



Office of Health Care Access Certificate of Need Application

Final Decision

Hospital: The Hospital of Saint Raphael

Docket Number: 07-30952-CON

Project Title: Acquisition and Operation of CyberKnife®
Stereotactic Radiosurgery System

Statutory Reference: Section 19a-639 of the Connecticut General Statutes

Filing Date: August 17, 2007

Decision Date: November 13, 2007

Default Date: November 15, 2007

Staff Assigned: Diane Duran
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Project Description: The Hospital of Saint Raphael proposes to acquire and operate a CyberKnife® stereotactic radiosurgery system for its on-campus cancer facility at a total capital cost of \$5,500,000.

Nature of Proceedings: On August 17, 2007, the Office of Health Care Access ("OHCA") received a Certificate of Need ("CON") application from The Hospital of Saint Raphael ("Hospital") to acquire and operate a CyberKnife® stereotactic radiosurgery system for the Hospital's on-campus cancer facility at a total capital cost of \$5,500,000. The Hospital is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes ("C.G.S.").

A notice to the public concerning OHCA's receipt of the Hospital's Letter of Intent was published on May 3, 2007, in *The New Haven Register*. OHCA received no responses from the public concerning the Hospital's proposal.

Pursuant to Section 19a-639 of the Connecticut General Statutes ("C.G.S.") three individuals or an individual representing an entity with five or more people had until September 7, 2007, the twenty-first calendar day following the filing of the Hospital's CON application, to request that OHCA hold a public hearing on the Hospital's proposal. OHCA received no hearing requests from the public.

On September 19, 2007, the Hospital requested a waiver of hearing pursuant to Section 19a-643-45 of OHCA's Regulations. The request was made based on the grounds that the CON application is non-substantive as defined in Section 19a-643-95(3) of OHCA's Regulations. OHCA determined that the CON application was eligible for consideration of waiver of hearing pursuant to Section 19a-643-45 of OHCA's Regulations. A notice to the public concerning OHCA's receipt of the Hospital's request for waiver of hearing was published in *The New Haven Register* on September 20, 2007, pursuant to Section 19a-639, C.G.S. OHCA received no response from the public concerning the Hospital's request for waiver of hearing. On November 1, 2007, OHCA determined that the Hospital's request for waiver of hearing be GRANTED based upon the reason specified by the Hospital.

OHCA's authority to review, approve, modify, or deny this proposal is established by Section 19a-639, C.G.S. The provisions of this section, 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 of the Proposal on the Hospital's Current Utilization Statistics

Proposal's Contribution to the Quality of Health Care Delivery in the Region

Proposal's Contribution to the Accessibility of Health Care Delivery in the Region

1. The Hospital of Saint Raphael ("Hospital") is a tertiary teaching hospital located at 1450 Chapel Street, New Haven, Connecticut. (*August 17, 2007, Initial CON Submission, page 1*)

2. The Hospital proposes to acquire and operate a CyberKnife® stereotactic radiosurgery system¹ (“CyberKnife®”) to be placed on the Hospital’s on-campus cancer facility, Father McGivney Cancer Center (“McGivney Center”). *(August 17, 2007, Initial CON Submission, pages 2, 4, 5 and 6)*
3. The Hospital indicates that the CyberKnife® technology would augment its existing radiation and surgical oncology programs, upgrade its existing SRS radiation therapy equipment and expand the scope of conditions treated within the Hospital’s radiation therapy program. *(August 17, 2007, Initial CON Submission, page 4)*
4. The proposal is intended to serve patients residing in the Hospital’s existing primary (“PSA”) and secondary (“SSA”) service areas. *(August 17, 2007, Initial CON Submission, pages 7 and 8)*
5. The Hospital indicates it’s PSA and SSA consists of the following Connecticut towns:

Table 1: Service Area Towns

| PSA: | | | | |
|-------------|------------|-------------|------------|--------|
| New Haven | East Haven | North Haven | West Haven | Hamden |

| SSA: | | | | |
|----------------|------------|----------|----------|---------|
| Ansonia | Bethany | Branford | Cheshire | Clinton |
| Derby | Guilford | Madison | Meriden | Milford |
| North Branford | Orange | Oxford | Seymour | Shelton |
| Wallington | Woodbridge | | | |

