



Office of Health Care Access Certificate of Need Application

Final Decision

Hospital: Hospital of Saint Raphael

Docket Number: 05-30450-CON

Project Title: McGivney Cancer Center Equipment Replacements and Upgrades, and Establishment of a Radiation Therapy Satellite Facility in Hamden, Connecticut

Statutory Reference: Sections 19a-638 & 19a-639, C.G.S.

Filing Date: September 26, 2005

Decision Date: December 21, 2005

Default Date: December 25, 2005

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Project Description: The Hospital of Saint Raphael (“Hospital”) proposes to replace and upgrade radiation therapy equipment at its McGivney Cancer Center and establish a radiation therapy satellite facility in Hamden, at an estimated total capital expenditure of \$12,207,916.

Nature of Proceedings: On September 26, 2005, the Office of Health Care Access (“OHCA”) received the Certificate of Need (“CON”) application of the Hospital of Saint Raphael (“Hospital”) to replace and upgrade radiation therapy equipment at its McGivney Cancer Center and establish a radiation therapy satellite facility in Hamden, at an estimated total capital expenditure of \$12,207,916. The Hospital is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes (“C.G.S.”).

Pursuant to Sections 19a-638 and 19a-639, C.G.S., a notice to the public concerning OHCA’s receipt of the Hospital’s Letter of Intent was published in the *New Haven Register*, on March 18, 2005. OHCA received no responses from the public concerning the Hospital’s proposal.

OHCA's authority to review and approve, modify or deny this proposal is established by Sections 19a-638 and 19a-639, C.G.S. The provisions of these sections as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were fully considered by OHCA in its review.

Findings of Fact

Clear Public Need Impact on the Hospital's Current Utilization Statistics Contribution of the Proposal to the Accessibility and Quality of Health Care Delivery in the Region

1. The Hospital of Saint Raphael ("Hospital"), a member of the Saint Raphael Healthcare System, Inc. ("SRHS"), is a tertiary, community teaching hospital, located at 1450 Chapel Street in New Haven, Connecticut. (*March 9, 2005, Letter of Intent ("LOI"), page 1*)
2. The Hospital has offered comprehensive cancer treatment services to the greater New Haven region since 1957 and opened the Father Michael J. McGivney Center for Cancer Care ("McGivney Center" or "Cancer Center") on its main campus in 1994. (*August 2, 2005, CON application, page 3*)
3. The Hospital proposes to undertake the following radiation therapy project: (*August 2, 2005, CON application, page 2*)
 - Selected replacements and upgrades of the Cancer Center's equipment through the acquisition of new state-of-the-art equipment to ensure the continued provision of high-quality radiation therapy services at the Center; and
 - Expansion of service through the establishment of a new radiation therapy satellite facility at 2080 Whitney Avenue in Hamden, CT, to enhance access to radiation therapy services in the region.
4. An itemization of the requested equipment replacements and upgrades for the McGivney Center component is as follows: (*August 2, 2005, CON application, pages 32, 33 & 36, Attachment 18, page 340 and Attachment 20, pages 339 through 428*)

Table 1: McGivney Center Equipment Itemization

Description
Medical Equipment: Replacement Acquisitions & Upgrade:
a. TomoTherapy Hi-Art Adaptive Linear Accelerator System Acquisition
b. Varian Clinac iX Linear Accelerator System Acquisition
c. Multilease collimator ("MLC") Linear Accelerator Upgrade
Imaging Equipment: Upgrade
d. Phillips CT Scanner Upgrade (1 to 16 slice) for Simulation use only

5. An itemization of the requested equipment acquisitions for the satellite facility component is as follows: *(August 2, 2005, CON application, pages 32, 33 & 36, Attachment 18, page 340 and Attachment 20, pages 339 through 428)*

Table 2: Satellite Facility Equipment Itemization

Description
Medical Equipment: New Acquisitions
a. Varian Clinac iX Linear Accelerator System
Imaging Equipment: New Acquisition
b. Refurbished Siemens CT Scanner (8 slice) for Simulations & Diagnostic Exams

