STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

OFFICE OF COMMISSIONER

October 19, 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: 09-31289-CON

Proposal to Establish Three Imaging Operating Rooms: One Room with an Intraoperative Magnetic Resonance Imaging Scanner; a Second Room with Biplane Angiography Equipment; and a Third Room with Single-plane Robotic Angiography Equipment

Yale-New Haven Hospital

To: Jean Ahn
System Director
Yale-New Haven Hospital
20 York Street, CB1007
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 October 19, 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 Division of
Office of Health Care Access
Department of Public Health

Kimberly R. Martone
Director of Operations

KM: cgc
Enclosure

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Department of Public Health
Office of Health Care Access
Certificate of Need Application

Final Decision

Applicant:	**Yale-New Haven Hospital**
Docket Number:	**08-31289-CON**
Project Title:	**Proposal to Establish Three Imaging Operating Rooms: One Room with an Intraoperative Magnetic Resonance Imaging Scanner; a Second Room with Biplane Angiography Equipment; and a Third Room with Single-plane Robotic Angiography Equipment**
Statutory Reference:	**Section 19a-639 of the Connecticut General Statues**
Filing Date:	**July 23, 2009**
Decision Date:	**October 19, 2009**
Default Date:	**October 21, 2009**
Staff:	**Carmen Cotto** **Laurie Greci**

Project Description: Yale-New Haven Hospital ("Hospital" or "YNHH") is proposing to establish three imaging operating rooms: one room with an intraoperative magnetic resonance imaging ("iMRI") scanner; a second room with biplane angiography ("Biplane Angiography") equipment; and a third room with single-plane robotic angiography ("RA") equipment at a total capital expenditure of $15,000,000.

Nature of Proceedings: On July 23, 2009, the Office of Health Care Access ("OHCA") received a Certificate of Need ("CON") application from YNHH regarding a proposal to establish three imaging operating rooms: one room with an intraoperative magnetic resonance imaging ("iMRI") scanner; a second room with biplane angiography ("Biplane Angiography") equipment; and a third room with single-plane robotic angiography ("RA") equipment at a total capital expenditure of $15,000,000.

A notice to the public concerning OHCA's receipt of the Hospital's Letter of Intent was published on January 3, 2009 in *The New Haven Register.* OHCA received no response 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 August 12, 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 Hospital's proposal. OHCA received no hearing requests from the public.

On July 23, 2009, the Hospital submitted a waiver of public hearing request pursuant to Section 19a-643-45 of OHCA's Regulations. The waiver request was based on the grounds that the CON application was non-substantive as defined in Section 19a-643-95(3) of OHCA's Regulations. On September 22, 2009, OHCA determined that the CON application was eligible for consideration of a waiver of public hearing pursuant to Section 19a-643-45 of OHCA's regulations. A notice to the public concerning the waiver of public hearing was published on September 26, 2009 in *The New Haven Register.* Interested persons were invited to submit written comments regarding the request for waiver of hearing by no later than October 6, 2009. OHCA received no comments from the public.

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 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 ("Hospital" or "YNHH") is an acute care general hospital located at 20 York Street in New Haven, Connecticut. *(April 21, 2009, Initial CON Application, page 5)*

2. The Hospital asserts that YNHH is the only Adult and Pediatric Level I Trauma Center in the southern half of the state and is the primary teaching hospital for the Yale University School of Medicine. YNHH serves as a referral resource for other hospitals for tertiary- and quaternary-level services, and as such receives critically and severely injured patients who may benefit from the implementation of this leading technology. *(July 23, 2009, Completeness Response, pages 423-424)*

3. The Hospital proposes to establish three imaging operating rooms as follows:

a) One with an intraoperative magnetic resonance imaging ("iMRI") scanner;
b) One with biplane angiography ("Biplane Angiography") equipment; and
c) One with single-plane robotic angiography ("Single-plane RA") equipment.
(April 21, 2009, Initial CON Application, page 5)