(August 17, 2007, Initial CON Submission, pages 7 and 8)

6. The McGivney Center is a 29,000 square foot facility that offers a technologically advanced range of cancer treatment and supportive services as follows:

| | |
|-----------------------------------|--|
| Linear accelerator operation | Intensity modulated radiation therapy (IMRT) |
| High & low dose brachytherapy | Stereotactic radiosurgery (SRS) |
| Dimensional treatment planning | Conformal radiation therapy |
| Nutritional guidance | Prevention and screening |
| Dedicated inpatient oncology unit | Medical, surgical, & radiological care |
| Tumor conferences & registry | Cancer committee |
| Home health & hospice care | Expanding Clinical Research Activities |

(August 17, 2007, Initial CON Submission, page 3)

¹ The CyberKnife® is a minimally invasive, frameless stereotactic radiosurgery (SRS) technology used to treat malignant and benign solid tumors throughout the body with sub-millimeter accuracy. The CyberKnife® uses a lightweight linear accelerator in conjunction with a robotic arm to precisely target a tumor from virtually any direction. It uses real-time image guidance and directs highly focused beams of radiation without using a rigid frame for immobilization of the patient, as it is programmed to compensate for small movements.

7. The Hospital operates three linear accelerators that provide external beam radiation therapy, IMRT, and SRS services. *(August 17, 2007, Initial CON Submission, page 4)*
8. OHCA recently approved under Docket Number: 05-30450 the Hospital's proposal to establish a radiation therapy satellite service to complement its medical oncology services located in Hamden. The service is expected to become operational in the summer of 2008. *(August 17, 2007, Initial CON Submission, page 4 and October 30, 2007, Additional Information provided by the Hospital, page 2)*
9. OHCA's authorization under Docket Number: 05-30450 allowed the Hospital to accomplish the following on-campus radiation therapy equipment replacements and upgrades at the McGivney Center:
 - a. **Two Linear accelerator replacements:** to date one of the two replacements has been accomplished, the Elekta Synergy ("ES") for the Varian 2100C, which failed on 2/12/2007 and required replacement. The ES unit performs external beam and IGRT treatments. The Varian 2100 CD unit will be replacement soon with a tomotherapy Hi Art Adaptive radiotherapy unit, which will possess IGRT capability.
 - b. **One Linac Upgrade:** to date the Varian 600 C remains to be upgraded. The Hospital will wait to see if actual service volumes necessitate a service upgrade. Associated BrainLab equipment will not be replaced with it becomes non-operating. An upgraded unit will not have IGRT capability.
 - c. **One CT simulator upgrade:** this upgrade has been accomplished.
(October 30, 2007, Additional Information provided by the Hospital, page 2)
10. The Hospital has dedicated the Varian 600 C unit to SRS service for approximately 20 hours per week. *(August 17, 2007, Initial CON Submission, page 4)*
11. The current linear accelerator (i.e. 600 C unit) utilized for SRS services is 14 years old and requires frequent servicing which causes disruption in patient scheduling and longer wait times for patients. *(August 17, 2007, Initial CON Submission, page 4)*
12. Although the Hospital provides SRS, the current technology BrainLab has limited application (cranial only) and requires the patient to endure the invasive placement of a metal frame secured by screws. The establishment of a CyberKnife® program will negate the need for the use of invasive frames and future updates of this BrainLab SRS technology. *(August 17, 2007, Initial CON Submission, page 4)*
13. As a result of limited capacity, the Hospital indicates that it is not unusual for there to be a month long backlog for the SRS service. *(August 17, 2007, Initial CON Submission, page 9)*
14. The Hospital intends to continue to use the linear accelerator with BrainLab equipment for a few select cranial cases where patients can be better treated using the lower dose BrainLab equipment until such time as the BrainLab equipment is retired from service. *(August 17, 2007, Initial CON Submission, page 4)*

