



## Office Of Health Care Access Certificate of Need Application

### Final Decision

**Hospital:** Saint Francis Hospital and Medical Center

**Docket Number:** 05-30429-CON

**Project Title:** Acquisition of a CyberKnife® Stereotactic Radiosurgery System

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

**Filing Date:** May 5, 2005

**Decision Date:** June 21, 2005

**Default Date:** August 3, 2005

**Staff Assigned:** Laurie K. Greci

**Project Description:** Saint Francis Hospital and Medical Center (“Hospital”) proposes to acquire a CyberKnife® Stereotactic Radiosurgery System for the Radiation Therapy Department at a total capital expenditure of \$5,231,282.

**Nature of Proceedings:** On May 5, 2005, the Office of Health Care Access (“OHCA”) received a Certificate of Need (“CON”) application from Saint Francis Hospital and Medical Center to acquire a CyberKnife® Stereotactic Radiosurgery System for the Radiation Therapy Department at a total capital expenditure of \$5,231,282. 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 January 30, 2005, in *The Hartford Courant*. OHCA received no responses from the public concerning the Hospital’s proposal.

OHCA's authority to review, approve, modify, or deny this proposal is established by Sections 19a-638 and 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. Saint Francis Hospital and Medical Center ("Hospital"), located at 114 Woodland Street, Hartford, Connecticut, is a tertiary, general, acute care hospital that provides inpatient and outpatient health care services. *(April 14, 2005, Initial CON Submission, pages 4 and 303)*

2. The Hospital's primary service area includes the following towns:

Avon	Canton	Granby	Newington
Bloomfield	East Hartford	Hartford	Simsbury
Burlington	Farmington	New Britain	West Hartford

*(April 14, 2005, Initial CON Submission, page 5)*

3. The Hospital's secondary service area includes the following towns:

Barkhamsted	Glastonbury	Plainville	Torrington
Berlin	Hartland	Plymouth	Vernon
Bristol	Harwinton	Rocky Hill	Wethersfield
Cromwell	Litchfield	Southington	Winchester
East Granby	Manchester	South Windsor	Windsor
East Windsor	New Hartford		

*(April 14, 2005, Initial CON Submission, page 5)*

4. One of the Hospital's Centers of Excellence is the Cancer Care Services ("Cancer Center"). The Cancer Center offers state-of-the-art comprehensive outpatient radiation therapy, hematology, and medical oncology services. *(April 14, 2005, Initial CON Submission, page 5)*
5. The Hospital proposes to acquire a CyberKnife® Stereotactic Radiosurgery System ("CyberKnife") for its Radiation Therapy Department, at a total capital expenditure of \$5,231,282. *(April 14, 2005, Initial CON Submission, page 2)*

6. The CyberKnife Scanner system is manufactured by Accuray Incorporated (“Accuray”) and includes the following components: the X-ray imaging system and computer systems; treatment planning subsystem and operator control systems; the linear accelerator and associated control systems; a robotic manipulator; and the treatment couch. The system also includes the Express™ treatment delivery module, Synchrony™ and an Axum™ treatment couch. *(April 14, 2005, Initial CON Submission, pages 336 and 337)*
7. Radiosurgery is an ablative technique that combines principles of stereotactic localization with multiple cross-fired beams from a highly collimated high-energy radiation source. *(April 14, 2005, Initial CON Submission, page 85)*
8. The CyberKnife provides radiosurgery for lesions anywhere in the body when treatment is indicated. It concentrates radiation on the tumor or structure and can treat tumors that cannot be treated by traditional radiotherapy. *(April 14, 2005, Initial CON Submission, page 5)*
9. 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. *(April 14, 2005, Initial CON Submission, page 90)*
10. The benefits of the CyberKnife to patients include:
  - Radiation beams may be adjusted to avoid critical organs;
  - Dosage distributions adjusted to minimize radiation exposure to healthy tissues;
  - Treatment of lesions untreatable by open surgery or other radio surgical systems;
  - Improved comfort due to the elimination of the invasive head frame;
  - Less pain and blood loss;
  - No scalpel and no sedation during treatment;
  - No hospitalization required and no recovery time;
  - Lower risks and fewer complications than traditional open surgery;
  - Accurate target localization;
  - Targets extracranial lesions; and
  - Minimal side effects.*(April 14, 2005, Initial CON Submission, page 9)*
11. There are currently 25 CyberKnife units installed in the United States. There are no existing providers in the Hospital’s service area or Connecticut. *(April 14, 2005, Initial CON Submission, page 9)*
12. The Hospital diagnoses nearly 1,500 new cancer cases every year. It provided 27,198 outpatient medical oncology visits and 14,654 radiation therapy treatments in FY (“Fiscal Year”) 2004. *(April 14, 2005, Initial CON Submission, page 6)*

