



Office Of Health Care Access Certificate of Need Application

Final Decision

Hospital: The Hospital of Central Connecticut

Docket Number: 06-30882-CON

Project Title: Proposing to Purchase the Novalis Stereotactic Radio Surgery System

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

Filing Date: May 3, 2007

Decision Date: August 10, 2007

Default Date: August 16, 2007 (15 Day Extension)

Staff Assigned: Diane Duran
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Project Description: The Hospital of Central Connecticut ("Hospital") proposes to purchase the Novalis Stereotactic Radio Surgery System ("Novalis SRSS") at a total capital expenditure of \$5,800,000.

Nature of Proceedings: On May 3, 2007, the Office of Health Care Access ("OHCA") received a Certificate of Need ("CON") application from The Hospital of Central Connecticut to purchase the Novalis Stereotactic Radio Surgery System at a total capital expenditure of \$5,800,000. 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 December 6, 2006, in *The Herald*. 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 May 24, 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 May 24, 2007.

On July 13, 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 Herald* on July 13, 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 July 27, 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 the 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 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 Central Connecticut ("Hospital") is an acute care hospital located at 100 Grand Street, New Britain, Connecticut. *(May 3, 2007, Initial CON Submission, pages 1)*
2. The Hospital's primary service area includes the following towns:
 Berlin New Britain
 Southington Plainville
(May 3, 2007, Initial CON Submission, page 3)
3. The Hospital's secondary service area includes the following towns:
 Bristol Burlington
 Cheshire Crowell
 Farmington Meriden
 Newington West Hartford
(May 3, 2007, Initial CON Submission, page 3)
4. On December 5, 2002, under The Office of Health Care Access Docket Number 02-543, the Hospital received authorization for the replacement of the Hospital linear accelerator. *(December 5, 2002, OHCA Docket Number 02-543, Final Decision)*

5. The Hospital proposes to purchase the Novalis Stereotactic Radio Surgery System (“Novalis SRSS”), at a total capital expenditure of \$5,800,000. *(May 3, 2007, Initial CON Submission, page 1)*
6. The Hospital indicates that the Novalis SRS technology would augment its current repertoire of neurological and radiation oncology procedures. *(December 4, 2006, Letter of Intent, page 1)*
7. The Hospital states that it currently has two rooms that perform radiation therapy. One is the newer room which has Intensity Modulated Radiation therapy (“IMRT”) capability. The second room does radiation therapy and is also utilized to perform High Dose Rate (“HDR”) exams. *(July 31, 2007, Additional CON Information Submitted, page 1)*
8. The current capacity of the existing Radiation Therapy is as follows:

Table1: Existing HCC Radiation Therapy Capacity

Linear Accelerator	35 Treatments/Day
IMRT	12 Treatments/Day
HDR	3 Treatments/Day
Total Capacity @250 Days	12,500 Treatments Per Year

(August 1, 2007, Additional CON Information Submitted, page 1)

9. The following table shows the actual and projected number of treatments for HCC’s current setup:

Table 2: HCC Radiation Therapy Treatment Current and Projections

	FY 04	FY 05	FY 06	FY 07	FY 08	FY09
Existing HCC Radiation Therapy Setup	7,686	7,170	8,171	8,125	8,750	9,375

(July 31, 2007, Additional CON Information Submitted, page 1)

The assumption is that the current setup will experience a 5% increase from the current capacity per year over the next three years. This results in reaching 75% of capacity in year 3.

10. The Hospital states that the Novalis SRS System can back up the IMRT, but is limited to lesions no larger than 10cm in size. The Novalis SRS System will allow HCC to perform more precise treatment of lesions as compared to the existing linear accelerator. It does this through the utilization of highly precise shaped beams of radiation currently not attainable. *(July 31, 2007, Additional CON Information Submitted, page 1)*
11. The Hospital determined the need for stereotactic radiosurgery¹ through referrals from its affiliated neurosurgeons and from the growth of cancer cases in the Hospital’s service area. *(May 3, 2007, Initial CON Submission, page 2)*

¹ The stereotactic radiosurgery (SRS) is strictly defined as radiation therapy delivered via stereotactic guidance with ~1 mm targeting accuracy to a cranial lesion in a single fraction. For information regarding multiple fraction cranial lesion treatment and extra cranial treatments, refer to the Practice Guideline for the Performance of Stereotactic Body Radiation Therapy.