15. Unlike traditional radiosurgery systems that can only treat tumors in the head and neck, the CyberKnife® provides radiosurgery for both intracranial and extracranial tumors. *(August 17, 2007, Initial CON Submission, page 2)*
16. The CyberKnife® can be used to treat a range of medical conditions, most of which are untreatable with other SRS systems. *(August 17, 2007, Initial CON Submission, pages 4 through 6)*
17. The major advantages of the CyberKnife® system include:
 - a. Treats tumors anywhere in the body;
 - b. Continuously tracks, detects, and corrects for tumor and patient movement throughout the treatment;
 - c. Delivers treatment with sub-millimeter accuracy, minimizing damage to the surrounding healthy tissue;
 - d. Utilizes the skeletal structure of the body as a reference, eliminating the need for fiducials or invasive frames typically used with traditional radiosurgery systems;
 - e. Provides an option for inoperable or surgically complex tumors;
 - f. Successfully treats patients in single or multiple fractions;
 - g. Provides linear accelerator maneuverability and complete access and coverage for any tumor volumes;
 - h. Has a patient-centric design providing a relaxed treatment experience;
 - i. Enables superior flexibility in treatment planning:
 1. Forward or inverse treatment planning;
 2. Isocentric or non-isocentric treatment plans;
 3. Simultaneous treatment of multiple tumors;
 - j. Allows for flexible scheduling of treatments.*(August 17, 2007, Initial CON Submission, pages 4 through 6)*
18. The Hospital based the need for the proposed service based on the unavailability of this technology in the New Haven County area. *(August 17, 2007, Initial CON Submission, page 2)*
19. Currently, there is one Connecticut acute care provider of CyberKnife® services located in Hartford with future service providers located in Stamford and New Britain. *(OHCA Final Decisions, Docket Numbers: 05-30429 – Saint Francis Hospital and Medical Center; 06-30828 – Stamford Hospital; and 07-30882 – Hospital of Central Connecticut)*

20. The capacity of the Hospital's existing radiation oncology department is 21,168 radiation therapy treatments per year, itemized by unit as follows:

Table 2: Existing Radiation Therapy ("RT") Equipment Capacity

| Model | Varian 600 C | Varian 2100 CD | Elekta Synergy |
|---------------------------------|--|------------------|--------------------------|
| Operation Date | October 1993 | December 1993 | July 2007 |
| Services Offered | External Beam RT SRS/SRT | External Beam RT | External Beam RT IGRT |
| Capacity- In # Treatments/FY | Ext Beam RT 4,536 SRS/SRT <u>2,016</u> Total 6,552 | 8,568 0 | 6,048 0 |

Notes: Calculations based on a 9 hours of operation, Monday through Friday, and 252 work days per year. Treatments on the Varian 600 C are divided between external beam for 4.5 hours/day and Brain Lab & stereotactic cranial procedures at 4 hours/day at 30 minute intervals. Time allotted for external beam are calculated at 15 minute intervals except patients treated on the Elekta Synergy requiring IGRT which is scheduled at 30 minute intervals.

(October 30, 2007, Additional Information provided by the Hospital, page 2)

21. The actual number of radiation therapy treatments performed on the Hospital's equipment in FY 2007 totaled 22,445 treatments and is itemized by unit as follows:

Table 3: FY 2007 Actual Radiation Therapy Treatments

| Model | Varian 600 C | Varian 2100CD | Varian 2100 C | Elekta Synergy |
|-----------------------------------|---|------------------|--|---|
| Service Offered | External Beam RT SRS/SRT | External Beam RT | External Beam RT | External Beam RT IGRT |
| Actual Volume- Treatments/Year | Ext Beam RT 5,577 SRS/SRT* <u>1,378</u> Total 6,955 | 9,570 0 | 5,067 0 | 853 0 |
| Actual SRS/SRT Patients | 78 Patients – Cranial Cases Only | | | |
| Unit Notes: | The unit was used as a replacement for Varian 2100 C from 2/2007 through 9/2007. Actual usage for SRS/SRT procedures was limited as a result. | | Operational from 10/2006 to 2/12/2007 (91 days). The equipment failed requiring replacement. | Operational from 7/16/07 through 9/30/2007 (54 days). Replaced the Varian 2100C unit. Actual volume limited during physician and staff training period. |