4. The Hospital proposes to position the Biplane Angiography operating room in a suite that includes the iMRI operating room and the Magnetic Resonance Imaging ("MRI") scanner. The MRI scanner will be housed between the two operating rooms and moved into each room as needed. *(April 21, 2009, Initial CON Application, page 8)*

5. The Hospital contends that at the proposed iMRI operating room, YNHH will use real-time imaging and data processing to:

   a) Link images of the soft tissue to spatial positioning of surgical tools relative to the patient's anatomy;
   b) Better identify tumors and lesions;
   c) Differentiate diseased and healthy tissue; and
   d) Account for tissue motion induced by cranial fluid loss, tumor resection and patient movement.

   (April 21, 2009, Initial CON Application, page 7)

6. The Hospital contends that the proposed Biplane Angiography operating room will be used either before or after an open surgical procedure to:

   a) Image a fully interventional procedure to allow for combined open/interventional procedures; or
   b) In lieu of an open procedure to provide necessary imaging capability to enhance patient care quality and outcomes.

   (April 21, 2009, Initial CON Application, page 8)

7. The Hospital contends that the proposed Single-plane RA operating room will allow YNHH surgeons to perform intraoperative diagnostic angiography and will improve the ability to perform image-guided vascular and cardiac surgeries. *(April 21, 2009, Initial CON Application, pages 7 & 8)*

8. The Hospital's agreement with IMRISneuro ("the Vendor") indicated that the iMRI system will allow the surgical team to position the patient exactly as required for the procedure without any compromises because, once positioned, the patient will never need to be moved for scanning, and all associated ventilation and peripheral devices will not require adjustment for the imaging procedure. *(July 23, 2009, Completeness Response, appendix VI, pages 449)*

9. The Hospital contends that the unique combination of iMRI, Biplane Angiography and Single-plane RA operating rooms will enhance the Hospital's standard of care. The following table compares the standard of care that the Hospital can provide with and without the acquisition of the new equipment.

Table 1: YNHH standard of care with and without the proposal

Operating Room Equipment	Without the proposal	With the proposal
iMRI	**a.** The surgeon relies on the naked eye to differentiate between brain tumor tissue and healthy brain tissue.*	**a.** The surgeon will be able to more accurately differentiate between brain tumor and healthy brain tissue since iMRI can provide during surgery immediate feedback regarding the precise boundaries of the tumor.
	b. The Hospital images patients before and after surgery (once the swelling has subsided). Time and traveling between imaging and surgery allows for tissue motion, and the patient must return to surgery if the second image shows incomplete tumor resection.	**b.** The information would be captured before surgery in the operating room, eliminating tissue motion, and captured again prior to closure of the surgical site to ensure comprehensive resection.
Biplane Angiography	**a.** The Hospital uses direct line of sight to determine the success of clipping aneurysms and arteriovenous malformations.	**a.** The residual is found in real-time and the clip can be easily repositioned. **
Single-plane RA	**a.** Endovascular procedures are performed in the operating room with the use of a portable C-arm.	**a.** The fixed unit will offer a larger field view and reduce the need to reposition the C-arm and the radiation exposure to patients and staff.

*The Hospital asserts that brain tumor tissue and healthy tissue mimic each other in color and texture.
**The Hospital asserts that failing to address issues with the residual leaves the patient at a continued risk of subarachnoid hemorrhage.
(July 23, 2009, Completeness Response, pages 420-422)

10. The Hospital contends that studies showed that the use of iMRI in the operating room will benefit patients because it will reduce the need for repeat resection due to early detection of incomplete tumor removal. In one study, iMRI showed incomplete tumor removal in 73% of glioma (brain tumor) cases. *(April 21, 2009, Initial CON Application, page 10)*

11. The Hospital submitted an article as evidence to support the statement that the use of iMRI will reduce the need for repeat resection. *(April 21, 2009, Initial CON Application, Appendix IV, pages 33-46)*