13. The Hospital projected the number of cases for the CyberKnife using data provided by Accuray. The methodology is based on statistics from the American Cancer Society, SEER<sup>1</sup>, and SRP<sup>2</sup> as well as other selected references and publications. (*April 14, 2005, Initial CON Submission, page 10*)
14. Using the Accuray model for Connecticut, based on a population of 3,500,000, and the Hartford metropolitan service area, based on a population of 1,180,000, the Hospital projected the total number of cancer cases eligible for treatment with the CyberKnife. The following table reports the projected number of eligible cases:

**Table 1: Projected Number of Eligible Cases**

	Incidence per Million	% Cyber-Knife Eligible	Annual Cases per Million <sup>1</sup>	2004 Service Area Population (1.18) <sup>2*</sup>	2004 CT Population (3.50) <sup>3*</sup>
Vascular AVM	19	70	13	15	46
Benign Tumor:					
Meningioma	20	50	10	12	35
Pituitary	21	35	7	8	25
Acoustic Neuroma	9	90	8	9	28
Malignant Tumor:					
Intracranial	630	40	252	297	882
Spinal	467	50	233	275	816
Glioma	40	30	12	14	42
Head and Neck	100	40	40	47	140
Primary Spinal Lesions	36	50	18	21	63
Other Tumors	12	25	3	4	11
Primary Lung	584	30	175	207	613
Lung Metastases	750	25	187	221	655
Prostate	788	50	394	465	1,379
Pancreas	93	75	70	83	245
Liver	60	33	20	24	70
Liver Metastases	180	50	90	106	315
Renal	109	30	33	39	116
Functional Trigeminal Neuralgia	43	75	32	38	112

<sup>1</sup> Calculation = Incidence per Million multiplied by percent eligible.

<sup>2</sup> Calculation = Annual Cases per Million multiplied by 1.18.

<sup>3</sup> Calculation = Annual Cases per Million multiplied by 3.50.

\* Source of Population: *Claritas*.

(*April 14, 2005, Initial CON Submission, page 11*)

<sup>1</sup> The Surveillance, Epidemiology, and End Results (SEER) Program of the National Cancer Institute.

<sup>2</sup> Scientific Review Panel of the National Cancer Institute. SRP manages the SEER program.

15. Using the population projections, cancer incidence rates, and the CyberKnife applicability percentages, the projected number of new estimated cases per year were determined:

**Table 2: Projected New Cases Per Year**

Location	Annual Cases/ million	2004 Service Area Population (1.18)	2004 CT Population (3.50)
Intracranium	375	440	1,310
Spine	251	296	879
Lung	363	428	1,268
Prostate	394	465	1,379
Pancreas	70	83	245
Liver	110	130	385
Kidney	33	39	116
Other	3	4	11
Total	1,599	1,885	5,593

*(April 14, 2005, Initial CON Submission, page 5)*

16. Using CHIME data from the Connecticut Hospital Association and limiting it to cancer diagnosis only, the Hospital received 19.0% of the market share of all inpatient cancer cases that occurred in the 55 town service area in FY 2004. The Hospital would expect 358 ( $1,885 \times 0.19$ ) CyberKnife cases on an annual basis. *(April 14, 2005, Initial CON Submission, page 12)*
17. A second methodology, based on the total number of cancer cases treated at the Hospital annually that had as a principal diagnosis one of the cancers appropriate to treat with CyberKnife, confirmed that the Hospital treated 583 cancer patients over three years that would have potentially benefited from the CyberKnife technology. *(April 14, 2005, Initial CON Submission, page 12)*
18. Dr. Richard Shumway, Co-Director of the Hospital's CyberKnife program provided, reviewed the records of cancer patients currently receiving radiation therapy and estimated that 123 patients would be eligible for CyberKnife therapy. *(April 14, 2005, Initial CON Submission, pages 14 and 15)*
19. Dr. Stephen Lange, also a Co-Director of the Hospital's CyberKnife program, reviewed the existing practice volumes from his four physician practice group, as well as the volumes from other physicians in the Neurology Department. He estimated that the number of patients eligible for CyberKnife therapy to be 118 cases. *(April 14, 2005, Initial CON Submission, page 15)*
20. The Hospital used a conservative estimate of 110 cases as the first year's patient volume and applied growth rates based on Accuray's experience of 52% in the second year and 20% in the third year. The total patients estimated by the Hospital to be treated in the first, second, and third year of operations are 110, 167, and 200, respectively. *(April 14, 2005, Initial CON Submission, page 16)*