12. The Hospital stated the two neurosurgeons are referring patients who are candidates for stereotactic radiosurgery out of the area at a rate of 50 each per year, which equates to a total of 100 cases per year. *(May 3, 2007, Initial CON Submission, pages 2 and 3)*
13. The Hospital states that the American Cancer Society predicted 19,780 new cancer cases in the state in 2007. The same report states for 2003, the prevalence rate of cancer per 100,000 is 597.3 and 448.3 for females and males respectively. This indicates that up to 2,700 out of the 441,857 people in the Applicant's service area as diagnosed with cancer. The Novalis SRS affords the Applicant the ability to treat a portion of these patients using shaped beam computer guided treatment. *(May 3, 2007, Initial CON Submission, page 2)*
14. The Hospital also based the need on the following:
 - The Novalis SRSS affords the Hospital the ability to treat a good portion of the patients using shaped beam computer guided treatment if needed or it can function as a traditional linear accelerator;
 - The Novalis SRSS will primarily treat lesions that call for precise treatment without exposing surrounding areas to unnecessary doses of radiation; and
 - The Novalis SRSS increases access to state of the art non-invasive treatment of lesions and select neurological disorders such as neuralgia. *(May 3, 2007, Initial CON Submission, pages 2,3 and 7)*
15. The Hospital stated that the Novalis SRSS brings to the Hospital's service area the ability to perform brain surgery in about 20 minutes without a scalpel. This reduces complication and recovery time for the patients. The system can treat lesions in one visit, compared to other units like the Cyber Knife™ or traditional linear accelerators that require multiple visits exposing patients to more doses of radiation. *(May 3, 2007, Initial CON Submission, page 7)*
16. The Hospital stated candidates for stereotactic radiosurgery are currently treated with less precise equipment, which exposes larger areas of the body to radiation. *(May 3, 2007, Initial CON Submission, page 5)*
17. The Hospital performed 8,171 treatments at its American Savings Foundation Oncology Treatment Center in fiscal year 2006. *(May 3, 2007, Initial CON Submission, page 5)*
18. The Hospital projected the units of service for the Novalis SRSS from discussions with the Hospital's affiliated neurosurgeons regarding their best estimate of what cases they currently see that can be treated using the Novalis SRSS equipment. *(May 3, 2007, Initial CON Submission, page 5)*
19. The Hospital stated it anticipates serving 100 patients (70 SRS + 30 SRT) in the first full year of operation with an additional 15 treated with IMRS/IMRT for a total of 115 patients in year 1. Thereafter, the Hospital projects a 10% growth rate in the number of patients treated. *(May 3, 2007, Initial CON Submission, pages 3 and 5)*

20. The following table shows the projected number of patients that will be served in the next four years:

Table 3: Projected number of visits for the next four years

	Implementation Year March 2008	Year 1	Year 2	Year 3
Number of Patients – SRS	45	30	33	36
Number of Patients – SRT	35	70	77	85
Number of Patients – IMRS/IMRT	8	15	17	19
Total Number of Patients	58	115	127	140

(May 3, 2007, Initial CON Submission, page 22)