12. The article submitted by the Hospital from "Neurological Research," July 2006, volume 28, pp 483-487, indicated that in glioma cases iMRI revealed complete

tumor removal initially in 27% (37 of 137 patients) of all patients. Extension of the resection owing to iMRI resulted in a final gross total removal of 40% (55 of 137) of all patients. Out of the 55 patients, further tumor removals were performed in 33% (18 of 55) of the patients due to the use of iMRI in the operating room. *(April 21, 2009, Initial CON Application, Appendix IV, pages 33-39)*

13. The Hospital contends that studies showed that the ability to complete a gross total resection when possible with the use of iMRI is critical given that patients with incomplete resection are at 1.4 times the risk of disease recurrence and 4.9 times the risk of death, and submitted an article in support of the same. *(April 21, 2009, Initial CON Application, pages 10-11)*

14. The article submitted by the Hospital from "Cancer," March 2005, volume 103, pp 1227-1233, indicated that patients with incomplete resection are at 1.4 times the risk of disease recurrence and 4.9 times the risk of death and concluded that there is a possible association between surgical resection and survival for neurosurgical patients who underwent surgery for low-grade glioma under iMRI guidance. *(April 21, 2009, Initial CON Application, Appendix IV, pages 40-46)*

15. OHCA finds that the Hospital provided sufficient evidence demonstrating that iMRI reduces the risk for repeat resections and enhances the ability to complete a total gross resection thereby reducing the risk of disease and death.

16. The Hospital contends that the use of iMRI for epilepsy patients has been shown to provide clarity in the extent of temporal lobectomy and to ensure appropriate placement of electrodes, catheters and biopsies, and submitted an article in support of the same. *(April 21, 2009, Initial CON Application, pages 10-11)*

17. The article submitted by the Hospital from "Intraoperative High Field-Strength MR Imaging," October 2004, volume 233, pp 67-78, indicated that iMRI resulted in a modification of surgical strategy related to the placement of a biopsy needle or catheter in 55 (27.5%) of the 200 cases studied. In addition, the article provided images where in surgery for epilepsy patients, iMRI allowed for a clear view of the temporal lobectomy to ensure accurate placement of electrodes. *(April 21, 2009, Initial CON Application, Appendix IV, pages 47-58)*

18. The Hospital contends that postoperative total length of stay for a brain tumor has been shown to be significantly lower for patients when iMRI was utilized in the tumor excision, and submitted an article in support of the same. *(April 21, 2009, Initial CON Application, pages 10-11)*

19. The article submitted by the Hospital from "Cancer Control," March/April 2003, volume 10, pp 115-124, indicated that postoperative total length of stay for brain tumor with the use of iMRI was 5.1 days compared to 9.4 days for non-iMRI patients. *(April 21, 2009, Initial CON Application, pages 10-11, and Appendix IV, pages 59-67)*

20. OHCA finds that the Hospital demonstrated that iMRI reduced the length of stay after surgery for a brain tumor and provided clarity in the extent of temporal lobectomy for epilepsy patients.

21. The Hospital contends that although many of the simple endovascular procedures can be performed in existing angiographic suites, Biplane Angiography and a Single-plane RA operating rooms will provide the environment that is needed to perform combined surgical exposures and endoluminal procedures, and submitted an article in support of the same. *(April 21, 2009, Initial CON Application, page 11, and Appendix IV, pages 68-78)*

22. The article submitted by the Hospital "The New Operating Room Environment," June 1999, volume 79, pp 477-487, indicated that due to the evolvement of endovascular procedures, availability of a well-equipped endovascular suite has gained wide acceptance among physicians and patients. The article also outlines the necessary equipment, hardware and software necessary to have in a contemporary operating room environment. *(April 21, 2009, Initial CON Application, Appendix IV, pages 68-78)*