Note: Actual SRS/SRT volume reflects as follows: SRS – 1 treatment per patient; SRT – an average of 26 treatment/patient.
(October 30, 2007, Additional Information provided by the Hospital, page 2)

22. The Hospital chose to project volume for the proposal using a methodology based on a systematic review of the Hospital's internal tumor registry. (August 17, 2007, Initial CON Submission, page 10)
23. During FYs 2004 through 2006, the Hospital diagnosed between 1,400 and 1,500 new cancer cases each year. (August 17, 2007, Initial CON Submission, page 10)

24. The tumor registry data was analyzed to determine which of the newly diagnosed cases at the Hospital would be potential candidates for CyberKnife® treatment. The following table shows the total number of cases that presented to the Hospital and the estimated number of Hospital eligible CyberKnife® cases from FY 2004 through FY 2006:

**Table 4: Actual New Cancer Cases versus Hospital's
Estimated of CyberKnife® Eligible Cases**

| FY 2004 | | FY 2005 | | FY 2006 | |
|-------------|----------------|-------------|----------------|-------------|----------------|
| Total Cases | Cases Eligible | Total Cases | Cases Eligible | Total Cases | Cases Eligible |
| 1,497 | 152 | 1,438 | 160 | 1,457 | 172 |

Note: Source HSR Tumor Registry

(August 17, 2007, Initial CON Submission, page 10 and Attachment 2, pages 29 through 32)

25. An analysis of the FY 2006 cases by tumor site revealed the following information for those cases considered eligible for CyberKnife® treatment:

**Table 5: Actual Number of CyberKnife®
Eligible Cases by Tumor Site- FY 2006**

| Cancer Type: | # Cases |
|---------------|---------|
| Brain | 53 |
| Head and Neck | 9 |
| Primary Lung | 26 |
| Pancreas | 9 |
| Liver | 1 |
| Prostate | 60 |
| Renal | 14 |
| Total Cases | 172 |

Note: Source HSR Tumor Registry

(August 17, 2007, Initial CON Submission, page 10 and Attachment 2, pages 29 through 32)

25. The projected number of CyberKnife® cases with the resulting number of CyberKnife® treatments as estimated by the Hospital is as follows:

Table 6: Projected Number of Hospital CyberKnife® Cases and Treatments

| Fiscal Year | FY 2007 | FY 2008 | FY 2009 | FY 2010 | FY 2011 |
|------------------------|---------|---------|---------|---------|---------|
| Projected Cases* | 181 | 190 | 199 | 209 | 220 |
| Projected Treatments** | 462 | 485 | 507 | 533 | 561 |

Note: *The methodology assumes a 5% case volume increase per year.

** The methodology assumes the average number of treatments per case is 2.55 CyberKnife® treatments based on Accelitech, LLC's SRS experience, the vendor/consultant for the Hospital in this CON application.

(August 17, 2007, Initial CON Submission, page 10 and Attachment 2, pages 29 through 32)

26. The Hospital estimate of a 5% increase in the number of CyberKnife® cases annually is based on the following factors:
- a. Strength of the existing SRS service;
 - b. Increasing physician comfort level with the technology;
 - c. Hospital's ability to market the new technology; and
 - d. Increasing incidence of cancer in the Hospital's service area.
- (August 17, 2007, Initial CON Submission, page 10 and Attachment 2, pages 29 through 32)*
27. The McGivney Center was surveyed in December 2006 by the College of Surgeons and was granted a 3-Year award commendation. *(August 17, 2007, Initial CON Submission, pages 3 and 4)*
28. The Hospital follows the standards of practice outlined in the guidelines of the American College of Radiology and the American Society for Therapeutic Radiology and Oncology. *(August 17, 2007, Initial CON Submission, page 12)*

**Financial Feasibility and Cost Effectiveness 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 the
Payers for Such Services
Consideration of Other Section 19a-637, C.G.S., Principles and Guidelines**