21. The Hospital translated that yearly estimated to coincide with the Hospital's fiscal year of October 1 to September 30. During the eight months of FY 2006 that the proposed CyberKnife will be in operation, 73 patients<sup>3</sup> have been estimated to receive treatment during FY 2006. Using a similar translation, the Hospital projects 148, and 189 patients<sup>4</sup> will receive CyberKnife treatment during FYs 2007 and 2008. (*May 5, 2005, Completeness Response, page 15*)
22. Based on Accuray's experience, the average number of CyberKnife treatments per cancer case has been 2.55 treatments. Applying the 2.55 treatment rate and the translation for fiscal year, the Hospital expects to perform 281, 426, and 510 treatments in the first, second, and third year of operations, respectively. (*May 5, 2005, Completeness Response, page 15*)
23. The Hospital follows the standard of practice outlined in the guidelines of the American College of Radiology and the American Society for Therapeutic Radiology and Oncology as follows:
- The current staff meets or exceeds the qualifications for personnel as published in the two guidelines;
  - The Hospital will develop written policies and procedures for the CyberKnife treatments; and
  - The Hospital will establish procedures for machine maintenance, calibration, and patient-specific quality control.
- (*April 14, 2005, Initial CON Submission, page 18*)
24. Accuray will provide training on the CyberKnife to physicians. (*April 14, 2005, Initial CON Submission, page 18*)

**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**

25. The total capital expenditure for the CyberKnife and associated construction and renovations are given below:

**Table 3: Total Capital Expenditure**

<b>Item</b>	<b>Cost</b>
Medical Equipment	\$3,293,485
Non-medical Equipment	36,500
Construction/Renovation	1,901,297
<b>Total Capital Expenditure</b>	<b>\$5,231,282</b>

(*April 14, 2005, Initial CON Submission, page 24*)

<sup>3</sup> Eight months divided by 12 months/year \* 110 patients per year = 73 patients.

<sup>4</sup> (4 months/12 \* 110) + (8 months/12 \* 167) = 148; (4 months/12 \* 167) + (8 months/12 \* 200) = 189.

26. The Hospital will finance the proposal through its operating funds by using cash and short term investments. *(April 14, 2005, Initial CON Submission, page 27)*
27. The construction/renovation costs consist of the following:

**Table 4: Construction/Renovation Costs**

Item	Cost
Total Building Work	\$1,586,729
Total Site Work	85,935
Architectural and Engineering	125,000
Contingency Allowance	103,633
<b>Total</b>	<b>\$1,901,297</b>

*(April 14, 2005, Initial CON Submission, page 25)*

28. The required construction and renovations will not impact patient care for existing services. The construction project will be phased to minimize the disruption to staff and patients. Special attention will be given to the Hospital's Infection Control Risk Assessment Plan. This will include the use of temporary construction protection barriers, pressurization of zoned areas of construction, and HEPA filtered exhaust ventilation systems. *(April 14, 2005, Initial CON Submission, page 26)*
29. The construction is scheduled to being in July 2005 and be completed in January 2006. The Hospital expects to obtain the required Department of Public Health licenses in January 2006 and begin operation of the CyberKnife in February 2006. *(April 14, 2005, Initial CON Submission, page 26)*
30. The proposal will add the following additional full-time equivalent ("FTE") staff to the Hospital:

**Table 5: Additional FTE Staff**

Staff Position	FTE in FY 2006	FTE for FYs 2007 and 2008
Office Manager	0.8	1.0
Medical Physicist	0.8	1.0
Registered Nurse	0.8	1.0
Radiation Therapy Technician	0.8	1.0

*(April 14, 2005, Initial CON Submission, page 320)*

31. The projected payer mix and the respective number of patients are listed in the following table:

**Table 8: Projected Payer Mix for CyberKnife Patients**

<b>Payer</b>	<b>Projected Percentage</b>	<b>FY 2006 Projected Number of Patients</b>	<b>FY 2007 Projected Number Of Patients</b>	<b>FY 2008 Projected Number Of Patients</b>
Medicare	50	37	74	94
Medicaid	6	4	9	11
Managed Care/ Commercial	40	29	59	76
Uninsured	4	3	6	8
<b>Total</b>	<b>100</b>	<b>73</b>	<b>148</b>	<b>189</b>

