



Office of Health Care Access Certificate of Need Application

Final Decision

Hospital: The Stamford Hospital

Docket Number: 06-30828-CON

Project Title: Acquisition of CyberKnife Stereotactic Radiosurgery System Technology

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

Filing Date: March 14, 2007

Decision Date: May 31, 2007

Default Date: June 12, 2007

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Project Description: The Stamford Hospital ("Hospital") proposes to acquire a CyberKnife Stereotactic Radiosurgery System for its ambulatory campus at a total capital expenditure of \$5,855,800.

Nature of Proceedings: On March 14, 2007, the Office of Health Care Access ("OHCA") received a Certificate of Need ("CON") application from The Stamford Hospital to acquire a CyberKnife Stereotactic Radiosurgery System for the ambulatory campus at a total capital expenditure of \$5,855,800. 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 September 24, 2006, in *The Stamford Advocate*. 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 April 4, 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 by April 4, 2007.

On May 9, 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 Stamford Advocate* on May 14, 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 May 30, 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 Stamford Hospital (“Hospital”) is an acute care hospital located at 30 Shelburne Road, Stamford, Connecticut. (*January 10, 2007, Initial CON Submission, page 1*)
2. The Hospital’s primary service area includes the towns of Darien and Stamford. (*January 10, 2007, Initial CON Submission, page 5*)
3. The Hospital’s secondary service area includes the towns of Greenwich, New Canaan, Norwalk, Westport, and Wilton. (*January 10, 2007, Initial CON Submission, page 5*)

4. The Hospital proposes to acquire a CyberKnife Stereotactic Radiosurgery System¹ (“CyberKnife”) to be placed on its ambulatory campus, The Tully Health Center, located at 32 Strawberry Hill Court in Stamford, Connecticut. *(January 10, 2007, Initial CON Submission, page 4)*
5. The Hospital indicates that the CyberKnife technology would augment its existing radiation and surgical oncology programs and would expand the scope of conditions treated with radiation therapy at the Hospital and the Hospital’s Bennett Cancer Center (“Center”). *(January 10, 2007, Initial CON Submission, pages 3 and 9)*
6. Through the Center and the Oncology Service Line, the Hospital currently provides patients with a range of treatment options and supportive services as follows: *(January 10, 2007, Initial CON Submission, pages 3-4)*
 - Dedicated Inpatient Oncology Unit with 28 beds;
 - Autologous Bone Marrow/Stem Cell Transplant program;
 - Expression Through Art;
 - Mobile Mammography Program;
 - Cancer Risk and Prevention Program;
 - Lymphedema Treatment Program;
 - The Prostate Seed Implant Program;
 - Women’s Breast Center program;
 - Lung Cancer Program;
 - IMRT therapy;
 - Comprehensive Integrative Medicine Program; and
 - Post-Treatment Exercise and Nutrition Program.
7. The Cyberknife is technology approved by the American College of Surgeons Commission on Cancer with “Teaching Hospital Cancer Program” status and with commendation in the areas of clinical trials, outreach, and patient care studies. *(January 10, 2007, Initial CON Submission, pages 3-4)*
8. The Hospital houses a community-based research center and clinical trials program in Fairfield County. It currently has twenty-five research studies open for patient treatment and ten new studies currently pending approval. *(January 10, 2007, Initial CON Submission, pages 4, 5, 44 and 138)*

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.

9. There are no existing providers of the proposed service within the Hospital's service area, and the only provider of CyberKnife services in Connecticut is located in Hartford. *(January 10, 2007, Initial CON Submission, pages 5 and 7)*
10. The proposed CyberKnife Scanner system is manufactured by Accuray Incorporated ("Accuray") and includes the following components: a robotic treatment delivery system (X-ray imaging system and computer systems, linear accelerator and associated control systems, robotic manipulator, and treatment couch); a treatment planning system; clinical application modules; and a data management system. The system also includes a CyRIS™ InView™ Workstation. *(January 10, 2007, Initial CON Submission, pages 492-494)*
11. Unlike traditional radiosurgery systems that can only treat tumors in the head and neck, the CyberKnife provides radiosurgery for both intracranial and extracranial tumors. *(January 10, 2007, Initial CON Submission, page 2)*
12. The CyberKnife can be used to treat a range of medical conditions, most of which are untreatable with other SRS systems. *(January 10, 2007, Initial CON Submission, page 13)*
13. The major advantages of the CyberKnife system include:
 - Treats tumors anywhere in the body;
 - Continuously tracks, detects, and corrects for tumor and patient movement throughout the treatment;
 - Delivers treatment with sub-millimeter accuracy, minimizing damage to the surrounding healthy tissue;
 - Utilizes the skeletal structure of the body as a reference, eliminating the need for fiducials or invasive frames typically used with traditional radiosurgery systems;
 - Provides an option for inoperable or surgically complex tumors;
 - Successfully treats patients in single or multiple fractions;
 - Provides unsurpassed linac maneuverability and complete access and coverage for any tumor volumes;
 - Has a patient-centric design providing a relaxed treatment experience;
 - Enables superior flexibility in treatment planning:
 - Forward or inverse treatment planning;
 - Isocentric or non-isocentric treatment plans;
 - Simultaneous treatment of multiple tumors;
 - Allows for flexible scheduling of treatments.*(January 10, 2007, Initial CON Submission, page 3)*
14. According to the Hospital, the Hospital's medical oncologists, radiation oncologists, and neurosurgeons have made approximately 37 CyberKnife or Gamma Knife referrals annually over the last three years. *(March 14, 2007, CON Completeness Response, pages 3-4)*

