

Office of Health Care Access Certificate of Need Application

Final Decision

Applicant:	John Dempsey Hospital
Docket Number:	06-30754-CON
Project Title:	Acquisition of a Replacement Linear Accelerator for the Radiation Oncology Division
Statutory Reference:	Section 19a-639, Connecticut General Statutes
Filing Date:	September 13, 2006
Decision Date:	October 10, 2006
Default Date:	December 12, 2006
Staff:	Laurie K. Greci

Project Description: John Dempsey Hospital ("Hospital") proposes to acquire a replacement linear accelerator for the Hospital's Radiation Oncology Division. The project's total proposed capital expenditure is \$3,700,000.

Nature of Proceedings: On September 13, 2006, the Office of Health Care Access ("OHCA") received the Certificate of Need ("CON") application of John Dempsey Hospital ("Hospital") seeking authorization to acquire a replacement linear accelerator for the Radiation Oncology Division. The total proposed capital expenditure is \$3,700,000. The Hospital is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes ("C.G.S.").

Pursuant to Section 19a-639, C.G.S., a notice to the public concerning OHCA's receipt of the Hospital's Letter of Intent was published in the *Hartford Courant* on May 27, 2006. OHCA received no responses from the public concerning the Hospital's proposal. Pursuant to Public Act 05-75, three individuals or an individual representing an entity with five or more people had until October 4, 2006, 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 October 4, 2006.

OHCA's authority to review and 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 on the Hospital's Current Utilization Statistics Contribution of the Proposal to the Accessibility and Quality of Health Care Delivery in the Region

- 1. John Dempsey Hospital ("Hospital") is the acute care general hospital associated with the University of Connecticut Health Center ("UCHC") located at 263 Farmington Avenue, Farmington, Connecticut. (*May 19, 2006, Letter of Intent, page 1*)
- 2. The Hospital's primary service area includes the following towns: Avon, Bloomfield, Burlington, Canton, East Hartford, Farmington, Granby, Hartford, New Britain, Newington, Simsbury, and West Hartford. (*August 10, 2006, Initial CON Submission, page 11*)
- 3. The Hospital's secondary service area includes the following towns: Barkhamsted, Berlin, Bozrah, Bristol, Cromwell, East Granby, East Windsor, Glastonbury, Hartland, Harwinton, Litchfield, Manchester, New Hartford, Plainville, Plymouth, Rocky Hill, South Windsor, Southington, Torrington, Vernon, Wethersfield, Winchester, and Windsor. (August 10, 2006, Initial CON Submission, page 11)
- 4. The UCHC is engaged in a strategic planning process that focuses on four "Signature Programs"; one of those programs is Cancer. The Hospital and UCHC provide a full spectrum of cancer services, including education and prevention, early detection, and innovative treatment. (*August 10, 2006, Initial CON Submission, pages 2 and 5*)
- 5. The Hospital proposes to replace its Varian Clinac 2100 ("Clinac") that was approved for use under Docket Number 92-577 with the new radiation oncology linear accelerator. The unit has been in operation since 1994 and is well beyond its seven year useful life. (*August 10, 2006, Initial CON Submission, page 2*)
- 6. The Hospital based the need for a new linear accelerator on the following:
 - Age of the equipment;
 - Outdated technology; and
 - The development of the clinical component of the Cancer Program. (*August 10, 2006, Initial CON Submission, page 2*)

- 7. The Hospital proposes to purchase a Tomotherapy HI-ART[™] radiation oncology linear accelerator that incorporates rotational intensity modulation radiation therapy ("IMRT") and image guided radiation therapy ("IGRT") capabilities. These features will improve the accuracy and precision of treating cancerous tissue, allowing escalation of dose to enhance tumor control and lowering dose to normal tissues to reduce toxicity. (*August 10, 2006, Initial CON Submission, page 2*)
- 8. The Hospital stated that IMRT technology is available on the Elekta Precise linear accelerator used at the Hospital which received CON authorization under Docket 01-531. However, the Elekta Precise does not have IGRT capability. It will be used for less sophisticated IMRT cases, conventional three-dimensional treatments and palliative care. (*August 10, 2006, Initial CON Submission, pages 2 and 3*)
- 9. The Hospital reported the following number of procedures by service area town for the past three fiscal years ("FY") provided to Connecticut residents:

Town or	FY 2004		FY 200	5	FY 2006	
Service Area	Procedures	%	Procedures	%	Procedures	%
Avon	586		475		905	
Burlington	132		128		240	
Canton	317		118		379	
Farmington	907	63.2	1,151	60.5	849	60.0
Simsbury	771		715		564	
West Hartford	1,027		1,171		1,067	
Other PSA Towns	1,574		1,173		1,761	
All SSA Towns	2362	28.1	2274	27.9	3048	31.8
Other Towns in CT	735	8.7	942	11.6	790	8.2
Total	8,411	100	8,147	100	9,603	100

 Table 1: Actual Radiation Therapy Procedures by Service Area Town¹

(September 13, 2006, CON Completeness Response, page 2)

¹ The volumes for out-of-state patients were 179, 284, and 369 procedures for FYs 2004, 2005, and 2006, respectively, and are not included in the reported volumes. OHCA cannot verify the data reported by the Hospital.

10. The Hospital projected the following number of procedures to be performed during FYs 2007, 2008, 2009, and 2010:

Town or	FY 200)7	FY 2008		FY 2009		FY 2010	
Service	Procedures	%	Procedures	%	Procedures	%	Procedures	%
Area								
Avon	763		1,000		1,021		1,043	
Burlington	203		267		272		278	
Canton	275		360		368		375	
Farmington	1,105		1,449		1,480		1,511	
Simsbury	707	60.2	927	60.2	946	60.2	966	60.2
West								
Hartford	1,237		1,622		1,656		1,691	
Other PSA		r						
Towns	1,622		2,126		2,171		2,217	
All SSA								
Towns	2,952	30.1	3,870	30.1	3,952	30.1	4035	30.1
Other								
Towns								
in CT	957	9.7	1,255	9.7	1,282	9.7	1,308	9.7
Total	9,821	100	12,876	100	13,148	100	13,424	100

 Table 2: Projected Radiation Therapy Procedures by Service Area Town²

(September 13, 2006, CON Completeness Response, page 3)

- 11. The Hospital projects 13,337, 13,617, and 13,903 procedures to be performed during FYs 2008, 2009, and 2010, respectively, including patients from outside of Connecticut. The projected yearly numbers of procedures were based on a 2.1% annual increase. The Hospital also allowed for a six month period during which only one linear accelerator would be functional. The six month period overlaps FY 2007 and FY 2008, and the projected number of procedures for each fiscal year was adjusted accordingly. (*August 10, 2006, Initial CON Submission, page 313*)
- 12. The project is expected to become operational August 2007. (August 10, 2006, Initial CON Submission, page 313)

 $^{^{2}}$ The volumes for out-of-state patients are projected to be 351, 460, 469, and 479 for FYs 2007, 2008, 2009, and 2010, respectively and are not included in the projected volumes made by the Hospital.

13. The following table reports the number of radiation therapy patients, treatments and procedures by CPT³ code for FY 2005 to FY 2010:

Table 3: Number of Radiation Therapy Patients, Treatments, and Procedures				
for FY 2005 to FY 2010				

	Fiscal Year					
Description	2005	2006	2007	2008	2009	2010
Total Number of Individual	366	408	421	430	438	448
Patients						
Total Number of Treatment	8,431	9,406	9,593	9,710	9,914	1,0122
Sessions						
CT with IMRT Tomography	0	0	0	2,952	3,014	3,078
IMRT Treatments	1,158	2,417	2,468	4,109	4,195	4,283
Stereoscopic X-ray Guided	0	566	578	586	598	611
Treatment						
Radiation Treatment Procedures	6,724	6,422	6,557	4,953	5,057	5,163
Simulations	219	541	552	561	572	584
Stereotactic Procedures	31	26	16	177	180	184
Total Number of Procedures	8,431	9,972	10,171	13,337	13,617	13,903
Average Number of Procedures	23.0	24.4	24.2	31.0	31.1	31.0
per Patient						
Average Number of Procedures	1.0	1.1	1.1	1.4	1.4	1.4
per Treatment Session						

Note: The Hospital based its projections on the following:

• An annual increase of 2.1%.