21. The Hospital stated in order to ensure stereotactic radiosurgery procedures to the patients of the Hospital, the Department of Radiation Oncology will employ the practice guidelines delineated by the American College of Radiology. The guidelines will be used in assisting practitioners in providing appropriate radiologic care for their patients. *(May 3, 2007, Initial CON Submission, page 9)*
22. The Applicant states that it has a skilled team consisting of physicians, dosimetrists and radiation therapists for the proposed service. The team has prior experience at running CT simulations and providing IMRT services; therefore there will be minimal training needed since the system relies on these technologies to operate. *(August 6, 2007, Additional CON Submission, page 1)*
23. The Applicant states that it will rely on the expertise of its radiation oncology physician to develop the treatment plan for patients who would be better served by SRS. The neurosurgeons will provide consultations and will be involved in the treatment plan. The majority of the patients referred to the Novalis SRS system will come from the Hospital's affiliated neurosurgeons. *(August 6, 2007, Additional CON Submission, page 2)*
24. The Hospital's American Saving Foundation Oncology Treatment Center, where the Novalis SRSS equipment will be housed, is open every weekday from 8:00 a.m. to 5:00 p.m. *(May 3, 2007, Initial CON Submission, page 4)*

**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 Novalis Stereotactic Radio Surgery System and associated construction and renovations are given below:

Table 4: Total Capital Expenditure

Item	Cost
Medical Equipment	\$3,300,000
Non - Medical Equipment	80,000
Construction/Renovation	2,420,000
Total Capital Expenditure	\$5,800,000

(May 3, 2007, Initial CON Submission, page 14)

26. The Hospital will finance the proposal through its operating funds and short term investments. *(May 3, 2007, Initial CON Submission, page 17)*
27. The construction/renovation costs consist of the following:

Table 5: Construction/Renovation Costs

Item	Cost
Total Building Work	\$1,700,000
Total Site Work	500,000
Total Contingency	220,000
Total	\$2,420,000

(May 3, 2007, Initial CON Submission, page 15)

28. The Novalis SRSS will be housed in a vault adjacent to the American Savings Foundation Radiation Oncology Treatment Center. The current building will have a 3,210 square foot addition on its western side. The site of the addition is currently occupied by two parking spaces and mechanicals. The 1st phase of the project will be the relocation of the mechanicals to the roof of the existing center. It will be followed by the actual addition including the concrete vault with walls 3-6 feet thick for shielding of radiation. The additional two offices, an exam room, a break room, a control room, a dosimetry station, hazardous material storage and a room for related mechanicals. The final phase will be the renovation of 290 square feet of the existing center and porting utilities and mechanicals to pass through. *(May 3, 2007, Initial CON Submission, page 15)*
29. The construction is scheduled to being in July 2007 and be completed in November 2007. They will begin operation of the Novalis SRSS in March 2008. *(May 3, 2007, Initial CON Submission, page 16)*
30. The Hospital stated that the proposal is cost effective and it allows treating patients that need precise treatment of a tumor with the Novalis SRSS rather than the current linear

accelerator complement at the New Britain General campus. It frees up the current linear accelerator for more appropriate cases. Additionally the Novalis SRSS can be used as a traditional linear accelerator if there is any downtime of the existing equipment. (May 3, 2007, Initial CON Submission, page 20)

31. The current and projected payer mix for the Novalis SRSS are listed in the following table:

Table 6: Projected Payer Mix for Novalis SRSS

Payer	Current Payer Mix	FY 2008 Projected Payer Mix	FY 2009 Projected Payer Mix	FY 2010 Projected Payer Mix
Medicare	46.7%	46.7%	46.7%	46.7%
Medicaid	5.9%	5.9%	5.9%	5.9%
Total Government	52.6%	52.6%	52.6%	52.6%
Commercial Insurers	46.2%	46.2%	46.2%	46.2%
Uninsured	1.2%	1.2%	1.2%	1.2%
Total Non- Government Payer Mix	47.4%	47.4%	47.4%	47.4%
Payer Mix	100%	100%	100%	100%

(May 3, 2005, Completeness Response, page 18)