29. The total capital cost for the CyberKnife® system acquisition and the associated renovation work is as follows:

Table 7: Total Capital Cost

| Item | Cost |
|-------------------------------|--------------------|
| Medical Equipment (FMV lease) | \$4,000,000 |
| Renovation Work | 1,500,000 |
| Total Capital Cost | \$5,500,000 |

(August 17, 2007, Initial CON Submission, page 16)

30. The total square footage being renovated is approximately 1,800 square feet. *(August 17, 2007, Initial CON Submission, page 17)*
31. The renovation cost associated with the proposal is itemized follows: *(August 17, 2007, Initial CON Submission, page 18)*

Table 8: Renovation Costs

| Item | Cost |
|-------------------------------|--------------------|
| Total Building Work | \$1,164,000 |
| Architectural and Engineering | 105,000 |
| Contingency Allowance | 231,000 |
| Total | \$1,500,000 |

32. The CyberKnife® system will be installed in a newly remodeled vault, which formerly housed a conventional external beam linear accelerator, prior to the establishment of the McGivney Center. *(August 17, 2007, Initial CON Submission, page 18)*
33. The Hospital states that the required renovations associated with the proposal will not affect the delivery of patient care for existing services. *(August 17, 2007, Initial CON Submission, page 18)*
34. Building work required for the accommodation of the CyberKnife® system, equipment support area and support service area is scheduled as follows: *(August 17, 2007, Initial CON Submission, page 18 and 19)*

Table : Renovation Schedule

| Stage | Time Frame |
|---------------------------------|-------------------|
| Renovation Commencement Date | November 1, 2007 |
| Renovation Completion Date | February 15, 2008 |
| Commencement of Operations Date | April 15, 2008 |

35. The Hospital intends to lease the equipment from Connecticut CK Leasing, LLC, a single purpose limited liability company that acquires and leases new technology to end providers. *(August 17, 2007, Initial CON Submission, pages 6 and 7)*
36. Connecticut CK Leasing, LLC, will also finance the Hospital's renovations to create the dedicated vault to house the CyberKnife® and will provide funding for technology upgrades and maintenance over the lease period. *(August 17, 2007, Initial CON Submission, pages 6, 7 and 18)*
37. Connecticut CK Leasing, LLC, will be established as a joint venture between the Hospital, Accelitech, LLC and Radiation Oncology Specialists of Southern Connecticut. *(August 17, 2007, Initial CON Submission, page 7)*
38. The lease model under consideration calls for an operating lease with the Hospital being charged a fixed per patient fee over a ten year period. *(August 17, 2007, Initial CON Submission, pages 6 and 19)*
39. The financing for the proposal is based on a leasing model developed by Accelitech, LLC, a company which specializes in providing the resources necessary to acquire, deploy and operate programs built around new and emerging technologies. *(August 17, 2007, Initial CON Submission, page 7)*

40. The additional staffing requirements necessary to provide the proposed CyberKnife® service is presented in the following table:

Table 9: Incremental Staffing Requirements

| Positions by Title | Operating Years 1 & 2 | Operating Year 3 |
|------------------------------------|-----------------------|------------------|
| Registered Nurse | 1.0 | 1.0 |
| Administrative & Marketing Liaison | 1.0 | 1.0 |
| Physicist | 1.0 | 2.0 |
| Radiation Therapist | 2.0 | 2.0 |
| Total FTEs | 5.0 | 6.0 |

(October 30, 2007, Additional Information provided by the Hospital, pages 4 and 5)

41. The Hospital will assemble a skilled team consisting of radiation oncologists, surgical oncologists, physicists, radiation therapists and registered nurses for the proposed CyberKnife® service. Individual team members will possess the prerequisite educational credentials, specialized training and continuing educational credits necessary for providing the proposed service. (October 30, 2007, Additional Information provided by the Hospital, pages 4 and 5)

42. The Hospital projects gains/(loss) from operations incremental to the CyberKnife® project as follows:

Table 10: Projected Incremental Gain/(Loss) from CyberKnife® Proposal

| Fiscal Year | FY 2008* | FY 2009 | FY 2010 |
|--------------------|-----------|-----------|-----------|
| Gain/(Loss) | (\$8,873) | \$343,231 | \$484,780 |

