



Office of Health Care Access Certificate of Need Application

Final Decision

Applicant: Hospital of Saint Raphael

Docket Number: 02-552

Project Title: Acquisition of PET-CT Scanning Equipment
and Associated Renovations

Statutory Reference: Sections 19a-638 and 19a-639, Connecticut General
Statutes

Filing Date: December 13, 2002

Hearing: Waived

Decision Date: February 11, 2003

Default Date: March 13, 2003

Staff Assigned: Laurie Greci

Project Description: The Hospital of Saint Raphael proposes to acquire PET-CT Scanning Equipment with Associated Renovations at a total capital expenditure of \$3,414,796.

Nature of Proceedings: On December 13, 2002 the Office of Health Care Access (“OHCA”) received The Hospital of Saint Raphael’s (“Hospital”) Certificate of Need (“CON”) application seeking authorization to acquire PET-CT Scanning Equipment and perform associated renovations at the Hospital of Saint Raphael, 1450 Chapel Street, New Haven, Connecticut. The Hospital is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes (“C.G.S.”).

On December 13, 2002, the Hospital 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-643-95(3) of OHCA's Regulations. On December 20, 2002, the Applicant was informed that the CON application was eligible for consideration of waiver of public hearing, and a notice to the public was published in the *New Haven Register*. OHCA received no comments from the public concerning the Applicant's request for waiver of hearing during the public comment period, and therefore on January 15, 2003, OHCA granted the Applicant's request for waiver of hearing.

OHCA's authority to review and approve, modify or deny this application is established by Sections 19a-638 and 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, or from other external sources of information. 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

Proposal's Contribution to 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. The Hospital of Saint Raphael ("Hospital") is a nonprofit acute care hospital located at 1450 Chapel Street, New Haven, Connecticut. *(December 13, 2002, CON Application, page 438.)*
2. The Hospital proposes to replace its current mobile PET service with a fixed location state-of-the-art PET-CT scanner. *(December 13, 2002, CON Application, page 2)*
3. The Hospital proposes to purchase a GE Medical Systems Discovery LS PET/CT fully integrated scanner system. *(December 13, 2002, CON Application, page 451.)*
4. The Hospital's proposed acquisition will augment its current cancer diagnostic and staging capabilities. *(December 13, 2002, CON Application, page 2)*
5. Cancer services have been considered one of the key clinical strengths of the Hospital. The Hospital provides all three major modalities of cancer treatment: surgery; medical oncology; and radiation therapy. *(December 13, 2002, CON Application, page 3).*

6. The PET-CT scanner combines metabolic information with morphological information enhancing the sensitivity and specificity for the diagnosis of malignant disease. *(December 13, 2002, CON Application, page 4).*
7. The Hospital has identified the benefits of the combination PET-CT scanner, as follows: *(December 13, 2002, CON Application, page 4)*
 - a. It is 20% more accurate than PET imaging alone.
 - b. It eliminates the need for post acquisition image alignment between a PET scan and a CT scan which results in improvement in the quality and accuracy of cancer diagnosis and treatment.
 - c. The detailed quality of the images provides clinicians with the ability to find cancers that would not have been detected through other non-invasive imaging exams.
8. In addition to the purchase of the PET-CT scanner, the Hospital will make minor renovations to the radiology department. Renovations will include the addition of a patient bathroom and the conversion of an office into a patient injection room. *(December 13, 2002, CON Application, page 23).*
9. Mobile PET scanning service began at the Hospital in May 2001 with service provided one day per week. In January 2002, a second day per week service was added. *(December 13, 2002, CON Application, pages 6 and 8).*
10. The Hospital will continue to operate the mobile PET scanner during the construction/renovation and installation period for the new scanner. The mobile service will discontinue once the new scanner is operational. Patients will not experience an interruption of service. *(December 13, 2002, CON Application, page 24).*
11. The limited on-site schedule for the mobile PET scanner has a persistent two-week backlog of patients resulting in significant delays in patient treatment. *(December 13, 2002, CON Application, page 4).*
12. The physical aspects of the mobile unit present the following significant challenges to patient care and comfort: limited interior space in the event of a patient emergency; access barriers for patients requiring a stretcher; and difficulty in maintaining comfortable room temperatures. *(December 13, 2002, CON Application, page 5).*
13. The Hospital anticipates that the fixed scanner will provide the following enhancements to the PET scanning services: *(December 13, 2002, CON Application, pages 4 and 5)*
 - a. enhanced ability to care for unexpected or emergency cases; and
 - b. improvements in patient access, operational efficiency, quality of patient care, and patient comfort.