32. The Hospital projects an excess of revenues incremental to the proposed service of \$492,966, \$874,081, \$1,041,465, and \$1,332,783 in FYs 2008, 2009, 2010 and 2011, respectively. Implementation of the proposal will have no impact in FY 2007. (May 23, 2007, Initial CON Submission, page 2)
33. There is no State Health Plan in existence at this time. (May 3, 2007, Initial CON Submission, page 3)
34. The proposal is consistent with Hospital's long-range plan. (May 3, 2007, Initial CON Submission, page 8)
35. The Hospital's proposal will not change the Hospital's teaching or research responsibilities. (May 3, 2007, Initial CON Submission, 13)
36. There are no distinguishing characteristics of the patient/physician mix with regard to the proposal. (May 3, 2007, Initial CON Submission, page 13)
37. The Hospital has improved productivity and contained costs through energy conservation, group purchasing, reengineering, and the application of technology. (May 3, 2007, Initial CON Submission, page 10)
38. The Hospital has sufficient technical and managerial competence to provide efficient and adequate service to the public. (May 3, 2007, Initial CON Submission, pages 9 and Attachment F)
39. 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 a case by case basis. Certificate of Need (“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 proposed services.

The Hospital of Central Connecticut (“Hospital”) proposes to purchase the Novalis Stereotactic Radio Surgery System (“NSRSS”) to augment its current repertoire of neurological and radiation oncology procedures. The Hospital determined the need for stereotactic radiosurgery through referrals from its affiliated neurosurgeons and from the growth of cancer cases in the Hospital’s service area. The Hospital’s two affiliated neurosurgeons currently refer their patients who are candidates for stereotactic radiosurgery out of the area at a rate of 50 each per year, which equates to a total of 100 cases per year. The Hospital performed 8,171 treatments at the American Savings Foundation Oncology Treatment Center in fiscal year 2006. The Hospital states that it currently has two rooms that perform radiation therapy. One is the newer room which has IMRT capability. The second room does radiation therapy and is also utilized to perform HDR exams. The current capacity of the existing Radiation Therapy is 12,500 treatments per year. The Hospital states that the Novalis SRS System can back up the IMRT, but is limited to lesions no larger than 10cm in size. The Novalis SRS System will allow HCC to perform more precise treatment of lesions as compared to the existing linear accelerator. It does this through the utilization of highly precise shaped beams of radiation currently not attainable.

The proposed Novalis SRSS affords the Hospital the ability to treat patients using shaped beam computer guided treatment if needed or it can function as a traditional linear accelerator. It primarily treats lesions that call for precise treatment without exposing surrounding areas to unnecessary doses of radiation, and increases access to state of the art non-invasive treatment of lesions and select neurological disorders such as trigeminal neuralgia. In order to effectively utilize the treatment capabilities of the Novalis SRS System it requires a highly trained and skilled radiation oncologist working as a team with neurosurgeons that have experience with this technology. The Hospital of Central Connecticut meets these requirements.

Based on the foregoing reasons, OHCA finds that the CON proposal will improve accessibility of an important treatment modality to the Hospital’s patients.

The CON proposal’s total capital expenditure of \$5,800,000 will be funded by current operating funds of cash and short-term investments. The Hospital is projecting incremental earnings from the operation of the proposed service of \$492,966, \$874,081, \$1,041,465, and \$1,332,783 in FYs 2008, 2009, 2010 and 2011, respectively. Implementation of the proposal will have no impact in FY2007. The volume and financial projections upon which the proposal is based appear to be both reasonable and achievable.

In summary, the acquisition of the Novalis Stereotactic Radio Surgery System will improve patient care and enhance the quality of the neurosurgical and radiation oncology services that are currently provided by the Hospital.

Order

Based upon the foregoing Findings and Rationale, the Certificate of Need application of The Hospital of Central Connecticut ("Hospital") to purchase the Novalis Stereotactic Radio Surgery System at a total capital expenditure of \$5,800,000, is hereby GRANTED, subject to the following conditions:

1. This authorization shall expire on August 10, 2008. 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 \$5,800,000. 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 stereotactic radiosurgery procedures that have been approved for the operation of the Novalis Stereotactic Radio Surgery System by the Food and Drug Administration ("FDA").

Should the Applicant fail to comply with any of the aforementioned conditions, OHCA reserves the right to take additional actions 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

August 10, 2007

Signed by Cristine A. Vogel
Commissioner

CAV:dd