

STATE OF CONNECTICUT  
OFFICE OF HEALTH CARE ACCESS

M. JODI RELL  
GOVERNOR

CRISTINE A. VOGEL  
COMMISSIONER

September 10, 2009

**IN THE MATTER OF:**

An Application for a Certificate of Need  
filed pursuant to Section 19a-639, C.G.S.  
by:

Notice of Final Decision  
Office of Health Care Access  
Docket Number: 09-31352-CON

**Yale-New Haven Hospital**

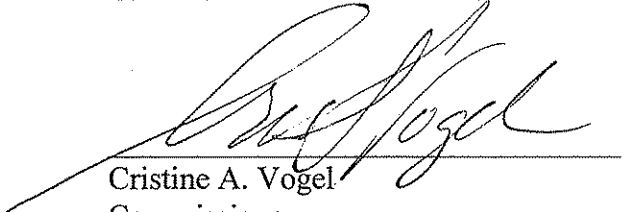
**Acquisition of Leased Gamma Knife  
in New Haven**

To: Jean Ahn  
System Director  
Yale-New Haven Hospital  
20 York Street, CB 1007  
New Haven, CT 06504

Dear Ms. Ahn:

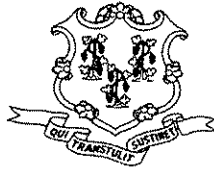
This letter will serve as notice of the Final Decision of the Office of Health Care Access in the above matter as provided by Section 19a-639, C.G.S. On September 10, 2009, the Final Decision was rendered as the finding and order of the Office of Health Care Access. A copy of the Final Decision is attached hereto for your information.

By Order of the  
Office of Health Care Access



Cristine A. Vogel  
Commissioner

CAV:agf



## Office of Health Care Access Certificate of Need Application

### Final Decision

**Hospital:** Yale-New Haven Hospital

**Docket Number:** 09-31352-CON

**Project Title:** Acquisition of Leased Gamma Knife in New Haven

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

**Filing Date:** August 13, 2009

**Decision Date:** September 10, 2009

**Default Date:** November 11, 2009

**Staff Assigned:** Alexis Fedorjaczenko

**Project Description:** Yale-New Haven Hospital (“Hospital”) proposes to acquire a leased Leskell Perfexion Gamma Knife, to be located at the Smilow Cancer Hospital in New Haven, with an associated capital cost of \$4,774,900.

**Nature of Proceedings:** On August 13, 2009, the Office of Health Care Access (“OHCA”) received a Certificate of Need (“CON”) application from Yale-New Haven Hospital (“Hospital”) proposing to acquire a leased Leskell Perfexion Gamma Knife, to be located at the Smilow Cancer Hospital in New Haven, with an associated capital cost of \$4,774,900. 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 *New Haven Register* on April 20, 2009. OHCA received no requests for a public hearing. Pursuant to Section 19a-639, C.G.S.,

three individuals or an individual representing an entity with five or more people had until September 3, 2009, the twenty-first calendar day following the filing of the Hospital's CON Application, to request that OHCA hold a public hearing on the proposal. OHCA received no hearing requests from the public.

OHCA's authority to review and approve, modify or deny the CON application 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.

### **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. It is found that Yale-New Haven Hospital ("YNHH" or "Hospital") is an acute care general hospital located at 20 York Street in New Haven, Connecticut. *(April 9, 2009, Letter of Intent, page 13)*
2. It is found that on November 21, 1997, in an Agreed Settlement under Docket Number 97-546, Yale-New Haven Ambulatory Services Corporation ("ASC") received CON authorization from the Office of Health Care Access ("OHCA") to establish and operate a radiosurgery center and purchase a Gamma Knife. *(November 21, 1997, Agreed Settlement, Docket Number 97-546)*
3. It is found that on March 13, 2006, in a Determination under Docket Number 06-30709, OHCA found that a CON was not required for the transfer of certain services, including a Gamma Knife, from ASC to the Hospital. *(March 13, 2006, Determination, Docket Number 06-30709)*
4. It is found that on September 7, 2005, in an Agreed Settlement under Docket Number 04-30410, the Hospital received CON authorization from OHCA to construct the North Pavilion and establish the Yale-New Haven Cancer Center (now known as the "Smilow Cancer Hospital"). As part of this proposal, the Hospital indicated that all radiation therapy services would be relocated to the basement of the new building. *(September 7, 2005, Agreed Settlement, Docket Number 04-30410)*
5. The Hospital submitted articles from peer-reviewed journals describing two studies that found the Perfexion Gamma Knife has increased treatment range, decreased treatment time, and greater conformity, compared to earlier models from the same manufacturer, including the Hospital's current Elekta Model C Gamma Knife. *(August 13, 2009, Completeness Response, pages 178-197)*
6. The Hospital stated that with the Perfexion Gamma Knife, safety is enhanced due to the equipment's superior dosimetry performance, allowing for more precise sculpting

of the dose distribution and dynamic shaping compared to the Elekta Model C. *(July 1, 2009, Initial CON Submission, pages 19-20 and August 13, 2009, Completeness Response, page 173)*

7. The Hospital stated that the proposed Perfexion Gamma Knife's enhanced reach permits greater access to treat anatomical structures such as metastases in the patient's lower head and neck, as well as greater ability to treat multiple metastases in the entire head and neck region. *(August 13, 2009, Completeness Response, page 173)*
8. OHCA finds that the Hospital provided sufficient evidence to demonstrate the proposal's treatment benefits for patients.
9. The Hospital indicated that with the proposed Perfexion Gamma Knife, the Hospital will continue to serve the existing patient population, and will add 10 incremental cases per fiscal year ("FY") from 2010 to 2012, based on the increased throughput and wider range of treatable anatomical structures made possible by the new unit. The projected volumes are provided below.