15. The Hospital projected two volume level scenarios for FY 2008 – FY 2012 (Years 1 – 5) as follows: *(March 14, 2007, Completeness Response, page 6)*

Table 1: Projected CyberKnife Volume

| | FY 2008 (Year 1; 6 months) | FY 2009 (Year 2) | FY 2010 (Year 3) | FY 2011 (Year 4) | FY 2012 (Year 5) |
|---------------------------|---|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
| Scenario I Volume | 29 | 80 | 103 | 125 | 148 |
| Scenario II Volume | 29 | 69 | 80 | 92 | 103 |

Note: Scenario I represents a market population that comprises Fairfield County. The market size was estimated to be 902,775 with an oncology market capture of 17%. Scenario II represents the Hospital's Primary Service Area, Secondary Service Area, and Extended Service Area market populations excluding cities and towns in New York State. The market size was estimated to be 447,220 with an oncology market capture of 23%. The Hospital based Year 1 annual volume projections on the Hospital's FY 2006 volumes for selected cancers. This was adjusted by the percentage of cases likely to be treatable with SRS and by the projected utilization rates. The Hospital based Year 2-4 volume projections on a linear regression between Year 1 and Year 5. The Hospital based Year 5 annual volume projections on 2002 national incidence rates per million for specific tumor sites. This was adjusted by the percentage of cases treatable with SRS as well as the market size and market capture. *(March 14, 2007, Completeness Response, pages 4-12)*

16. According to the Hospital, it follows the standards 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 in the Department of Radiation Oncology meets or exceeds the qualifications for personnel as published in the Guidelines;
 - The Hospital will develop written policies and procedures for Stereotactic treatments which will follow the published Guidelines and cover the responsibilities for all personnel involved with the process; and
 - The Hospital will develop written Quality Control procedures and policies for machine maintenance, calibration, and patient-specific quality control as outlined in the Guidelines.
- (January 10, 2007, Initial CON Submission, pages 10-11)*
17. Training on the CyberKnife will be implemented by Accuray, and physicians using the new technology will be fully trained before treating any patients. *(January 10, 2007, Initial CON Submission, page 11)*

**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**

18. The total capital expenditure for the CyberKnife and associated construction and renovations are as follows: *(January 10, 2007, Initial CON Submission, page 15)*

Table 2: Total Capital Expenditure

| Item | Cost |
|----------------------------------|--------------------|
| Medical Equipment | \$3,895,000 |
| Construction/Renovation | 1,960,800 |
| Total Capital Expenditure | \$5,855,800 |

19. The Hospital will finance the proposal through its equity from operations. *(January 10, 2007, Initial CON Submission, page 17)*
20. The construction/renovation costs consist of the following: *(January 10, 2007, Initial CON Submission, page 16)*

Table 3: Construction/Renovation Costs

| Item | Cost |
|-------------------------------|--------------------|
| Total Building Work | \$1,584,000 |
| Total Site Work | 50,000 |
| Architectural and Engineering | 196,080 |
| Contingency Allowance | 130,720 |
| Total | \$1,960,800 |

21. The Hospital projects gains/losses from operations incremental to the project as follows: *(March 14, 2007, Completeness Response, pages 14, 16)*

Table 4: Projected Incremental Revenues from CyberKnife

| | FY 2008* | FY 2009 | FY 2010 |
|--------------------|-------------|-------------|-------------|
| Scenario I | (\$231,000) | (\$720,000) | (\$270,000) |
| Scenario II | (\$231,000) | (\$480,000) | \$233,000 |

Note: * The proposal commences operations in second quarter of FY 2008. The incremental losses that result from the implementation and operation of the proposal reflect the start-up nature of a capital intensive program. The Hospital indicates that they are confident that revenues resulting from the proposal will cover and surpass expenses by Year 3. *(January 10, 2007, Initial CON Submission, pages 16&20)*

22. The Hospital projects gains from operations with the proposal as follows: (*March 14, 2007, Completeness Response, pages 14, 16*)