Note: * The Hospital expects CyberKnife® operations to commence in second quarter of FY 2008. The incremental loss that results from the start-up nature of the program. The Hospital indicates that it is confident that revenues resulting from the proposal will cover and surpass expenses by Year 2. (August 17, 2007, Initial CON Submission, page 22 and Attachment 11, page 327)

43. The current SRS and projected CyberKnife® payer mix is listed in the following table:

Table 11: Service Payer Mix

| Payer | Current | Year 1 | Year 2 | Year 3 |
|--------------------------------|---------------|---------------|---------------|---------------|
| Medicare | 31.0% | 31.0% | 31.0% | 31.0% |
| Medicaid* | 2.0% | 2.0% | 2.0% | 2.0% |
| CHAMPUS & TriCare | 0.0% | 0.0% | 0.0% | 0.0% |
| Total Government Payers | 33.0% | 33.0% | 33.0% | 33.0% |
| Commercial* | 65.0% | 65.0% | 65.0% | 65.0% |
| Uninsured | 2.0% | 2.0% | 2.0% | 2.0% |
| Workers Compensation | 0.0% | 0.0% | 0.0% | 0.0% |
| Total Non-Gov't Payers | 67.0% | 67.0% | 67.0% | 67.0% |
| Total | 100.0% | 100.0% | 100.0% | 100.0% |

(October 30, 2007, Additional Information provided by the Hospital, page 4)

44. There is no State Health Plan in existence at this time. *(August 17, 2007, Initial CON Submission, page 2)*
45. The proposal is consistent with Hospital's long-range plan. *(August 17, 2007, Initial CON Submission, page 2)*
46. The proposal will not change the Hospital's teaching or research responsibilities. *(August 17, 2007, Initial CON Submission, page 15)*
47. There are no distinguishing characteristics of the patient/physician mix with regard to the proposal. *(August 17, 2007, Initial CON Submission, page 15)*
48. The Hospital has improved productivity and contained costs through energy conservation, group purchasing, reengineering, and applications of technologies. *(August 17, 2007, Initial CON Submission, pages 14 and 15)*
49. The Hospital has sufficient technical and managerial competence to provide efficient and adequate service to the public. *(August 17, 2007, Initial CON Submission, page 6)*
50. The Hospital's rates are sufficient to cover the proposed capital expenditure and operating costs. *(August 17, 2007, Initial CON Submission, page 327)*

Rationale

The Office of Health Care Access (“OHCA”) approaches community and regional need for the proposed service on case by case basis. Certificate of Need (“CON”) applications do not lend themselves to general applicability due to a variety of complexity 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 proposed services.

The Hospital of Saint Raphael (“Hospital”) is a tertiary teaching hospital located in New Haven, Connecticut. The Hospital proposes to acquire a CyberKnife® stereotactic radiosurgery system (“CyberKnife®”) to be placed on the Hospital’s on-campus, Father McGivney Cancer Center (“McGivney Center”). The Hospital is seeking to augment its existing radiation and surgical oncology programs by adding CyberKnife® technology, which would expand the Hospital’s ability to treat cancerous tumors with radiation therapy. Through the McGivney Center and its oncology service line, the Hospital currently provides prevention, education, and early detection programs, along with the latest in treatment options, post-treatment care, supportive services, and clinical research activities.

The Hospital chose to project volume for the proposed service using a methodology based on a systematic review of the Hospital’s internal tumor registry. During FYs 2004 through 2006, the Hospital diagnosed between 1,400 and 1,500 new cancer cases annually. The tumor registry data was analyzed to determine which of the newly diagnosed cases at the Hospital would be potential candidates for CyberKnife® treatment. The estimated number of Hospital eligible CyberKnife® cases from FY 2004 through FY 2007 is 152, 160, 172 and 181 cases, respectively. Based on the review of the internal tumor registry data the Hospital anticipates treating between 190 CyberKnife® eligible cases in FY 2008 to 220 CyberKnife® eligible cases in FY 2011. In that each CyberKnife® case would generate 2.55 treatment visits, the Hospital projects the number of treatment visits for the proposed program to be from 485 treatments in FY 2008 to 561 treatment visits in 2011.