**Table 1: Historical, Current, and Projected Case Volume**

	Actual Volume			CFY**	Projected Volume		
	FY 2006*	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Elekta Model C	57	215	227	231	--	--	--
Perfexion	--	--	--	--	241	251	261

Note: The Hospital's FY is October 1 through September 30

\*The Gamma Knife became part of YNHH in Q4 of FY 2006; volumes reflect only this period.

\*\* 2009 Volume is annualized based on 7 months of actual volume.

*(July 1, 2009, Initial CON Submission, pages 20-22)*

10. The Hospital provided case volume by town for FY 2008. These data show that the Hospital's Gamma Knife serves patients from throughout the State of Connecticut. *(July 1, 2009, Initial CON Submission, page 46)*
11. The Hospital stated that inspection reports from the Nuclear Regulatory Commission ("NRC") will not be available for the Smilow Cancer Hospital facility until construction is completed and the unit is installed and inspected by the NRC. To install the Gamma Knife, YNHH must amend its NRC Broad Scope License, which is scheduled for later this year. *(July 1, 2009, Initial CON Submission, page 22)*

**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**

12. The proposed Gamma Knife will be acquired through a lease with GKF, executed as a second amendment to the original lease agreement. *(July 1, 2009, Initial CON Submission, appendix VI)*

13. The fair market value of the lease for the proposed Gamma Knife is \$4,774,900. *(July 1, 2009, Initial CON Submission, page 24 and appendix VII, pages 122-159)*
14. The lease term will be for seven years, and the lease agreement stipulates a per-use rate of \$4,925 per treatment for the first 1,000 treatments, \$4,250 for each treatment between 1,001 and 1,750, and \$4,150 for each treatment thereafter. *(July 1, 2009, Initial CON Submission, page 24 and appendix VI, pages 113-20)*
15. Upon the expiration of the lease term, the Hospital shall have the option to purchase GKF's ownership interest in the Perfexion Gamma Knife for \$150,000. *(July 1, 2009, Initial CON Submission, page 116)*
16. The Hospital projects gains from operations incremental to the project in the first four years of the proposal. Net patient revenue, operating expenses, and gains from operations are presented in the following table.

**Table 2: Projected Incremental Gain from Operations**

	FY 2010	FY 2011	FY 2012	FY 2013
Net Patient Revenue	\$181,000	\$363,000	\$544,000	\$725,000
Operating Expense	\$49,000	\$99,000	\$148,000	\$197,000
<b>Gain from Operations</b>	<b>\$132,000</b>	<b>\$264,000</b>	<b>\$396,000</b>	<b>\$528,000</b>

*(July 1, 2009, Initial CON Submission, appendix IX, pages 163-164)*

17. The Hospital does not anticipate a change in the projected patient population mix for the Gamma Knife service. The current and projected patient population mix for the Gamma Knife service are presented in the following table.

**Table 3: Gamma Knife Patient Population Mix**

	Current FY 2008	Projected FY 2009	Projected FY 2010	Projected FY 2011	Projected FY 2012
Medicare	29.1%	29.1%	29.1%	29.1%	29.1%
Medicaid*	7.0%	7.0%	7.0%	7.0%	7.0%
CHAMPUS & TriCare	0.0%	0.0%	0.0%	0.0%	0.0%
<b>Total Government Payers</b>	<b>36.1%</b>	<b>36.1%</b>	<b>36.1%</b>	<b>36.1%</b>	<b>36.1%</b>
Commercial*	59.9%	59.9%	59.9%	59.9%	59.9%
Uninsured	4.0%	4.0%	4.0%	4.0%	4.0%
Workers Compensation	0.0%	0.0%	0.0%	0.0%	0.0%
<b>Total Non-Gov't Payers</b>	<b>63.9%</b>	<b>63.9%</b>	<b>63.9%</b>	<b>63.9%</b>	<b>63.9%</b>
<b>Total</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

*(July 1, 2009, Initial CON Submission, appendix VIII, pages 160-161 and August 13, 2009, Completeness Response, page 231)*

18. The Hospital stated that there is no downtime anticipated with the proposal, as the current Elekta Model C Gamma Knife will be in operation at the Temple Surgical Center until the replacement Perfexion unit at the Smilow Cancer Hospital is installed. *(August 13, 2009, Completeness Response, page 172)*
19. There is no State Health Plan in existence at this time. *(July 1, 2009, Initial CON Submission, page 19)*