6. The Hospital indicates that the project will serve those patients in need of radiation therapy, who predominately reside within the Hospital's service area, a twenty-two (22) town area that comprises the south central region of Connecticut. Service area towns include the following: Ansonia, Bethany, Branford, Cheshire, Clinton, Derby, East Haven, Guilford, Hamden, Madison, Meriden, Milford, New Haven, North Branford, North Haven, Orange, Oxford, Seymour, Shelton, Wallingford, West Haven and Woodbridge. *(March 9, 2005, LOI, page 3)*
7. The Hospital based the need for the project on the following factors: *(August 2, 2005, CON application, page 5)*
- Cancer incidence rates and demographic shifts;
 - Clinical and technological advances in cancer care;
 - Increased capacity requirements at the McGivney Center;
 - Benefits that will be derived from expanding services to a satellite location; and
 - The attendant quality of care improvements that patients will derive from the proposal.
8. The Hospital attributes increasing cancer incidence rates to the aging of the population, where the majority of new cancer cases occur in adults age 65 and over and demographic shifts within its service area to the anticipated changes in the ethnic and racial diversity found within the population. *(August 2, 2005, CON application, pages 6 through 11)*
9. The Hospital stated that the blending of better patient education, earlier detection, improved cancer survival rates and technological advances in radiation therapy allow for more prolonged and localized treatment of specific cancers. *(August 2, 2005, CON application, pages 12 through 14)*
10. The Hospital indicates that as the three (3) McGivney Center's linear accelerators consistently operate at or above 100% capacity, the Hospital cannot manage to effectively deliver prompt radiation therapy treatment to its patients. The Hospital believes that it is limited in its options to expand the existing program within the current confines of the existing physical facility. *(August 2, 2005, CON application, pages 14 through 15)*

11. The Hospital reported the following total service volumes and capacity percentages that are associated with the Cancer Center’s activities for previously completed fiscal years (“FYs”) 2000 through 2004. *(August 2, 2005, CON application, pages 14 through 15)*

Table 3: Linear Accelerator Utilization at the McGivney Center

Description	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004
Total Service Volume*	24,384	25,137	27,213	27,527	26,542
% Capacity of Lin. Accelerators**					
@ 8 hours/day	101.6%	104.7%	113.4%	118.3%	119.5%
@ 9 hours/day	90.3%	93.1%	100.8%	105.2%	106.2%

Note: * Volume includes radiation therapy (“RT”), intensity modulating radiation therapy (“IMRT”), and radiosurgery treatments (“SRS”).
 ** Assumes 250 treatment days per year; 3 linear accelerators; 4 RT treatments per hour; 3 IMRT per hour and 1.5 hours per SRS treatment.

12. There are five (5) radiation oncologists and seventeen (17) medical oncologists who provide consultative and cancer care at the McGivney Center and at their private offices in the greater New Haven area. *(September 26, 2005, Completeness Response, page 7)*
13. The Cancer Center’s actual utilization statistics for radiation therapy services between FYs 2000 through 2004 are as follows: *(August 2, 2005, CON application, page 16)*

Table 4: Actual Radiation Therapy Utilization Statistics

Description	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004
Number of Patients	826	852	922*	911*	870
McGivney Center Treatments					
Radiation Therapy	24,384	25,137	27,213	24,805	20,876
IMRT				2,722	5,595
Radiosurgery					71
Total Service Volume	24,384	25,137	27,213*	27,527*	26,542

Note: *The observed spike in radiation therapy volumes for FYs 2002 and 2003 are attributable to temporary utilization patterns that developed when Yale-New Haven Hospital (“YNHH”) experienced a disruption in their radiation therapy services caused by a flood in their Radiation Therapy Department.

14. To arrive at the projected growth in radiation therapy treatments the Hospital developed an age-adjusted, population-based projection model. The Hospital conducted reasonableness tests of its treatment volume projections by comparing its results to projections that were obtained using information supplied from Solucient, Inc. and the Health Care Advisory Board (“HCAB”). Data and associated assumptions used in the formulation of the Hospital’s projections could not be verified by OHCA nor could the consultant’s projections be verified by OHCA due to the proprietary nature of this information. *(August 2, 2005, CON application, pages 16 & 17 and Attachment 3, page 94 through 97)*
15. The Hospital projects annual utilization statistics for radiation therapy services between FYs 2005 through 2010 by service site as follows: *(August 2, 2005, CON application, page 16)*

