



Office of Health Care Access Certificate of Need Application

Final Decision

Hospital: Yale New Haven Hospital and Yale University School of Medicine

Docket Number: 02-501

Project Title: Replace PET Scanner

Statutory Reference: Section 19a-639, Connecticut General Statutes

Filing Date: June 4, 2002

Hearing: Waived

Decision Date: June 26, 2002

Default Date: September 6, 2002

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Project Description: Yale New Haven Hospital and Yale University School of Medicine (“Applicants”) propose replacement of existing PET scanning equipment. The proposed capital expenditure of the project is \$1,750,000.

Nature of Proceedings: On June 4, 2002, the Office of Health Care Access (“OHCA”) received the Certificate of Need (“CON”) application of Yale New Haven Hospital and Yale University School of Medicine (“Applicants”) seeking authorization to replace an existing PET scanner. The total proposed capital expenditure is \$1,750,000. Each Applicant is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes (“C.G.S.”).

The Applicants requested a waiver of public hearing for the CON application pursuant to Section 19a-643-45 of OHCA's Regulations and claimed that the proposal was non-substantive as defined in Section 19a-643(3) of OHCA's Regulations. On June 6, 2002, the Applicants were informed that the CON application was eligible for consideration of waiver of public hearing. Notice to the public was published in the *New Haven Register* and the *Northeast Minority News*. OHCA received no comments concerning the Applicants' request for waiver of public hearing during the public comment period and therefore, on June 25, 2002, OHCA granted the Applicants' request for waiver of public hearing.

OHCA's authority to review and approve, modify or deny this proposal is established by Section 19a-639, C.G.S. The provisions of these 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

Each finding of fact included in this Final Decision has been taken from the CON application and related CON filings. A source reference is included with each finding of fact. All CON applicants must attest to the accuracy and correctness of the information submitted to OHCA as part of the CON application process.

Clear Public Need
Impact on the Applicants' Current Utilization Statistics
Contribution of the Proposal to the Accessibility of Health Care
Delivery in the Region
Impact of the Proposal on the Interests of Consumers of Health Care
Services and Payers for Such Services

1. Yale New Haven Hospital ("Hospital") is an acute care hospital, located at 20 York Street, in New Haven, Connecticut. (*CON Application, April 25, 2002, page 5*)
2. The Hospital and the Yale University School of Medicine ("Applicants") seek authorization to replace the existing Positron Emission Tomography ("PET") scanner with a new, Siemens PET scanner. (*CON Application, April 25, 2002, page 8*)
3. The existing PET scanner is located at the PET Center at the Department of Veterans Affairs Medical Center, 950 Campbell Avenue in West Haven, Connecticut and is the sole fixed-base PET scanner in Connecticut. (*CON Application, April 25, 2002, page 7*)
4. The existing PET scanner was initially approved by the Office of Health Care Access ("OHCA") as a demonstration project under Docket Number 92-543 and

later approved for permanent status under Docket Number: 99-552R. (CON Application, April 25, 2002, page 7)

5. The proposed replacement PET scanner will be a clinical/research partnership between the Applicants. (CON Application, April 25, 2002, page 8)
6. The existing equipment is 10 years old, technologically obsolete, operating beyond its useful life and has deteriorated to a point where certain procedures cannot be performed. Equipment failure of the existing scanner has created delays for patients and referring physicians and has resulted in the need to transfer patients to another PET facility. (CON Application, April 25, 2002, page 7)
7. The Yale University School of Medicine (“YSM”) radiology residency training program and their Nuclear Medicine residency and fellowship program require state-of-the-art equipment to maintain their Accreditation Council for Graduate Medical Education accreditation. (CON Application, April 25, 2002, page 13)
8. A state-of-the-art PET scanner will provide greater reliability and will be capable of performing all types of PET procedures. The Applicants anticipate this will reduce delays and the need to refer patients to other PET facilities. (CON Application, April 25, 2002, page 8)
9. Research volume is expected to increase with the new scanner as it will enable researchers to undertake initiatives that are not possible with the existing outdated PET scanner. (Response to Completeness, June 4, 2002, page 1)
10. The number of projected PET scans, assuming the addition of a fixed-based PET scanner at YNNH starting in year 3, by procedure type are as follows:

YNNH Projected PET Scans by Procedure

	Year 1	Year 2	Year 3	Year 4	Year 5
Lung	216	304	279	262	216
Lymphoma	62	87	80	75	62
Colon	134	190	174	163	135
Melanoma	64	91	83	78	65
Head & Neck	64	91	83	78	65
Esophageal	17	24	23	21	17
Breast	100	142	130	122	101
Oncology @ 85%	657	929	852	799	661
Neuro @ 10%	77	109	100	94	78
Clinical	773	1,093	1,002	940	778
Research	134	208	261	295	344
Total	907	1,301	1,263	1,235	1,122

(CON Application, April 25, 2002, page 12)

11. There are presently no significant scheduling backlogs at the PET Center. Given the expanding research and increased clinical applications, however, it is unlikely that the single existing scanner will meet the Applicants' growing clinical needs. *(CON Application, April 25, 2002, page 9)*
12. The Applicants provided the following number of PET procedures between 1995-2001:

Applicant's PET Procedures 1995-2001

Year	Clinical	Research	Total
1995	189	5	194
1996	388	25	413
1997	280	51	331
1998	365	68	433
1999	273	50	323
2000	257	71	328
2001	381	52	433

(CON Application, April 25, 2002, page 9)

13. The Hospital of St. Raphael and MidState Medical Center currently provide mobile PET scanning services and will not be adversely impacted by the proposal. *(CON Application, April 25, 2002, page 10)*
14. The hours of operation of the PET Center are from 8:30 a.m. to 4:00 p.m., Monday through Friday. *(CON Application, April 25, 2002, page 10)*
15. YSM will be responsible for direct payment of all operating expenses associated with the PET scanner and cyclotron and all PET revenue (from the first three years) will accrue to YSM in order to cover projected operating expenses. *(Response to Completeness, June 4, 2002, page 3)*
16. There will be a period of down time of approximately eleven days when existing equipment will be decommissioned, the suite will be upgraded and the replacement PET scanner will be installed. *(CON Application, April 25, 2002, page 16)*
17. The proposed construction/renovation schedule is as follows:

Commencement Date	August 2002
Completion Date	August 2002
Occupancy Date	August 2002

(CON Application, April 25, 2002, page 16)

**Financial Feasibility of the Proposal and its Impact on the Hospital's
Rates and Financial Condition**

18. The proposal has a total capital expenditure of \$1,750,000, which consists of the following, which does not include capitalized financing costs:

Total Capital Expenditure Breakdown

Description	Amount
Movable Equipment (Purchase)	\$1,569,525
Other (Contingency, Legal & CON Fees)	\$180,475
Total Capital Expenditure	\$1,750,000

(CON Application, April 25, 2002, page 15)

19. There are no construction/renovation costs associated with the replacement of the existing PET scanner. Installation costs are included in the purchase price. *(CON Application, April 25, 2002, page 16)*
20. The Applicants project excess revenue incremental to this project of \$19,446, \$20,030 and \$20,631 for FYs 2002, 2003 and 2004, respectively. *(CON Application, April 25, 2002, page 249)*
21. YSM will utilize CHEFA bonds to fund its portion of the project while YNNH will fund its portion of the project with an equity contribution. *(CON Application, April 25, 2002, page 8)*
22. YSM will fund 75% of the total capital expenditure and will own 75% of the unit while the Hospital will fund 25% of total capital expenditure and will own 25% of the unit. *(CON Application, April 25, 2002, page 8)*

**Consideration of Other Section 19a-637, C.G.S.
Principles and Guidelines**

The following findings are made based upon other principles and guidelines set forth in Section 19a-637, C.G.S.:

23. There is no State Health Plan in existence at this time. *(CON Application, April 25, 2002, page 6)*
24. The Applicants have adduced evidence that this proposal is consistent with the Hospital's long-range plan. *(CON Application, April 25, 2002, page 6)*
25. The Applicants have improved productivity and contained costs through energy conservation, reengineering, the application of technology and group purchasing. *(CON Application, April 25, 2002, page 13)*