20. The Hospital asserted that the proposal is consistent with the Hospital's planning for the Smilow Cancer Hospital, as approved under Docket Number 04-30410. *(July 1, 2009, Initial CON Submission, page 19)*
21. The Hospital asserted that the proposal will not change the Hospital's teaching or research responsibilities. *(July 1, 2009, Initial CON Submission, page 22)*
22. The Hospital asserted that it has improved productivity and contained costs through energy conservation, group purchasing, and applications of technologies. *(July 1, 2009, Initial CON Submission, page 22)*
23. Based on the resumes of key professional and administrative staff related to the proposal, along with staff who will be providing the services using the proposed equipment, the Hospital has sufficient technical and managerial competence to provide efficient and adequate service to the public. *(July 1, 2009, Initial CON Submission, appendix V, pages 48-111)*
24. The Hospital's rate of \$4,800 per procedure is sufficient to cover the proposed capital cost and operating expenditures. *(July 1, 2009, Initial CON Submission, appendices IX and X, pages 163-164 and 166-168)*
25. The Hospital asserted that the proposal is cost effective because the Hospital will incur no installation costs, saving the Hospital the cost of de-rigging the existing unit, transporting the unit, and rigging the new unit into the new location at the Smilow Cancer Hospital. *(July 1, 2009, Initial CON Submission, page 27)*

## 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.

Yale-New Haven Hospital (“Hospital”) is an acute care general hospital located at 20 York Street in New Haven, Connecticut. The Hospital currently operates an Elekta Model C Gamma Knife at the Temple Surgical Center. The current unit was purchased in 1998. With the establishment of the Smilow Cancer Hospital, expected to open in October 2009, the Hospital will relocate all radiation therapy services to the basement of the new building. As part of this relocation of services, the Hospital proposes to acquire a Leksell Perfexion Gamma Knife through a lease agreement, and to no longer lease the current Elekta Model C Gamma Knife.

OHCA finds that the Hospital provided evidence that the proposed Perfexion unit has increased treatment range, decreased treatment time, and greater conformity, compared to the current Elekta Model C unit. These advancements will benefit the service’s existing patient base, which comes to the Hospital for cancer services from throughout Connecticut, and will also benefit additional patients with metastases in the lower head and neck who were unable to be treated with the current Elekta Model C unit but will be able to receive treatment on the Perfexion unit. Accordingly, OHCA finds that the replacement of the Elekta Model C Gamma Knife with the Perfexion Gamma Knife will improve the quality of care for patients receiving radiation therapy services at Yale-New Haven Hospital’s Smilow Cancer Hospital.

The proposal’s total capital cost of \$4,774,900 is for the fair market value of the lease for the proposed Perfexion Gamma Knife. With the proposal, the Hospital projects incremental gains from operations of \$132,000 in FY 2010, \$264,000 in FY 2011, \$396,000 in FY 2012, and \$528,000 in FY 2013. The Hospital’s financial projections, and the volumes upon which they are based, appear to be reasonable and achievable. Therefore, OHCA finds that the CON proposal is financially feasible.

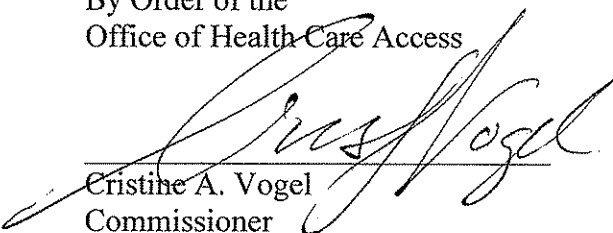
## Order

Based upon the foregoing Findings and Rationale, the Certificate of Need ("CON") application from Yale-New Haven Hospital ("Hospital") proposing to acquire a leased Gamma Knife, to be located at the Smilow Cancer Hospital in New Haven, with an associated capital cost of \$4,774,900, is hereby GRANTED, subject to the following conditions:

1. This authorization shall expire September 10, 2010. 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. The Hospital shall not exceed the approved capital cost of \$4,774,900. 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 notify OHCA immediately.
3. This authorization requires the removal of the Hospital's existing Elekta Model C Gamma Knife for certain disposition, outside of and unrelated to the Hospital's service provider locations. Furthermore, the Hospital will provide evidence to OHCA of the final disposition of said Gamma Knife, by no later than six months after the replacement Gamma Knife has become operational.
4. With respect to the acquisition of the new leased Perfexion Gamma Knife, the Hospital shall submit to OHCA in writing the following information by no later than three months after the equipment has become operational:
  - a. The name of the equipment manufacturer;
  - b. The model name and description of the equipment; and
  - c. The initial date of the operation of the equipment.
5. Should the Hospital propose any change in the array of health care services offered or a change in its complement of existing imaging equipment, the Hospital shall file with OHCA appropriate documentation regarding its change, including either a Certificate of Need Determination Request or a Certificate of Need Letter of Intent.

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

  
Cristine A. Vogel  
Commissioner

Date

9-10-09

CAV: agf