Table 5: Projected* Radiation Therapy Utilization Statistics

Description	FY 2005*	FY 2006*	FY 2007*	FY 2008*	FY 2009*	FY 2010*
Number of Patients	870	906	929	951	974	998
McGivney Center Treatments						
Radiation Therapy	19,274	19,272	14,167	12,732	12,075	12,793
IMRT	5,976	7,363	7,158	7,800	8,682	8,587
Radiosurgery	75	78	82	86	91	95
Subtotal McGivney Service Volume	25,325	26,713	21,407	20,618	20,848	21,475
Hamden Satellite Treatments						
Radiation Therapy			4,715	5,727	5,926	5,588
IMRT			1,535	2,273	2,824	3,162
Subtotal Satellite Service Volume			6,250	8,000	8,750	8,750
Total Hospital Treatments						
Radiation Therapy	19,274	19,272	18,882	18,459	18,001	18,381
IMRT	5,976	7,363	8,693	10,073	11,506	11,749
Radiosurgery	75	78	82	86	91	95
Projected Total Service Volume*	25,325	26,713	27,657	28,618	29,598	30,225

Note: *Data and associated assumptions used in the formulation of the projections could not be verified by OHCA.

16. The actual service volumes for FYs 2003 through 2005 and the projected service volumes for FYs 2006 through 2010 for each CT scanner/simulator by service site and by type of procedure (i.e. simulation vs. diagnostic testing) are presented in the following table. Simulation estimates are based on the projected number of patients that will be receiving radiation therapy treatment. Diagnostic testing estimates are based on an analysis of patient origin data for individuals receiving diagnostic CT exams from the Hamden area and on discussions with area radiation oncologists and medical oncologists regarding projected referral volumes. (August 2, 2005, CON application, page 17, Attachment 22, page 441 and December 13, 2005, Second Completeness Response, page 1)

Table 6: Actual and Projected* CT/Simulator and CT Diagnostic Volumes by Site

Description	FY 2003	FY 2004	FY 2005*	FY 2007*	FY 2008*	FY 2009*	FY 2010*
McGivney Center Scanner Activity							
Simulation CT	911	870	870	733	703	706	733
Diagnostic CT	--	--	--	0	0	0	0
Subtotal McGivney Center Volume				733	703	706	733
Hamden Satellite Scanner Activity							
Simulation CT	--	--	--	196	248	268	265
Diagnostic CT	--	--	--	688	722	759	796
Subtotal Satellite Facility Volume	--	--	--	884	970	1,027	1,061
Total HSR Activity							
Simulation CT	911	870	870	929	951	974	998
Diagnostic CT	--	--	--	688	722	759	796
Total CT Service Volume	911	870	870*	1,617*	1,673*	1,733*	1,794*

Note: *Data and associated assumptions used in the formulation of the projections could not be verified by OHCA.

17. The Hospital offered the list presented in the table below which represents the other providers of radiation therapy (“RT”) services in the greater New Haven area. The service volumes for these providers represent FY 2004 utilization statistics. (*August 2, 2005, CON application, page 25*)

Table 7: Current Service Area Radiation Therapy Providers

Service Description	Provider	Operating Schedule*	Current Utilization**
RT – 3 Linear Accelerators	Yale-New Haven Hospital, New Haven	Monday – Friday 8:00am – 5:00 pm	19,288
RT – 1 Linear Accelerator	MidState Medical Center, Meriden	Monday – Friday 7:30 am – 5:00 pm	7,692
RT – 1 Linear Accelerator	YNHH Shoreline Facility, Guilford	Monday – Friday 8:00 am – 5:00 pm	Not Available

Note: * Days of the week and hours each day the service is operational.