23. The Hospital contends that digital angiography imaging equipment in the operating room eliminates the need for preoperative angiography in the radiology suite. Also, angiography can be used to visualize success of the surgical procedure while the patient is still on the table, and submitted an article in support of the same. *(April 21, 2009, Initial CON Application, page 11, and pages 79-84)*

24. The Hospital contends that angiographic operating rooms allow for the prompt correction of lesions that are occasionally discovered during "open" transluminal arterial or venous procedures. *(April 21, 2009, Initial CON Application, page 11)*

25. The article submitted by the Hospital from the "Journal of Vascular Surgery," September 1996, volume 24, concluded that there are advantages to the use of the operating room for endovascular procedures such as correction of lesions first discovered during thrombectomy. *(April 21, 2009, Initial CON Application, Appendix IV, pages 85-94)*

26. OHCA finds that there are advantages to the use of the operating room for endovascular procedures such as correction of lesions.

27. Based upon all of the evidence, OHCA finds that the Hospital has demonstrated that the proposal will enhance the standard of care, patient safety and accuracy during complex surgical procedures.

28. The Hospital contends that it is not aware of any current providers of Biplane Angiography and iMRI capabilities in the operating room environment or Single-

plane RA operating rooms in Connecticut[1]. *(July 23, 2009, Completeness Response, page 420)*

29. The Hospital asserts that the cases currently provided in existing operating rooms that would be shifted to the proposed operating rooms include:
    a) Most open neurosurgeries
    b) Therapeutic biopsy and ablation of liver
    c) Kidney and breast tumors
    d) Cryoablation therapy for prostate and kidney tumors
    e) Thoracic aorta endografts
    f) Abdominal aortic aneurysms treated with endografts
    g) Peripheral vascular angiograms
    h) Endovascular stenting/angioplasty
    i) Endovascular procedures currently performed in operating rooms using a portable c-arm and any trials utilizing percutaneous placement of heart valves

    (April 21, 2009, Initial CON Application, page 16)

    (July 23, 2009, Completeness Response, page 420 and Appendix I-Incident Rates, pages 429-430)

30. The Hospital contends that the projected incidence rates do not include future additional applications using the proposed technologies that are currently under research at advanced medical centers. *(July 23, 2009, Completeness Response, page 420)*

31. Utilizing the incidence rates, the population of Connecticut and the Hospital's projected market share results, the Hospital concluded that the following surgical cases will be performed with the proposed equipment:

[1] Under Docket number: 08-31224, the Hospital of Saint Raphael has been authorized to acquire and operate a new fixed-based C-arm angiography system in a dedicated operating room.

Table 4: YNHH volume per medical condition and operating room

Conditions treated per operating room*	Connecticut Volume***	YNHH Share of State Volume***	YNHH Volume
I. A-iMRI **	**Volume**	**New Cases FY2005**	**Projected New Cases**
a. Cancer of the Brain and Other Nervous System	252	72%	182
b. Cancer of the Female Breast	2,802	17%	463
c. Cancer of the Kidney and Renal Pelvis	544	13%	72
d. Cancer of the Liver and Intrahepatic Bile Duct	223	22%	50
e. Cancer of the Prostate	2,502	9%	215
I. B-iMRI**	**Estimated Volume**	**Inpatient Cases FY2008**	**Estimated Volume**
a. Epilepsy	35,172	24%	8,441
b. Uterine Fibroids	352,029	13%	44,708
Total iMRI ****	**393,524**	**14%**	**54,131**
II. Biplane Angiography	**Estimated Volume**	**Inpatient Cases FY2008**	**Estimated Volume**
a. Arteriovenous Malformations (AVM)	415	25%	104
b. Stroke	94,447	9%	8,230
c. Parkinson's	471	11%	54
Total Biplane Angiography****	**95,333**	**9%**	**8,388**
III. Single-plane RA	**Estimated Volume**	**Inpatient Cases FY2008**	**Estimated Volume**
a. Abdominal Aortic Aneurysm	108,209	12%	12,617
b. Peripheral Artery Disease, Peripheral Vascular Disease (*one cause of Peripheral Vascular Stenting*)	24,111	3%	820
c. Thoracic Aortic Aneurysm	211	61%	129
Total Single-plane RA****	**132,531**	**10%**	**13,566**