Table 5: Hospital's Projected Revenues including CyberKnife

| | FY 2008 | FY 2009 | FY 2010 |
|--------------------|----------------|----------------|----------------|
| Scenario I | \$9,813 | \$7,848 | \$9,960 |
| Scenario II | \$9,813 | \$7,608 | \$9,458 |

23. The current and projected Hospital payer mix are listed in the following table: (*January 10, 2007, Initial CON Submission, page 19*)

Table 6: Current and Projected Hospital Payer Mix

| Payer | Current | Year 1 | Year 2 | Year 3 |
|----------------------|----------------|---------------|---------------|---------------|
| Medicare | 30.7% | 28.2% | 28.2% | 28.2% |
| Medicaid | 6.0% | 6.0% | 6.0% | 6.0% |
| Commercial | 60.1% | 62.1% | 62.1% | 62.1% |
| Uninsured | 1.6% | 1.5% | 1.5% | 1.5% |
| Workers Compensation | 1.6% | 2.2% | 2.2% | 2.2% |
| Total | 100% | 100% | 100% | 100% |

24. The Hospital states that the required construction and renovations associated with the proposal will not affect the delivery of patient care for existing services. (*January 10, 2007, Initial CON Submission, page 16*)
25. Construction required for the CyberKnife vault and equipment support area and renovation of the support service area is scheduled as follows: (*January 10, 2007, Initial CON Submission, page 16*)

Table 7: Construction and Renovation Schedule

| Stage | Time Frame |
|---------------------------------|------------------------|
| Construction Commencement Date | September 1, 2007 |
| Construction Completion Date | March 1, 2008 |
| DPH Licensure Date | Not Applicable |
| Commencement of Operations Date | Second Quarter FY 2008 |

26. There is no State Health Plan in existence at this time. (*January 10, 2007, Initial CON Submission, page 4*)
27. The proposal is consistent with Hospital's long-range plan. (*January 10, 2007, Initial CON Submission, page 4*)
28. The proposal will not change the Hospital's teaching or research responsibilities. (*January 10, 2007, Initial CON Submission, page 13*)
29. There are no distinguishing characteristics of the patient/physician mix with regard to the proposal. (*January 10, 2007, Initial CON Submission, page 14*)

30. The Hospital has improved productivity and contained costs through energy conservation, group purchasing, reengineering, and applications of technologies. *(January 10, 2007, Initial CON Submission, page 13)*
31. The Hospital has sufficient technical and managerial competence to provide efficient and adequate service to the public. *(January 10, 2007, Initial CON Submission, pages 343-411)*
32. The Hospital's rates are sufficient to cover the proposed capital expenditure and operating costs. *(March 14, 2007, Completeness Response, pages 14, 16)*

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 Stamford Hospital (“Hospital”) is an acute care hospital located at 30 Shelburne Road, Stamford, Connecticut. The Hospital proposes to acquire a CyberKnife Stereotactic Radiosurgery System (“CyberKnife”) to be placed on its ambulatory campus, The Tully Health Center, located at 32 Strawberry Hill Court in Stamford, Connecticut. The Hospital is seeking to augment its existing radiation and surgical oncology programs by adding this technology, which would expand the scope of conditions treated with radiation therapy at the Hospital and the Hospital’s Bennett Cancer Center (“Center”). Through the Center and the 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 research protocols, including the largest community-based research center and clinical trials program in Fairfield County. There are no existing providers of the proposed service within the Hospital’s service area, and the only provider of CyberKnife services in Connecticut is located in Hartford.

The CyberKnife is a state-of-the-art Stereotactic Radiosurgery technology used 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 the surrounding health 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 and providing an additional option for many patients with previously inoperable or surgically complex tumors. 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 CON proposal’s total capital expenditure of \$5,855,800 will be funded by the Hospital’s equity from operations. The Hospital projects incremental losses from operations that result from the implementation of this proposal, reflecting the start-up nature of a capital intensive program. The Hospital projects revenues over expenses in year 3 and overall gains from operations with the proposed project. Although OHCA cannot draw any conclusions, 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 and cancer center that are provided by the Hospital.

Based upon the foregoing Findings and Rationale, the Certificate of Need application of The Stamford Hospital to acquire a CyberKnife Stereotactic Radiosurgery System for the Tully Health Center, at a total capital expenditure of \$5,855,800, is hereby GRANTED, subject to conditions.

Order

The Stamford Hospital is hereby authorized to acquire a CyberKnife Stereotactic Radiosurgery System for its ambulatory campus, The Tully Health Center, located at 32 Strawberry Hill Court in Stamford, Connecticut, at a total capital expenditure of \$5,855,800 subject to the following conditions:

1. This authorization shall expire on May 29, 2009. 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 \$5,855,800. 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 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

May 31, 2007

Signed by Cristine A. Vogel
Commissioner

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