** Number of treatments performed in FY 2004.

18. The Hospital indicated that the proposal is intended to provide services to the Hospital’s existing patient population and is not expected to impact other area providers. (*August 2, 2005, CON application, page 25*)
19. The McGivney Center operates between the hours of 7:30 a.m. and 4:30 p.m. daily from Monday through Friday. The Hospital anticipates that the proposed Hamden satellite facility will have the same hours of operation. (*August 2, 2005, CON application, page 24*)
20. The Hospital has and will continue to maintain its radiation oncology program accreditation through the American College of Radiology. (*August 2, 2005, CON application, page 27*)

McGivney Center Equipment Replacements and Upgrades

21. The Cancer Center is a 29,000 square foot (“SF”) facility, offering treatment equipment including: high energy linear accelerators, intensity modulating radiation therapy (“IMRT”), high dose and low dose brachytherapy, stereotactic radiosurgery and three-dimensional conformal radiotherapy. (*August 2, 2005, CON application, page 3 and September 26, 2005, Completeness Response, pages 4, 9 & 10*)
22. The McGivney Center is equipped with three (3) linear accelerators, which were acquired during a time span ranging between 12 to 15 years ago. The Hospital indicates that the linear accelerators no longer represent state-of-the-art in the delivery of radiation therapy cancer treatment. (*August 2, 2005, CON application, page 2 and September 26, 2005, Completeness Response, page 4*)
23. The Hospital proposes to replace its two older linear accelerators with a TomoTherapy Hi-Art Adaptive Radiotherapy System and a Varian Clinac iX Linear Accelerator System. In addition, the Hospital is seeking to upgrade with a multileaf collimator the third accelerator, which was purchased in 1993 and was later retrofitted with stereotactic radiosurgery technology in 1998. (*August 2, 2005, CON application, page 2*)

24. The Hospital proposes to update the McGivney Center's existing computed tomography ("CT") scanner from a 1 to 16 slice capable unit and indicates that the updated unit will continue to utilize for simulation purposes only. *(August 2, 2005, CON application, Attachment 22, page 441 and December 13, 2005, Second Completeness Response, page 1)*
25. The Hospital based the need for the replacements and upgrades on the following factors : *(March 9, 2005, Letter of Intent, page 11 and August 2, 2005, CON application, page 2)*
 - Rapid pace of change in cancer treatment, technology, and care delivery; and
 - Age of the equipment that is well beyond the average useful life expectancy for this technology, which is typically accorded a depreciable of approximately seven years.
26. The Hospital stated that the existing linear accelerators have age-related problems that include: lack of serviceability; lack of precision measurement; technological limitations; increased frequency in unplanned downtime and difficulty in procuring replacement repair parts. *(August 2, 2005, CON application, page 5)*
27. The Hospital indicated that IMRT technology is only available on its retrofitted accelerator. IMRT capability on each of the proposed accelerators will improve the accuracy and precision of treating cancerous tissue, allowing escalation of radiation dosage to enhance tumor control and lowering of radiation dosage to normal tissues to reduce toxicity. *(August 2, 2005, CON application, page 5)*
28. The Hospital plans to remove the two linear accelerators designated for replacement from the Cancer Center when the new equipment is received and installed. *(December 13, 2005, Second Completeness Response, page 1)*

Radiation Therapy Satellite Facility in Hamden

29. The Hospital indicated that it's undertaken several years of clinical service and facilities planning to develop a viable approach that will alleviate capacity constraints at the Cancer Center and to foster continued growth in its radiation therapy program. *(August 2, 2005, CON application, page 17)*
30. Expanding radiation therapy capacity through new construction at the McGivney Center was rejected due to the following reasons: *(August 2, 2005, CON application, page 18)*
 - Limited availability of additional space for clinical and support service functions;
 - Limited parking facilities to accommodate additional patients;
 - Accessibility concerns for patients residing outside of the City of New Haven; and
 - Other Hospital priorities affecting such development, such as the recently OHCA approved on-campus construction project, authorized under Docket Number 04-30417CON, expanding the Verdi Building to accommodate forty-eight (48) additional inpatient medical-surgical beds.