Note: For ease of comparison, YNHH used the entire state to calculate volume, and YNHH's state share was then used to scale back the volumes to reflect YNHH patient populations.
**The Hospital's data and incidence rate sources: YNHH and Connecticut Tumor Registry (2005), Epilepsy Foundation, National Institutes of Health, National Institutes of Neurological Disorders and Stroke, Centers for Disease Control and Prevention, American Journal of Epidemiology and eMedicine.*
***The Hospital indicates that if capacity permits, the listed medical conditions could also be treated in the Biplane Angiography operating room.*
****YNHH Share of Inpatient Cases is from CHIME, estimated Connecticut volume is based on Claritas population estimates for 2008 as follows: Total Connecticut Population-3,517,186;65 and over-482,212;18 and over-2,705,233;Females 18 and over-1,408,118.*
***** totaled by OHCA*
(July 23, 2009, Completeness Response, page 420 and Appendix I-Incidence Rates, pages 429-432)

32. OHCA recognizes that the Hospital has projected a total utilization volume of 54,131 cases for iMRI, 8,388 cases for the Biplane Angiography equipment and 13,566 cases for the Single-plane angiography equipment that support the Hospital's request of the equipment for the operating rooms. OHCA also recognizes that the volume

does not recognize the future applications of the proposed equipment that is currently under research at advanced medical centers.

33. The Hospital proposes to obtain a 3.0 Tesla iMRI to assist in performing the surgical procedures in order to increase accuracy and quality, and to acquire greater functionality and speed during surgery. *(July 23, 2009, Completeness Response, page 424)*

34. The Hospital indicates that the iMRI and Biplane Angiography operating rooms will be constructed in the North Pavilion at the north end of the third floor. The overall suite, including all control, scrub space and staff lounges, will encompass approximately 3,550 square feet. While this area is within the Smilow Cancer Hospital, the area in question is not undergoing construction pending OHCA approval. *(April 21, 2009, Initial CON Application, page 20)*

35. The Hospital indicates that the location for the Single-plane RA operating room is currently being finalized. It is anticipated that this will be located within existing operating rooms and will involve the renovation of two existing rooms into one Single-plane RA operating room and appropriate support space. *(April 21, 2009, Initial CON Application, pages 20-21)*

36. The Hospital contends that there will be no disruption in the delivery of patient care since the iMRI and the Biplane Angiography operating room will be built into the North Pavilion construction project and the construction of the Single-plane RA operating room will be scheduled to begin after the North Pavilion operating rooms are opened. *(April 21, 2009, Initial CON Application, page 21)*

Financial Feasibility of the Proposal and its Impact on the Hospital's Rates and Financial Condition
Rates Sufficient to Cover Proposed Capital and Operating Costs
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

37. The total capital expenditure associated with this proposal is $15,000,000 and consists of the following:

Table 6: Total Capital Expenditure

Total Capital Expenditure Itemization	
iMRIS	$10,900,000
Siemens RA	1,050,000
Total Medical Equipment (Purchase)	**$11,950,000**
Renovation	3,050,000
Total Capital Expenditure	**$15,000,000**

(December 22, 2008 Letter of Intent, page 4 and April 21, 2009, Initial CON Application, page 20)

38. The proposed total capital expenditure of $15,000,000 for the CON proposal will be financed entirely through the Hospital's equity comprised of $3,000,000 in Operating

Funds and $12,000,000 in Funded Depreciation. *(April 21, 2009, Initial CON Application, page 22)*

39. OHCA finds that the amount of $513.1 million in Unrestricted Net Assets on YNHH's Audited Financial Statements, provided to OHCA as part of the FY2008 Annual Reporting filing, demonstrated that the Hospital's equity appears to be strong enough to sustain the cost of this proposal.