• An allowance for a six month period during which only one linear accelerator, the Elektra Precise, would be operational. The six month period overlaps FY 2007 and FY 2008, and the projected number of procedures for each fiscal year was adjusted accordingly.

Note: The data presented by the Applicant could not be verified by OHCA.

(September 13, 2006 CON Completeness Submission, page 6)

- 14. The Hospital will decommission and remove the Clinac in March 2007. Removal of the Clinac is required in order to perform renovations and prepare space for the Tomotherapy unit. The Clinac will be removed by the vendor, TomoTherapy Incorporated. (*August 10, 2006, Initial CON Submission, page 16*)
- 15. The Hospital maintains and adheres to the practice guidelines outlined by the American College of Radiology. (August 10, 2006, Initial CON Submission, page 24
- 16. The Hospital has been certified by The Commission on Cancer of the American College of Surgeons as a teaching hospital Cancer Program, effective through 2007. (*August 10, 2006, Initial CON Submission, page 186*)

³ CPT is the acronym for Current Procedural Terminology copyrighted by the American Medical Association.

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

17. The total capital expenditure of \$3,700,000 for the proposal consists of the following components:

Cost
\$2,979,106
\$720,894
\$3,700,000

Table 1: Total Proposed Capital Expenditure

(August 10, 2006, Initial CON Submission, page 29)

- 18. The project involves the renovation of one of the two existing Radiation Oncology linear accelerator vaults located on the ground floor of the clinic building at the UCHC. Electrical and mechanical services will be upgraded and the vault and control area will receive upgraded medical gases equipment, lighting, ventilation, sprinklers, and plumbing. (*August 10, 2006, Initial CON Submission, page 29*)
- 19. The renovations to the suite will be conducted in a manner that will minimize the impact on patient care. The renovation area can be isolated from patient treatment areas as most of the work will occur in the treatment vault and the mechanical spaces. (*August 10, 2006, Initial CON Submission, page 30*)
- 20. The proposed project will be financed with operating funds of \$1,200,000 and a charitable contributions of \$2,500,000. (*August 10, 2006, Initial CON Submission, page 32*)
- 21. The Hospital projects incremental gains from operations with the proposal of \$335,254, \$90,064, and \$105,126 for FYs 2008, 2009 and 2010, respectively. (*(August 10, 2006, Initial CON Submission, page 312)*

22. The Hospital's existing payer mix is not expected to change as a result of this project. The current payer mix and the projected payer mix for the first three years of operation are as follows:

Payer	Current and Projected (FYs 2007 to 2010)
Medicare (Includes Managed Care Activity)	42.4%
Medicaid (Included Other Medical Assistance)	11.8%
TriCare (CHAMPUS)	0.2%
Total Government	54.4%
Commercial Insurers	42.5%
Uninsured	0.3%
Workers Compensation	1.8%
Total Non-Government	44.6%
Uncompensated Care	1.0%
Total Payer Mix	100%

 Table 2: Three-Year Projected Payer Mix with the CON Proposal

(August 10, 2006, Initial CON Submission, page 34)

