disease or illness, St. Anthony calculated that 1,247 patients were admitted to St. Anthony's Hospital in fiscal year 1986 with a primary or secondary diagnosis of cancer. This figure could involve some double-counting of individual patients, particularly in light of the fact that many cancer patients, perhaps up to 50%, are readmitted to the hospital during the course of their disease process. The DRG data only shows 625 cancer patients being discharged by St. Anthony's Hospital in calendar year 1986. The

DRG classification system is primarily for reimbursement purposes and does not always include the secondary diagnoses, whereas the ICD-9-CM data is an international classification system for coding both primary and secondary diseases.

6. There are three major types of cancer treatment--surgery, chemotherapy and radiation therapy. Each form of treatment may be used individually or in combination with one another. Patients who receive radiation therapy are treated with either curative (with the elimination of the cancer being the objective) or palliative (with the alleviation of discomfort being the objective) intent. It is reasonable to assume that approximately 60% of all cancer patients will require radiation therapy at some time during the course of their disease. It is also reasonable to assume that the average patient receiving curative radiation therapy will receive 25 treatments and the average patient receiving palliative therapy will receive 14 treatments. Utilizing these assumptions, as well as assuming 1,247 cancer patients served by St. Anthony's, and further assuming a 50-50 split between curative and palliative treatments, St. Anthony projects a total of 14,586 visits (treatments or procedures) in its first year of operation and a 5% increase during its second year of operation. If these figures and assumptions are reasonably accurate, the proposed project is needed on an institution-specific level. Stated differently, there is a sufficient number of cancer patients presently served by St. Anthony's Hospital to justify a need for radiation therapy services without relying on referrals from others. Also, if one accepts that the economic efficiency standard per linear accelerator machine is 6,000 procedures or treatments per year, a figure found in some of the literature on the subject, it is reasonable to conclude that St. Anthony would have a need for at least two machines to adequately serve its cancer patients.

7. St. Anthony proposes a staff of six positions for its radiation therapy center. The positions include a physicist, a chief technician/manager, a registered nurse, a technician, a dosimetrist/mold room technician and a secretary/receptionist. Some of the duties of operating the proposed radiation therapy center, such as medical records transcription, will be assumed internally by the current staff of the hospital. The proposed staffing is from three to six positions below that utilized at the Bayfront Cancer Center, and is somewhat lower than that recommended in the "Blue Book," a 1981 report of the National Cancer Institute concerning criteria for radiation oncology in multidisciplinary cancer management. St. Anthony's vice-president and assistant administrator admitted that additional staff would be needed in the near future.

8. Based upon the volume of projected activity and projected charges, St. Anthony initially estimated that at the end of its first and second years of operations, its net income would be, respectively, \$72,092 and \$38,259. The evidence at hearing demonstrated that corrections to the pro formas are necessary with respect to both revenues and operating expenses, with both needing upward adjustments. The expert financial witnesses for St. Anthony and Bayfront had different opinions with regard to the long-term financial feasibility of the proposed project. In evaluating the project's financial feasibility, St. Anthony utilized historical financial information from its own facility, as well as the experience of two other Florida hospitals within the Allegheny health care system, and determined that the project would be profitable on a long-term basis. Bayfront, on the other hand, evaluated St. Anthony's pro formas largely on the basis of its own experience in operating the Bayfront Cancer Center, and determined that the facility would operate at a loss after its second year of operation. The parties stipulated that the proposed project would be financially feasible on a short-term basis. The provision of

services to a large percentage of Medicare patients, as well as the provision of 90% outpatient services, is a financial benefit with regard to cost-base reimbursement services.

9. Existing facilities offering radiation therapy services both on an inpatient and outpatient basis within St. Anthony's service area include Bayfront Medical Center, one unit adjacent to Palms of Pasadena Hospital and a freestanding center across the street from Humana Northside Hospital. There was no evidence presented regarding the utilization of the latter two facilities.

10. Bayfront Medical Center is located about 15 blocks from St. Anthony's Hospital. Bayfront is a 518-bed not-for-profit hospital leased from the City of St. Petersburg. It is the primary provider of indigent and charity care in the area, and operates a large indigent care program, called the Tumor Clinic, as a part of its cancer center. The Bayfront Cancer Center originated in 1978 as the Gulf Coast Oncology Center. It now operates with three linear accelerators and is accredited by the American College of Surgeons. In 1984, the Bayfront Cancer Center (BCC) served 1,048 patients. In its fiscal year 1987, it served 853 patients and performed 19,275 treatments or procedures. For the fiscal year July 1, 1988 through June 30, 1989, BCC projects that 20,500 procedures will be performed at its 3-unit facility. No patient has had to wait to obtain radiation therapy at BCC, though, on occasion, Bayfront has had to operate its facility from 7:00 a.m. to as late as 8:30 to 9:00 p.m. due to patient demand. It is opined that Bayfront's present equipment and staff has the capacity to perform an additional 3,000 to 4,000 treatments per year.