40. The Hospital's projects to receive no incremental revenues from the proposal as shown in the following table:

Table 8: Projected Incremental Losses from Operations

Activity	FY2010	FY2011	FY2012	FY2013	FY2014
Revenue from Operations	$0	$0	$0	$0	$0
Salaries and Fringe Benefits	$84,000	$84,000	$84,000	$84,000	$84,000
Depreciation/Amortization	$915,000	$1,829,000	$1,829,000	$1,829,000	$1,829,000
Total Operating Expenses	$998,000	$1,913,000	$1,913,000	$1,913,000	$1,913,000
Incremental Losses from Operations	**($998,000)**	**($1,913,000)**	**($1,913,000)**	**($1,913,000)**	**($1,913,000)**

(April 21, 2009, Initial CON Application, Appendix XIII, Financial Attachments IA and IB, pages 410-412)

41. The Hospital claims that the incremental losses from operations are related to the cost of the depreciation of the equipment and the hiring of one additional technician that will be required to offer the services. *(July 23, 2009, Completeness Response, pages 427- 428)*

42. OHCA recognizes that the Hospital will not realize incremental gains from operations until the eighth year after which the equipment will be fully depreciated. *(April 21, 2009, Initial CON Application, Appendix XII-Depreciation schedule, pages 404-409)*

43. Although the Hospital does not expect incremental gains from operations as the result of the implementation of this proposal, OHCA recognizes that the overall financial performance of the hospital indicates that YNHH expects to realize net gain from operations of $26.4, $28.4, $30.4, $32.7, and $35.2 million for FY's 2010 through FY 2014, respectively. *(April 21, 2009, Initial CON Application, Appendix XIII, Financial Attachment IA, pages 411-412)*

44. Although the Hospital will have incremental operating losses due to the depreciation of the equipment having a useful life of seven years and revenues will not increase as there will be no additional surgeries using this equipment and no rate increases, the Hospital's financial projections appear to be reasonable and achievable. Therefore, OHCA finds that the Hospital's proposal is financially feasible. *(July 23, 2009, Completeness Response, pages 427-428)*

45. There is no State Health Plan in existence at this time. *(April 21, 2009, Initial CON Application, page 6)*

46. The Hospital asserts that the proposal is consistent with YNHH's long-range plan. *(April 21, 2009, Initial CON Application, page 6)*

47. The Hospital asserts that YNHH has used energy conservation, group purchasing, and technology to improve productivity and contain costs. *(April 21, 2009, Initial CON Application, page 18)*

48. The Hospital contends that its teaching and research responsibilities will be affected by the proposal. The marriage of the operating rooms will bring additional opportunities for research, and to develop additional procedures for the treatment of conditions such as brain tumors and epilepsy. *(April 21, 2009, Initial CON Application, page 18)*

49. The Hospital asserts that YNHH possesses characteristics within its patient/physician mix that make the proposal unique. YNHH is the primary teaching hospital for the Yale University School of Medicine, a major community hospital that provides a full array of primary to quaternary patient services, and the only hospital that provides Adult and Pediatric Level 1 Trauma in the southern half of the state. *(April 21, 2009, Initial CON Application, page 18)*

50. The Hospital provided resumes of its executive and clinical leadership demonstrating that YNHH possesses sufficient technical and managerial competence and expertise to provide efficient and adequate service to the public. *(April 21, 200, Initial CON Application, pages 148-332)*

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" or "YNHH") is an acute care general hospital located in New Haven, Connecticut. The Hospital proposes to equip and establish three imaging operating rooms: one operating room with an intraoperative magnetic resonance imaging ("iMRI") scanner; a second room with biplane angiography ("Biplane Angiography") equipment; and a third room with single-plane robotic angiography ("RA") equipment. The Hospital intends to position the Biplane Angiography operating room in a suite that includes the iMRI. The magnetic resonance imaging scanner will be housed between the two operating rooms and moved into each room as needed.