*(May 5, 2005, Completeness Response, page 19)*

32. The Hospital projects an excess of revenues incremental to the proposed service of \$304,040, \$817,554, and \$1,281,923 in FYs 2006, 2007, and 2008, respectively. Implementation of the proposal will have no impact in FY 2005. *(May 5, 2005, Completeness Response, page 5)*
33. The Hospital's cash equivalent balance as of February 28, 2005, was \$24,942,420. *(April 14, 2005, Initial CON Submission, page 310)*
34. There is no State Health Plan in existence at this time. *(April 14, 2005, Initial CON Submission, page 3)*
35. The proposal is consistent with Hospital's long-range plan. *(April 14, 2005, Initial CON Submission, page 3)*
36. The Hospital's proposal will not change the Hospital's teaching or research responsibilities. *(April 14, 2005, Initial CON Submission, 22)*
37. There are no distinguishing characteristics of the patient/physician mix with regard to the proposal. *(April 14, 2005, Initial CON Submission, page 22)*
38. The Hospital has improved productivity and contained costs through energy conservation, group purchasing, reengineering, and the application of technology. *(April 14, 2005, Initial CON Submission, page 19)*
39. The Hospital has sufficient technical and managerial competence to provide efficient and adequate service to the public. *(April 14, 2005, Initial CON Submission, pages 209 to 221)*
40. The Hospital's rates are sufficient to cover the proposed capital expenditure and operating costs. *(May 5, 2005, Completeness Response, page 5)*



## 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.

Saint Francis Hospital and Medical Center (“Hospital”) proposes to acquire a CyberKnife® Stereotactic Radiosurgery System (“CyberKnife”) for its Radiation Therapy Department. The Radiation Therapy Department is one part of the Hospital’s Cancer Care Services (“Cancer Center”). The Cancer Center is one of the Hospital’s Centers of Excellence. The Cancer Center offers state-of-the-art comprehensive outpatient radiation therapy, hematology, and medical oncology services.

Using a lightweight linear accelerator in conjunction with a robotic arm, the CyberKnife performs radiosurgery by concentrating radiation on a patient’s tumor. The CyberKnife is able to treat tumors that cannot be treated by traditional radiotherapy. 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. The treatment advantages of the CyberKnife include the ability to minimize radiation exposure to healthy organs and tissues and the ability to treat tumors that otherwise would be untreatable by other conventional surgeries or treatments. Patients benefit from reductions in pain, blood loss, and risk associated with invasive surgery.

The Hospital diagnoses nearly 1,500 new cancer cases every year. It provided 27, 198 outpatient medical oncology visits and 14,654 radiation therapy treatment in Fiscal Year 2004. The Hospital presented two methodologies to determine the projected volume for the CyberKnife. One methodology based the volume on the Hospital’s market share of inpatient cancer cases, and the second methodology based the volume projections on the number of cancer cases that would be appropriate to receive CyberKnife treatment. The Hospital used a conservative estimate of 110 cases as the first year’s patient volume and applied growth rates based on Accuray’s experience of 52% in the second year and 20% in the third year. The projected utilization is based on the types of cancer appropriate for treatment with the CyberKnife, the projected rate of occurrence of the types of cancer, and the market share of cancer patients that the Hospital can expect to treat. The total number of patients that the Hospital estimated it would treat in the first, second, and third year of operations are 110, 167, and 200, respectively. Based on the foregoing reasons, OHCA finds that there is a clear public need for the Hospital’s proposed CyberKnife acquisition and the CON proposal will improve accessibility of an important treatment modality to the Hospital’s patients.

The CON proposal’s total capital expenditure of \$5,231,282 will be funded by current operating funds of cash and short-term investments. The Hospital is projecting

incremental earnings from operations of \$304,040, \$817,554, and \$1,281,923 in FYs 2006, 2007, and 2008, respectively. Implementation of the proposal will have no impact in FY 2005. The volume and financial projections upon which the proposal is based appear to be both reasonable and achievable. Therefore, OHCA concludes that the CON proposal is financially feasible and cost effective.

In summary, the acquisition of the CyberKnife will improve patient care and enhance the quality of the surgical and radiation therapy services that are provided by the Hospital.

Based upon the foregoing Findings and Rationale, the Certificate of Need application of the Saint Francis Hospital and Medical Center to acquire a CyberKnife® Stereotactic Radiosurgery System for the Radiation Therapy Department, at a total capital expenditure of \$5,231,282, is hereby GRANTED.

## Order

Saint Francis Hospital and Medical Center is hereby authorized to acquire a CyberKnife® Stereotactic Radiosurgery System for the Radiation Therapy Department, at a total capital expenditure of \$5,231,282, subject to the following conditions:

1. This authorization shall expire on June 21, 2007. Should the Hospital's new system not be operational 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 \$5,231,282. In the event that the Hospital learns of potential cost increases or expects that 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 shall perform procedures that have been approved for the CyberKnife® Stereotactic Radiosurgery System by the Food and Drug Administration.

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

June 21, 2005

Signed by Commissioner

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