11. Though no studies were conducted as to which facilities St. Anthony's cancer patients currently utilize to receive their radiation therapy treatments, Bayfront predicts a dramatic adverse impact upon its cancer center if St. Anthony were to initiate similar services. The impact would be in the areas of quality of care, the provision of indigent care and the economic viability of both the hospital and the cancer center. Even if Bayfront were to lose only a third of its current patient volume to St. Anthony's proposed new service, it is projected that Bayfront may have to decommission one of its three accelerators and cut back on staffing, indigent care and its student training program. It is further projected that its cancer center would change from a profitable venture to one having a loss in an amount close to its total operating margin. Staffing cutbacks could result in Bayfront losing its certification from the American College of Surgeons.

12. An important component of the treatment of cancer patients is continuity of care. At present, inpatients of St. Anthony needing radiation therapy services must either delay treatment until discharged, be transferred to an inpatient facility which provides such services or be transported back and forth for the treatments. It is often not in the patient's best interests to delay radiation therapy once the need for such treatment has been determined. Transporting a patient back and forth is disruptive to the patient and expensive. Transferring a patient to another inpatient facility is disruptive to the patient-physician relationship and the multidisciplinary team approach to cancer care. Inpatients at St. Anthony needing radiation therapy would benefit by the proposed project. However, the benefit with respect to patient comfort would not be particularly significant in light of the fact that the St. Anthony patient would still have to be transported out of the building to another building on campus, as opposed to another building some 15 blocks away.

13. HRS has no promulgated rule setting forth a methodology for predicting the need for community radiation therapy services. In performing its analysis

in this case, as it did in one other application for similar services, HRS evaluated need primarily on the basis of institution-specific data from the applicant, and further analyzed the utilization figures from another hospital-based facility, Bayfront, to determine whether that existing facility was being adequately used.

14. Other than reference to a previously-declared invalid methodology for determining numeric need for radiation therapy units, neither the State Health Plan nor the local District Health Plan contain specific standards or guidelines for the review of such units in the Certificate of Need process. The State Health Plan does stress continuum of care as a goal. The District plan contains general policies regarding review to determine the impact upon providers of a large amount of indigent care and to determine the adequate and effective utilization of existing services prior to the commencement of new services.

15. As noted above, 90% of the patients served by the proposed facility will be outpatients. Recent changes in the Certificate of Need laws make the provision of outpatient services no longer reviewable by HRS. Although St. Anthony desires to provide services to both outpatients and inpatients at its proposed facility, it might elect to construct and operate a radiation therapy center which only serves outpatients if its present application is denied.

CONCLUSIONS OF LAW

16. A Certificate of Need is required when a hospital proposes a capital expenditure over a threshold amount to provide inpatient health services or proposes a substantial change of inpatient institutional health services. Section 381.706(1)(c) and (h), Florida Statutes (1987). Since the application under consideration in this proceeding proposes radiation therapy services to inpatients, as well as outpatients, for a total project cost of almost \$4.2 million, a Certificate of Need is required.

17. An applicant for a Certificate of Need carries the burden of establishing that it satisfies the statutory and regulatory criteria for review set forth in Section 381.705, Florida Statutes, and Chapter 10-5, Florida Administrative Code. The parties in this proceeding have stipulated that certain of the criteria are either not applicable or have been met by St. Anthony, and therefore are not in dispute. The criteria primarily at issue include the need for the project in relationship to the State and District Health Plans; the availability, appropriateness, accessibility, extent of utilization and adequacy of like and existing services in the area; the availability and adequacy of alternatives to the proposed project; economies and improvements in service that might be derived from shared health care resources; the availability of technicians; the need for training programs; the impact of the project upon the costs of providing the service and the effects of competition with respect to quality assurance and cost-effectiveness; St. Anthony's provision of services to the medically indigent; long-term financial feasibility; the practicality of less costly, more efficient and more appropriate alternatives; the efficient and appropriate utilization of similar existing services; alternatives to new construction and whether or not inpatients will experience serious problems in obtaining the care proposed in the absence of the project.