31. The Hospital based the need for establishing the proposed Hamden satellite facility (“satellite facility”) on the following : *(March 9, 2005, Letter of Intent, page 11 and August 2, 2005, CON application, page 2)*
 - Current number of annual treatments;
 - Increased capacity requirements at the Center with few options to expand in place;
 - Allowances for better coordination of radiation therapy and doctor visits for those patients residing in the greater-Hamden area; and
 - Improving access by reducing the commute for radiation therapy patients over a course of therapy which usually spans many weeks to predominantly older residents.
32. The Hospital cited other factors affecting the development of the satellite facility beyond the Hospital’s New Haven campus as follows: *(August 2, 2005, CON application, page 19)*
 - The proposal was twice recommended by an independent consulting group, Oncology Solutions, that was retained by the Hospital to conduct external assessments of the Hospital’s cancer services in 1998 and 2002;
 - The proposal satisfies the need to reduce current overcapacity problems at the Center;
 - Operational efficiencies will be achieved as opportunities for shared supply purchasing, bio-hazard waste handling, trash removal, and linen services will exist with other Hospital services; and
 - The proposal will allow for better coordination of oncology services at a site as radiation therapy and medical oncology services will originate at the group practice site.
33. The Hospital anticipates that the Hamden satellite location will primarily treat radiation therapy patients from the towns of Hamden, North Haven, Cheshire, Meriden and Wallingford. North Haven, Cheshire and Wallingford are towns that are contiguous to Hamden. *(August 2, 2005, CON application, pages 20 & 21)*
34. The Hospital states that there are no current providers of radiation therapy services in the five town area which the satellite facility will primarily serve. *(August 2, 2005, CON application, page 19)*
35. Hamden ranks second only to the City of New Haven as the municipality that accounts for the highest number of radiation therapy treatments in the Hospital’s service area. *(August 2, 2005, CON application, page 19)*
36. Hamden is situated in the northern most sector of the Hospital’s primary service area. The satellite facility will be easily accessible to residents from the towns of Cheshire, Wallingford and Meriden in the Hospital’s northern service area and the Housatonic River Valley towns of Bethany, Woodbridge and Seymour, which make up the western ridge of the Hospital’s service area. Bethany and Woodbridge are towns that are contiguous to Hamden. *(August 2, 2005, CON application, pages 20 & 21)*
37. The satellite facility will operate as a separate department of the Hospital. The new cost center for the facility will be designated as the Hamden Radiation Diagnostic and Therapy Center. Charges will be for radiation therapy and related services. *(August 2, 2005, CON application, page 32)*

38. The satellite facility will be located directly adjacent to the Hospital's Ambulatory Surgical Center, Outpatient Physical Therapy and Occupational Health programs in Hamden. *(March 9, 2005, Letter of Intent, pages 3 & 11 and August 2, 2005, CON application, page 5)*
39. The Hospital plans to acquire a new Varian Clinac linear accelerator to provide external beam radiation therapy with IMRT capability. *(September 26, 2005, Completeness Response, page 18)*
40. The Hospital is also proposing to acquire a refurbished CT scanner for the proposed satellite facility. The refurbished unit will perform simulations for patients prior to receiving radiation therapy treatment. The unit will also perform diagnostic testing for the monitoring of a patient's tumor prior to their being seen by their medical oncologist and receiving continued chemotherapy at the Hamden satellite. *(August 2, 2005, CON application, Attachment 22, page 441 and December 13, 2005, Second Completeness Response, page 1)*
41. The proposed outpatient satellite facility will be located at Suite 290, 2080 Whitney Avenue, Hamden. The service site will occupy space that is being added to the existing medical building at that location. *(August 2, 2005, CON application, page 33 and Attachment 1, page 1 through 4)*
42. Of the seventeen (17) medical oncologists affiliate with the Cancer Center, fifteen (15) physicians are practitioners affiliated with Medical Oncology and Hematology, P.C. ("MOH"). MOH's Hamden office is located one floor above the proposed outpatient satellite service. *(September 26, 2005, Completeness Response, page 7)*
43. Medical supervision of the outpatient satellite facility will be provided by the Hospital's affiliated, board-certified radiation oncologists. *(March 9, 2005, Letter of Intent, page 6)*

**Financial Feasibility of the Proposal and its Impact on the Hospital's
Rates and Financial Condition
Impact of the Proposal on the Interests of Consumers of Health Care
Services and Payers for Such Services
Consideration of Other Section 19a-637, C.G.S. Principles and Guidelines**

44. The project's total capital expenditure of \$12,207,916 is itemized as follows:
(August 2, 2005, CON application, page 32)

Table 8: Project's Total Capital Expenditure Itemization

Description	Cost
Construction/Renovation Work	\$2,423,470
Medical Equipment Purchases & Upgrade	\$8,762,695
Imaging Equipment Purchase & Update	\$640,000
Non-Medical Equipment Purchases	\$381,751
Total Project Capital Expenditure	\$12,207,916