The Hospital's proposal to combine iMRI, Biplane angiography and Single-plane RA will enhance the Hospital's standard of care, patient safety and accuracy during complex surgical procedures. The Hospital's proposal will allow surgeons at YNHH to use real-time imaging and data processing to differentiate between brain tumor tissue and healthy brain tissue,

eliminate tissue motion and achieve a higher level of tumor removal. In addition, the fixed single-plane RA will offer a larger field view and reduce the need to reposition the C-arm and the radiation exposure to patients and staff.

The Hospital has submitted articles as supporting evidence of the benefit to surgical patients in reducing the need for repeat resection and shortening the length of stay; confirming the appropriate placement of electrodes, catheters and biopsies for epilepsy patients; providing a well-equipped environment to perform combined complex surgical procedures; and allowing surgeons to determine success of a surgical procedure and for the prompt correction of lesions while the patient is still in the operating room. The Hospital provided sufficient evidence demonstrating that iMRI reduces the risk for repeat resections and enhances the ability to complete a total gross resection thereby reducing the risk of disease and death. The Hospital demonstrated that iMRI reduced the length of stay after surgery for a brain tumor and provided clarity in the extent of temporal lobectomy for epilepsy patients and that there are advantages to the use of the operating room for endovascular procedures such as correction of lesions. [FINDINGS OF FACT 15, 20 and 26]. Based upon all of the evidence, OHCA finds that the Hospital has demonstrated that the proposal will enhance the standard of care, patient safety and accuracy during complex surgical procedures. [FINDING OF FACT 27].

The proposed total capital expenditure of $15,000,000 for the CON proposal will be financed entirely through the Hospital's equity comprised of $3,000,000 in Operating Funds and $12,000,000 in Funded Depreciation. OHCA finds that the amount of $513.1 million in Unrestricted Net Assets on YNHH's Audited Financial Statements, provided to OHCA as part of the FY2008 Annual Reporting filing, demonstrated that the Hospital's equity appears to be strong enough to sustain the cost of this proposal. [FINDING OF FACT 39]. Although the Hospital is projecting incremental operating losses due to the depreciation of the equipment and revenues will not increase as there will be no additional surgeries using this equipment and no rate increases, OHCA finds that the Hospital's projections in net operating gains of $30 million, $33 million and $35 million in FYs 2012, 2013, and 2014, respectively appear to be reasonable and achievable. (FINDING OF FACT 44). Therefore, OHCA concludes that the Hospital's proposal is financially feasible.

Order

Based upon the foregoing Findings and Rationale, the Certificate of Need application of Yale-New Haven Hospital ("Hospital" or "YNHH") to equip and establish three imaging operating rooms: one operating room with a intraoperative magnetic resonance imaging ("iMRI") scanner; a second room with biplane angiography equipment; and a third room with single-plane robotic angiography equipment, at a total capital expenditure of $15,000,000, is hereby GRANTED, subject to the following conditions:

1. This authorization shall expire on October 19, 2011. 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 total capital expenditure of $15,000,000. In the event that the Hospital learns of potential cost increases or expects that final project costs will exceed those approved, the Hospital shall immediately notify OHCA.

3. The Hospital shall notify OHCA in writing with the following information by no later than one month after the intraoperative MRI scanner and the robotic angiography equipment becomes operational:

   a) The name of the manufacturer;
   b) The model name and description of the equipment; and
   c) The initial date of the operation of the new operating rooms for each piece of equipment acquired.

4. Should the Hospital propose any change in the operating rooms or the imaging equipment used in each of the three operating rooms, the Hospital shall file with OHCA a Certificate of Need Determination Request or Certificate of Need Letter of Intent regarding the proposed service and/or equipment change.

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 Division of
Office of Health Care Access
Department of Public Health

10/19/09
Date

Kimberly R. Martone
Director of Operations