18. Unlike the traditional Certificate of Need proceeding, application of the above criteria in dispute in this instance is quite problematical. The provision of radiation therapy treatments is largely an outpatient service. Due to changes in the Certificate of Need law, the establishment and operation of

outpatient services no longer requires a Certificate of Need and/or HRS review. HRS can no longer control the proliferation of outpatient radiation therapy services nor can utilization of such outpatient services be adequately monitored. Unregulated outpatient services undoubtedly have a drastic impact upon such factors as competition, utilization, availability, accessibility and, perhaps, even the viability of existing services and facilities in the community. Yet, there is no longer any means to prevent such outpatient services or facilities from entering the community nor to protect existing regulated services or facilities from the effect they may have upon economics, quality of care, patient costs or other criteria with which the Certificate of Need laws have traditionally been concerned. Thus, while a Certificate of Need is a statement "evidencing community need" (Section 381.702(2), Florida Statutes) for a new health service, the "community need" of concern in the instant case is only one with respect to the provision of radiation therapy services to inpatients, approximately 10% of the proposal's projected patient load.

19. In resolving this dilemma, the following questions might be posed: Since St. Anthony's proposed project will provide 90% outpatient services and only 10% inpatient services, and since St. Anthony could now construct and operate a service entirely for outpatient use without a Certificate of Need, should the criteria be reviewed only with respect to 10% of the project? For example, should the impact upon Bayfront be measured by considering that only a certain percentage of 75% (10% of the 748 patients projected to be served by St. Anthony) or a certain percentage of 1,459 visits (10% of the 14,568 projected by St. Anthony) will be lost by Bayfront? Should the financial feasibility of the project be measured only with respect to that portion of revenues and expenses attributable to the 10% inpatient service? Should the factors of availability, accessibility, indigent care, manpower, the need for training programs, patient costs and other factors be measured only with respect to inpatient services? Likewise, should the adequacy and efficiency of Bayfront's three-unit radiation therapy center be measured only with respect to the inpatients it serves? Obviously, such a myopic review approach would not bring about any meaningful results. Similarly, to ignore the fact that outpatient facilities and services exist and may be added in a community without review and to hold applicants providing inpatient services (albeit a small amount) to traditional application of the standards for review would be both illogical and unfair.

20. It appears that the current HRS approach in evaluating applications for radiation therapy services is reasonable, logical and practical. That approach can be summarized as follows: recognize the inability to control or monitor the establishment of and informational data from unregulated radiation therapy services; assess the number of cancer patients treated by the applicant; estimate the number of treatments that would be generated by those patients to determine if the applicant can efficiently operate the facility; and assess the adequacy and efficiency of existing inpatient providers.

21. The evidence in this case reveals that St. Anthony presently serves a sufficient number of cancer patients who would be candidates for radiation therapy to warrant the project without referrals from other hospitals. Even if St. Anthony's ICD-9-CM generated calculations resulted in some double-counting of individual patients, it is reasonable to assume that some individual patients with multiple hospital admissions may require more than one series of radiation therapy treatments or may require more than the average number of treatments assumed. Given the increasingly large number of elderly persons within St. Anthony's service area, there is no reason to expect that the number of cancer patients services in 1986 will not increase in future years. Using historical

information from its own operations and experience over the years, St. Anthony has established the economic feasibility of its proposal on both a short-term and long-term basis. Other than demonstrating that the proposed staffing may need an upward adjustment, Bayfront's analysis of St. Anthony's pro formas did not discredit the testimony presented by St. Anthony with respect to the financial feasibility of the project. The proposal will increase the availability and accessibility of radiation therapy services to inpatients at St. Anthony and to outpatients who desire to utilize services operated by St. Anthony's Hospital. Continuity of care will be enhanced and the project will fill a void in St. Anthony's comprehensive cancer treatment program. The evidence demonstrates that construction of a separate facility on the campus of the existing hospital is advantageous to the outpatient, the prime user of the facility, and construction of a separate facility will cause less disruption inside the existing hospital.

22. There is little doubt that Bayfront may lose some of its patient load, and that its rate of expansion may be affected if St. Anthony opens a radiation therapy center on its nearby campus. However, the addition of unregulated outpatient treatment centers would have the same impact upon Bayfront; and HRS, through the Certificate of Need process, would be powerless to prevent such an impact. Bayfront currently has an active radiation treatment program with some excess capacity. The addition of new machines at another facility will probably increase that capacity (though the extent of that increase was never established), thus allowing future community need to be fulfilled. Given the changes in the Certificate of Need law with respect to outpatient services, the potential impact upon Bayfront is simply not a sufficient reason, standing alone, to deny St. Anthony's application.