45. The proposed project will be financed entirely through a fund raising campaign. The campaign's goal has been set at approximately \$15 million, which will allow for the establishment an endowment to support this project as well as the cancer program in future years. The campaign will be announced to the public after receipt of CON authorization from OHCA. As of March 2005, the Hospital has raised approximately \$1.2 million in pledges. *(August 2, 2005, CON application, page 37)*
46. The project will be phased-in with the satellite facility completed prior to the McGivney Center equipment upgrades. The project schedule is as follows: *(August 2, 2005, CON application, page 35)*

Table 9: Project Schedule

Description	Date
Construction Commencement Date	January 1, 2006
Renovation Completion Date	May 31, 2006
DPH Licensure Date	June 1, 2006
Commencement of Operation Date	June 1, 2006

47. The Hospital proposes to lease 9,200 square feet of new space for the satellite facility from Twenty Eight Limited Partnership, a Connecticut limited partnership. The initial monthly expense associated with the lease will be \$92,000. *(August 2, 2005, CON application, page 33 and Attachment 1, page1 through 4)*
48. The Hospital projects operating losses incremental to the project of \$142,300, \$669,300, and \$663,300 for FYs 2007, 2008 and 2009, respectively. The projected incremental operating losses are primarily due to the additional staffing requirements attributable to the satellite facility and equipment depreciation expense associated with each service site. *(August 2, 2005, CON application, pages 39 & 40 and Attachment 22, pages 439 through 444)*
49. The Hospital projects overall operating gains for the Hospital with the project of \$2,666,200, \$3,315,800, and \$3,479,200 for FYs 2007, 2008 and 2009, respectively. *(August 2, 2005, CON application, pages 39 & 40 and Attachment 22, pages 439 through 444)*
50. The proposed staffing for the satellite facility in full-time equivalents ("FTEs") is as follows: 3.0 radiation therapy technicians, 1.4 radiation technicians, 1.4 registered nurses, 1.0 physicist, 1.0 dosimetrist, 1.4 receptionists and 1.0 supportive services. *(August 2, 2005, CON application, pages 39 & 40 and Attachment 22, page 440)*
51. The Hospital's existing payer mix is not expected to change as a result of this project. The projected payer mix for the first three years of operation of the reconfigured service is as follows: *(August 2, 2005, CON application, page 39)*

Table 10: Current and Three-Year Projected Payer Mix with the CON Proposal

Payer Description	Current Mix	Year 1	Year 2	Year 3
Medicare w/ managed care	56%	56%	56%	56%
Medicaid w/ managed care	7.4%	9.8%	9.8%	9.8%
TriCare (CHAMPUS)	0.1%	0.1%	0.1%	0.1%
Total Government	63.5%	63.5%	63.5%	63.5%
Commercial Insurers	33.6%	33.6%	33.5%	33.5%
Uninsured	1.9%	1.9%	1.9%	1.9%
Workers Compensation	1.0%	1.0%	1.0%	1.0%
Total Non-Government	36.5%	36.5%	36.5%	36.5%
Total Payer Mix	100.0%	100.0%	100.0%	100.0%

52. There is no State Health Plan in existence at this time. *(August 2, 2005, CON application, page 2)*
53. The Hospital has adduced evidence that this proposal is consistent with both the SRHS's Strategic Plan and the Hospital's Oncology Services Strategic Plan. *(August 2, 2005, CON application, pages 2 & 3 and September 26, 2005, Completeness Response, pages 2 & 3)*
54. The Hospital participates in programs emphasizing energy conservation, group purchasing activities, and reengineering technology to improve productivity and contain operating costs. *(August 2, 2005, CON application, page 30)*
55. This proposal will improve the teaching and research responsibilities of the Hospital in that the project will benefit the graduate residency programs in internal medicine, surgery and radiology and collaborative medical education activities with Yale-New Haven Hospital. *(August 2, 2005, CON application, pgs 4 & 30 and September 26, 2005, Completeness Response, pgs 5 & 21)*
56. The Hospital's rates are sufficient to cover the proposed capital expenditures and operating costs. *(August 2, 2005, CON application, pages 39 & 40 and Attachment 22, pages 439 through 444)*
57. This proposal will improve the Hospital's patient/physician mix in that the project will assist in the recruitment of oncology physicians, the strengthening of subspecialty expertise and improvements in the monitoring and follow-up care for oncology patients. *(August 2, 2005, CON application, page 31 and September 26, 2005, Completeness Response, page 17)*
58. The Hospital has sufficient technical and managerial competence to provide efficient and adequate services to the public. *(August 2, 2005, CON application, page 28 and 9, Attachment 9, pages 167 through 251)*