26. This proposal will result in changes to the Applicants' teaching and research responsibilities. The Applicants' Radiology and Nuclear Medicine residency programs could be placed on probation by the Accreditation Council for Graduate Medical Education if the PET scanner is not replaced. *(CON Application, April 25, 2002, page 13)*
27. The Applicants have sufficient technical and managerial competence to provide efficient and adequate service to the public. *(CON Application, April 25, 2002, Attachment C, pages 33-127)*
28. The Applicants' proposal will not affect existing providers as the project is intended to replace existing equipment. *(CON Application, April 25, 2002, page 10)*
29. There are distinguishing characteristics of the Applicants' patient/physician mix. The Hospital offers a full array of primary to quaternary patient services; many quaternary services have been designated as regional or national referral services. *(CON Application, April 25, 2002, page 14)*

Rationale

Yale New Haven Hospital and Yale University School of Medicine (“Applicants”) propose to replace their existing, 10 year old PET scanner with a new, state-of-the-art Siemens PET scanner. The proposed replacement PET scanner will be a clinical/research partnership between the Applicants.

Yale New Haven Hospital obtained approval for permanent status of PET scanning services under CON DN: 99-552R. The existing PET scanner is technologically obsolete and has deteriorated to the point where a number of procedures cannot be performed. Additionally, equipment failure has led to delays for patients and referring physicians and has resulted in the need to transfer patients to other PET facilities.

A new, state-of-the-art PET scanner is expected to provide greater reliability and be capable of performing all types of PET procedures. The Applicants anticipate that it will reduce delays and eliminate the need to refer patients to other PET facilities. The Hospital of St. Raphael and MidState Medical Center currently provide mobile PET scanning services and will not be adversely impacted by the proposal.

While there are presently no significant scheduling backlogs at the PET Center, research volume is expected to increase with the new scanner. This new technology will enable researchers to undertake initiatives that are not possible with the existing outdated PET scanner. Expanded research capabilities and increased clinical applications will likely render the existing scanner incapable of meeting the growing clinical needs of the Applicants.

This proposal will likely enhance the Applicants’ teaching and research responsibilities. The Yale University School of Medicine radiology residency training program and its Nuclear Medicine residency and fellowship program require state-of-the-art equipment to maintain their Accreditation Council for Graduate Medical Education accreditation. The implementation of the proposal will provide the necessary equipment.

Finally, the proposal is financially feasible. The total capital expenditure of \$1,750,000 will be financed entirely from CHEFA financing. The Applicants are projecting excess revenue incremental to this project of \$19,447, \$20,030 and \$20,631 for Fiscal Years 2002, 2003 and 2004, respectively. If volume projections are achieved, the Applicants’ rates appear sufficient to cover the proposed capital expenditure and operating costs associated with the project.

Based on the foregoing Findings and Rationale, the Certificate of Need application of Yale New Haven Hospital and the Yale University School of Medicine to replace their existing PET scanner with a new, Siemens PET scanner at a total capital expenditure of \$1,750,000, is hereby GRANTED.

ORDER

Yale New Haven Hospital and Yale University School of Medicine are hereby authorized to acquire a new Siemens PET scanner to be located at 950 Campbell Avenue in West Haven, Connecticut at a total capital expenditure of \$1,750,000, subject to the following conditions:

1. This authorization shall expire June 26, 2003. Should the Applicants' project not be completed by that date, the Applicants' must seek further approval from OHCA to complete the project beyond that date.
2. The Applicants shall not exceed the approved capital expenditure of \$1,750,000. In the event that the Applicants learn of potential cost increases or expects that the final project costs will exceed those approved, the Applicants shall file with OHCA a request for approval of the revised budget.
3. Yale New Haven Hospital ("Hospital") shall file utilization statistics for the PET scanning service on a quarterly calendar basis for two full years of operations. Each quarterly filing shall be submitted to OHCA by no later than one month following the end of each reporting period (e.g., January, April, July, and October). The initial report shall list the date on which the mobile PET scanning service commenced operation. The quarterly reports shall include the following:
 - Total number of scans scheduled for the PET scanning service by the Hospital;
 - Total number of scans performed by the PET scanning service for the Hospital;
 - Average patient waiting time from the scheduling of the scan by the Hospital to the performance of the scan;
 - Number of scans performed for the Hospital by patient zip code; and
 - Number of scans by Medicare Diagnostic Code.

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

Date Signed:
June 26, 2002

Signed by:
Raymond J. Gorman
Commissioner

RJG/SEC/LG