23. Decisions on Certificate of Need applications must be based upon a balanced consideration of all applicable statutory criteria. As noted above, St. Anthony has demonstrated that it can construct and operate the proposed radiation therapy center in a manner which will be financially feasible and which will provide good quality of care. St. Anthony's proposal will increase competition, availability and accessibility. It currently serves a sufficient number of cancer patients to generate adequate and appropriate utilization of the proposed facility. The completion of its existing cancer care program will be an improvement in service, and will serve the goal of providing a continuum of care for cancer patients. When balancing the criteria for review, it is concluded that the benefits derived from the proposal outweigh the impacts upon Bayfront.

RECOMMENDATION

Based upon the findings of fact and conclusions of law recited herein, it is RECOMMENDED that the application of St. Anthony's Hospital to construct, equip and operate the proposed radiation treatment center be approved.

Respectfully submitted and entered this 1st day of August 1988, in Tallahassee, Florida.

DIANE D. TREMOR
Hearing Officer
Division of Administrative Hearings
The Oakland Building
2009 Apalachee Parkway
Tallahassee, Florida 32399-1550
(904) 488-9675

FILED with the Clerk of the
Division of Administrative Hearings
this 1st day of August 1988.

APPENDIX
(Case No. 87-2029)

The parties' proposed findings of fact have been fully considered and are accepted and/or incorporated in this Recommended Order, with the following exceptions:

Bay front:

1. The word "only" is rejected as contrary to the evidence.
3. First two sentences rejected as argumentative and contrary to the evidence.
5. Second sentence rejected.
- 8 and 9. Rejected as argumentative.
18. Discussed in conclusions of law section.
19. Rejected as contrary to the evidence.
28. Accepted only if "need" is defined in terms of "necessity."
30. Same as above with regard to last sentence.
33. Second sentence rejected, but discussed in conclusions of law.
- 34, 35. Rejected as contrary to the evidence with regard to inpatients at St. Anthony.
- 36-38. Accepted as being an accurate representation of the witness's opinion, but ultimate opinions rejected insofar as they do not take into account the completeness of St. Anthony's cancer program, patient choice and the patient-physician and multidisciplinary team approach to cancer care.
- 39-41. Accepted as potential occurrences should another facility enter the community, but not determinative of the issues, as discussed in the conclusions of law.
- 42-44. Rejected as unsupported by competent substantial evidence.
51. Third sentence rejected as contrary to the greater weight of the evidence.
52. Accepted only with regard to pure "numeric" need.
55. Rejected, as contrary to the evidence.
56. Rejected as to Palms of Pasadena and non-hospital outpatient facilities as unsupported by competent evidence.
- 57, 58. Accepted as reasonable statements of potential impacts, but not established as resulting solely from the proposed project or determinative of the issues.

HRS:

- 1, 3, 5. Accepted, but not included as irrelevant to the issues in dispute.
- 26. Accepted as only one of many factors to be considered and balanced against other criteria.
- 31. Rejected as not supported by competent substantial evidence.
- 46. Rejected insofar as it fails to consider other existing or future facilities.

St. Anthony:

- 4. First two sentences rejected as irrelevant.
- 9, 10. Rejected as irrelevant.
- 36. Rejected as to the word "committed," as not supported by the evidence.
- 53. Rejected as not supported by competent, substantial evidence with regard to the number of units.
- 57-59. Rejected insofar as it attempts to state legal conclusions, as opposed to factual findings.
- 118-120. Rejected as to impacts on other existing facilities unsupported by any evidence.
- 137. Rejected as contrary to the evidence.
- 140. Rejected as not supported by competent, substantial evidence.
- 147. Partially rejected as to certain goals.

COPIES FURNISHED:

Leslie Mendelson, Esquire
Assistant General Counsel
Department of Health and
Rehabilitative Services
1323 Winewood Boulevard
Tallahassee, Florida 32399-0700

Ivan Wood, Esquire
The Park in Houston Center
1221 Lamar, Suite 1400
Houston, Texas 77010-3015

Kenneth Hoffman, Esquire
Post Office Box 6507
Tallahassee, Florida 32314-6507

Judith S. Marber, Esquire
Southeast Financial Center
Two Biscayne Blvd., Suite 3700
Miami, Florida 33131-2359

Gregory L. Coler, Secretary
Department of Health and
Rehabilitative Services
1323 Winewood Boulevard
Tallahassee, Florida 32399-0700

R. S. Power, Agency Clerk
Department of Health and
Rehabilitative Services
1323 Winewood Boulevard
Tallahassee, Florida 32399-0700