Rationale

The Office of Health Care Access (“OHCA”) approaches community and regional need for Certificate of Need (“CON”) proposals on a case by case basis. CON applications do not lend themselves to general applicability due to a variety of factors, which may affect any given proposal; e.g. the characteristics of the population to be served, the nature of the existing services, the specific types of services proposed to be offered, the current utilization of services and the financial feasibility of the proposal.

The Hospital proposes to replace and upgrade its current radiation therapy equipment at the Father McGivney Center for Cancer Care (“McGivney Center” or “Cancer Center”). In addition, the Hospital proposes to expand its radiation therapy program through the establishment of a new radiation therapy satellite facility (“satellite facility”) at 2080 Whitney Avenue in Hamden. The Hospital based the need for the project on several factors including: quality of care, accessibility and programmatic improvements; the age and condition of the current radiation therapy equipment; the current treatment volume and future capacity requirements at the Center; and the limited options to expand the program within the context of the existing physical plant. The Hospital indicates that the project is intended to serve those patients who predominately reside within its service area which is the south central region of Connecticut.

Equipment Replacements and Upgrades

The Hospital proposes to replace the Cancer Center’s two older linear accelerators with a TomoTherapy Hi-Art Adaptive Radiotherapy System and a Varian Clinac iX Linear Accelerator System. The Hospital also is seeking to upgrade the third accelerator, retrofitted in 1993, to current state-of-the-art capability and to improve the Center’s simulator by upgrading the unit from a one slice to a sixteen slice capable CT unit. The unit will continue to be utilized solely for simulation purposes and will not be utilized for diagnostic testing purposes. The Hospital based the need for the proposed replacements and upgrades on the age of the equipment and the rapid pace of change in cancer treatment, technology, and care delivery. The equipment is well beyond the average useful life expectancy for this technology, which is typically accorded a depreciable life of seven years. The Hospital states that the current linear accelerators have age-related problems that include: lack of serviceability, lack of precision measurement, technological limitation, increased frequency in unplanned downtime, and difficulty in procuring replacement repair parts.

In addition, the Hospital indicates that intensity modulated radiation treatment (“IMRT”) technology is only available on the retrofitted 1993 accelerator, which is the accelerator designated for upgrading, and not the two older units designated for replacement. The quality of providing radiation therapy services will improve as IMRT capability on each of the new accelerator acquisitions will increase the accuracy and precision of treating cancerous tissue, while lowering the radiation dosage to normal tissues to reduce toxicity. Consequently, OHCA concludes that this initiative will improve the overall quality of care to cancer patients in the region served by the Hospital’s program.

Establishing a Radiation Therapy Satellite Facility in Hamden

The Hospital is also proposing to establish a radiation therapy satellite facility (“satellite facility”) to be located at 2080 Whitney Avenue, Hamden. The Hospital plans to acquire a new Varian Clinac linear accelerator to provide external beam radiation therapy with IMRT capability and a

refurbished Siemens computed tomography, 8 slice ("CT") scanner for simulation treatment planning and diagnostic CT examinations.