- 23. There is no State Health Plan in existence at this time. (August 10, 2006, Initial CON Submission, page 3)
- 24. The Hospital has adduced evidence that this proposal is consistent with its long-range plan. (*August 10, 2006, Initial CON Submission, page 3*)
- 25. The Hospital participates in energy conservation, group purchasing, reengineering, and the application of technology programs to improve productivity and contain costs. (*August 10, 2006, Initial CON Submission, page 25*)
- 26. The Hospital has a major commitment to the teaching of medical students, residents, and fellows. Modern cancer treatments make exposure to the latest radiation techniques critical to all those who may care for patients in the future. (*August 10, 2006, Initial CON Submission, page 27*)
- 27. Because of the Hospital's association with the UCHC, including the School of Medicine, the patient population is geographically diverse. Because the subspecialty mix of the faculty of the School of Medicine, the patient population is also clinically diverse. (*August 10, 2006, Initial CON Submission, page 27*)
- 28. The Hospital has sufficient technical and managerial competence to provide efficient and adequate services to the public. (*August 10, 2006, Initial CON Submission, Exhibits 11 and 17*)
- 29. The Hospital's rates are sufficient to cover the proposed capital expenditure and operating costs. (*August 10, 2006, Initial CON Submission, pages 28 and 312*)

Rationale

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

John Dempsey Hospital ("Hospital") proposes to acquire a replacement linear accelerator for its Radiation Oncology Division equipped with Intensity Modulated Radiation Therapy ("IMRT") and image guided radiation therapy ("IGRT") capabilities. The IMRT and IGRT technologies allow for the administration of more direct radiation to the tumor site, limiting the exposure of radiation to normal tissue. The proposal does not involve the expansion or introduction of new services, but rather the acquisition of new equipment to replace existing equipment used in the treatment of patients with cancer.

The Hospital utilizes two linear accelerators to provide radiation treatments. The Hospital's oldest linear accelerator, a Varian Clinac 2100, has been in operation since 1994 and is beyond its useful life. The Clinac 2100 is outdated and does not support the new technologies of IMRT and IGRT. The second linear accelerator is an Elekta Precise model which became operational in November 2003; it has IMRT capability only.

The Hospital is proposing to purchase a Tomotherapy HI-ART[™] unit. The Tomotherapy unit can perform rotational IMRT where treatment is delivered in a simultaneous motion similar to a helical computed tomography scanner. The new linear accelerator will improve the accuracy and precision of treating cancerous tissue by maximizing the radiation exposure to a target tumor and reducing the exposure to adjacent normal tissues. The Hospital proposes using the new unit for the majority of its IMRT cases and all stereotactic cases. OHCA finds that the Hospital's proposal to acquire the new linear accelerator will improve the overall quality of care to cancer patients in this region.

The proposal is financially feasible. The total capital expenditure associated with the project is \$3,700,000. The proposed project will be financed with charitable contributions and operating equity. The Hospital projects incremental gains of \$335,254, \$90,064, and \$105,126 for FYs 2008, 2009 and 2010, respectively. The Hospital's volume and financial projections upon which they are based appear to be reasonable and achievable. Therefore, the proposal will not adversely impact consumers of health care services and payers for such services.

Based on the foregoing Findings and Rationale, the Certificate of Need application of John Dempsey Hospital to acquire a replacement linear accelerator for its Radiation Oncology Division, at a total capital expenditure of \$3,700,000, is hereby GRANTED.

ORDER

John Dempsey Hospital is hereby authorized to acquire a replacement linear accelerator for its Radiation Oncology Division, at a total capital expenditure of \$3,700,000, subject to the following conditions:

- 1. This authorization shall expire October 10, 2008. Should the Hospital's project not be completed by that date, the Hospital must seek further approval from OHCA to complete the project beyond that date.
- 2. John Dempsey Hospital shall not exceed the approved capital expenditure of \$3,700,000. In the event that the Hospital learns of potential cost increases or expects that the final project costs will exceed those approved, the Hospital shall file with OHCA a request for approval of the revised budget.
- 3. This authorization requires the removal of the Hospital's existing Varian Clinac 2100 linear accelerator for certain disposition, such as sale or savage, outside of and unrelated to the Hospital's service provider locations. Furthermore, the Hospital will provide evidence to OHCA of the final disposition of the existing equipment, by no later than three months after the new linear accelerator has become operational.

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

By Order of the Office of Health Care Access

October 10, 2006

Signed by Cristine Vogel Commissioner

CAV:lkg