The Hospital performed 22,445 radiation therapy treatments at the McGivney Center in FY 2007. The Hospital indicates it currently has three functional linear accelerator rooms that perform radiation therapy. The room reconfigured in July 2007 has external beam and intensity modulated radiation therapy capability. The second room, outfitted in December 1993, performs external beam radiation therapy only. The third room, outfitted in October 1993, performs external beam radiation therapy, as well as stereotactic radiosurgery. The Hospital intends to continue to use the third room for a few select cranial cases where patients can be better treated using a lower dose BrainLab equipment, until the unit is retired from service. The current capacity of the radiation therapy department is 21,168 treatments per year.

The CyberKnife® utilizes stereotactic radiosurgery technology to treat malignant and benign solid tumors. Due to its use of real-time image guidance and extreme precision, the

CyberKnife® does not require use of a rigid frame to immobilize the patient and is able to minimize damage to surrounding healthy tissue. Furthermore, unlike traditional radiosurgery systems that can only treat tumors in the head and neck, the CyberKnife® is able to treat both intracranial and extracranial tumors, allowing for a greater range of cancers to be treated. The CyberKnife® also provides an additional option for many patients with previously inoperable or surgically complex tumors. The proposed CyberKnife® system will allow the Hospital to perform more precise treatment of lesions as compared to the existing linear accelerator. In order to effectively utilize the treatment capabilities of the proposed equipment, the CyberKnife® system requires highly trained and skilled radiation oncologists working with an assembled team of surgical oncologists, radiation therapy technicians and nursing personnel that have experience with this technology. The Hospital of Saint Raphael meets these requirements. Based on the foregoing reasons, OHCA finds that the proposed CyberKnife® acquisition will increase access and improve service quality for patients treated within the radiation and surgical oncology programs of the Hospital.

The total capital cost of the proposal is \$5,500,000, which represents the fair market value of the equipment and the renovation costs associated with equipment installation. The Hospital will lease the equipment from Connecticut CK Leasing, LLC, a single purpose limited liability company that acquires and leases new technology to end-providers. Connecticut CK Leasing, LLC, will be established as a joint venture between the Hospital, Accelitech, LLC, and Radiation Oncology Specialists of Southern Connecticut. The lease model under consideration calls for an operating lease with the Hospital being charged a fixed per patient fee for the equipment's use. The Hospital projects an incremental loss in FY 2008 from operations that result from the implementation of this proposal, reflecting the start-up nature of the program. The Hospital projects revenues over expenses in FYs 2009 and 2010. The Hospital's volume and financial projections upon which they are based appear to be reasonable and achievable.

In summary, OHCA finds that there is a clear public need for the Hospital's proposed CyberKnife® acquisition, as the CON proposal will enhance the quality of the radiation and surgical oncology programs provided by the Hospital.

Order

Based upon the foregoing Findings and Rationale, the Certificate of Need application of The Hospital of Saint Raphael ("Hospital") to acquire and operate a CyberKnife® stereotactic radiosurgery system for the Hospital's Father McGivney Cancer Center, at a total capital cost of \$5,500,000, is hereby GRANTED, subject to conditions.

1. This authorization shall expire on April 19, 2009. Should the Hospital's CyberKnife® stereotactic radiosurgery system not be operational by that date, the Hospital must seek further approval from OHCA to complete the project beyond that date.
2. The authorized capital cost of \$5,500,000 shall not exceed. In the event that the Hospital learns of potential cost increases or expects that final project costs will exceed those approved, the Hospital shall notify OHCA immediately.
3. The Hospital shall perform procedures that have been approved for the operation of the CyberKnife® stereotactic radiosurgery system by the United States Food and Drug Administration.

Should the Hospital fail to comply with any of the aforementioned conditions, OHCA reserves the right to take additional action as authorized by law.

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

Signed by Commissioner Vogel on November 13, 2007

Date

Cristine A. Vogel
Commissioner

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