The Hospital has undertaken several years of clinical service and facilities planning to develop their proposal. One goal of the project is to alleviate capacity constraints at the Cancer Center, thereby allowing the Hospital to foster continued growth in its radiation therapy program. Within the context of the program's increasing capacity requirements and physical constraints, the Hospital possesses few viable options for program expansion other than the establishment of a satellite facility outside of the Hospital's main campus facility. The proposed satellite facility will satisfy the need to reduce current overcapacity problems at the Center and provide radiation therapy services to patients predominantly residing in Hamden and towns contiguous to Hamden. While the satellite facility's service area currently has no providers of radiation therapy, Hamden has been a town that historically ranks second only to the City of New Haven as the municipality that accounts for the highest number of radiation therapy treatments in the Hospital's service area. Additionally, the proposed satellite location will be easily accessible to residents from each of the service area towns. The close proximity of the proposed satellite facility to the private medical oncology group practice, whose physicians are affiliated with the Cancer Center, will provide opportunity for improved coordination of care received by area patients. The quality of providing radiation therapy services will also improve as IMRT capability will be offered by the satellite facility's accelerator. Utilizing an accelerator with this technology will improve the accuracy and precision of treating cancerous tissue. Consequently, OHCA concludes that this initiative will also improve the overall quality of care as well as access to radiation therapy services in the region for cancer patients served by the Hospital's program.

The total capital expenditure associated with the project is \$12,207,916. The proposed project will be financed entirely through a fund raising campaign, which to date has raised approximately \$1.2 million in pledges. While the Hospital projects incremental operating losses due to the project of \$142,300, \$669,300, and \$663,300 for FYs 2007, 2008, and 2009, respectively, the overall financial condition of the Hospital is expected to be positive, ranging from operating gains of \$2,666,200 in FY 2007 to \$3,479,200 in FY 2009. The proposal's incremental operating losses are primarily due to the additional staffing requirements attributable to the satellite operation and the equipment depreciation expenses attributable to each service site. The Hospital's volume and financial projections upon which they are based appear to be reasonable and achievable. Therefore, the proposal will not adversely impact consumers of health care services and payers for such services.

Based on the foregoing Findings and Rationale, the Certificate of Need application of The Hospital of Saint Raphael ("Hospital") to replace and upgrade radiation therapy equipment at its McGivney Cancer Center and to establish a radiation therapy satellite facility in Hamden, at a total capital expenditure of \$12,207,916, is hereby GRANTED.

ORDER

The Hospital of Saint Raphael (“Hospital”) is hereby authorized to replace and upgrade radiation therapy equipment at its Father Michael J. McGivney Center for Cancer Care and to establish a radiation therapy satellite facility in Hamden, at a total capital expenditure of \$12,207,916, subject to the following conditions:

1. This authorization shall expire June 1, 2008. Should the Hospital’s radiation therapy project not be completed by that date, the Hospital must seek further approval from OHCA to complete the project beyond that date.
2. The Hospital shall not exceed the approved capital expenditure of \$12,207,916. In the event that the Hospital learns of potential cost increases or expects that the final project costs will exceed those approved, the Hospital shall file with OHCA a request for approval of the revised project budget.
3. The Hospital is authorized to acquire the following medical equipment systems and perform the following medical equipment upgrades as identified by each project component:
 - a. McGivney Center: Two Replacement Acquisitions and Two System Upgrades:
 - i. Replacing an older unit for a new TomoTherapy Hi-Art linear accelerator system;
 - ii. Replacing an older unit for a new Varian Clinac iX linear accelerator system;
 - iii. Multilease collimator upgrade to the existing retrofitted linear accelerator; and
 - iv. Phillips computed tomography scanner upgrade from 1 to 16 slice capability.
 - b. Hamden Outpatient Satellite Facility: Two Equipment Acquisitions
 - i. A new Varian Clinac iX linear accelerator system; and
 - ii. A refurbished Siemens Volume Zoom 8 slice CT scanner.
4. The CT scanner that will be acquired for used as a treatment simulator and diagnostic examination unit at the satellite facility in Hamden shall be limited for use to patients whose radiation oncologist and(/or) medical oncologist are(/is) affiliated with the Hospital of Saint Raphael’s Father Michael J. McGivney Center for Cancer.
5. This authorization requires the Hospital to remove its two older linear accelerators currently in operation at the McGivney Center for Cancer Care for certain disposition outside of and unrelated to the Hospital’s service provider locations. Furthermore, the Hospital shall provide evidence to OHCA of the final disposition of the existing linear accelerators, by no later than three months after the replacement linear accelerators have become operational.

All of the foregoing constitutes the final order of the Office of Health Care Access in this matter.

By Order of the
Office of Health Care Access

December 21, 2005

Signed by Cristine Vogel
Commissioner

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