14. In FY 2002, over 500 patients were discharged from the Hospital with a diagnosis of cancer. Additionally, there were over 4,600 nuclear medicine patient encounters, and over 33,000 outpatient radiation therapy treatments. *(December 13, 2002, CON Application, page 3).*
15. The numbers of PET-CT scans that have been performed at the Hospital are given in the following table:

Table 1: PET-CT Scans at Hospital of Saint Raphael

	Number of PET-CT Scans	Change FY2001-Y2002
FY 2001 Annualized	312	-
FY 2002 Actual	849	172%

(December 13, 2002, CON Application, page 8)

16. Since the start of the mobile service at the Hospital, the PET-CT scan volume has averaged 8 scans per day, representing a full schedule of patients. *(December 13, 2002, CON Application, page 9)*
17. The Hospital states that it adheres to the standards and guidelines developed by the Society of Nuclear Medicine and the American College of Radiology (“ACR”). The Hospital is in compliance with the following:
- *ACR Standard for the Performance of Computed Tomography of the Extracranial Head and Neck in Adults and Children*
 - *ACR Standard for Performing and Interpreting Diagnostic Computed Tomography*
 - *ACR Standard for the Performance of CT of the Abdomen and Computed Tomography of the Pelvis*
 - *ACR Standard for the Performance of Pediatric and Adult Thoracic Computed Tomography*
 - *The Society of Nuclear Medicine Procedure Guidelines for Tumor Imaging Using F-18FDG*
- (December 13, 2002, CON Application, pages 18 and 19)*
18. All PET-CT procedures are performed under the supervision of a physician certified by the American Board of Radiology. Medical personnel have been trained in the physics of diagnostic radiology, principals of radiation protection and the hazards of radiation exposure. *(December 13, 2002, CON Application, page 19)*
19. It is expected that virtually all scans will, at least initially, be used for detecting metastatic disease. In the future the application of PET-CT will move to other clinical applications, such as infectious and cardiac diseases. *(December 13, 2002, CON Application, page 27)*
20. The Hospital has experienced a significant decline in gallium scans since PET scanning services were initiated, most notably those for lymphoma patients. As the use and clinical application of PET and PET-CT expands, the use of gallium scans will continue to decrease. *(December 13, 2002, CON Application, page 27)*

21. The Hospital also expects a reduction in the number of radioactive iodine scans once PET scanning has been approved for thyroid cancer. *(December 13, 2002, CON Application, page 19)*
22. The Hospital presented three methodologies to justify the need for the fixed PET-CT scanner. One methodology is based on the Hospital's Tumor Registry data, one used historical claims data and national data, and the third is an average of the volumes projected by the two methodologies. *(December 13, 2002, CON Application, pages 11-14)*
23. The Hospital used its Tumor Registry to provide a conservative estimate of the future demand for PET-CT service. Adjustments were made for usage that included newly diagnosed patients and existing patients whose cancer diagnosis would be appropriate for PET-CT scans. The conservative estimate for PET-CT scan volume is given in the following table:

Table 2: Hospital of Saint Raphael Conservative Estimate of PET-CT Scan Volume

Type of New Cancer Case	FY 2002 Cases ^a	Percent Estimate of Usage	Estimated FY2002 Scans for New Cases	Percent Estimate Scans for Recurrent Cases	Estimate Number of Scans for Recurrent Cases	Total Estimated Scans for FY 2002
Colorectal	52	50	26	45	12	38
Lung	391	90	352	45	157	510
Lung Nodules	195	90	176	45	79	255
Lymphoma	217	90	195	45	88	283
Melanoma	21	50	11	45	5	16
Brain	40	25	10	45	5	15
Head/Neck	57	55	31	45	14	45
Breast	447	45	201	45	94	292
TOTAL	1,420		1,002		451	1,453
Average Scans/Day ^b			4		2	6

^a Annualized based on 9 months actual.

(December 13, 2002, CON Application, page 11)

^b Based on 250 days/year

24. The estimates based on the Tumor Registry data suggests the Hospital can support a volume of 1,453 scans per year, or approximately 6 scans per day for a dedicated fixed site machine that operates 250 days per year. *(December 13, 2002, CON Application, page 11)*

25. Solucient, Inc., a healthcare data and consulting firm, developed a second estimate methodology. This methodology is more aggressive and utilizes historical claims data and national ambulatory survey data. The Solucient model adjusts for growth in PET-CT procedures based on current adoption rates for the technology by health care professionals. The Solucient methodology estimates the following scan volumes:

Table 3: Solucient, Inc. Projection of HSR PET-CT Scan Volume

	FY 2002	FY2003	FY2004	FY2005
Annual Scans	535	918	1,575	2,701
Average Scans/Day	2	4	6	11

(December 13, 2002, CON Application, page 12)

26. The Hospital averaged the two methodologies and makes the following estimate of volume expected for the fixed PET-CT:

Table 4: Hospital of Saint Raphael Projection of PET-CT Scan Demand

Methodology	FY 2003	FY 2004	FY 2005
Tumor Registry	1,598	1,758	1,934
Solucient	918	1,575	2,701
Average No. of Scans	1,258	1,666	2,318
Average Scans/Day	5	7	9
Percent Utilization ^a	50%	69%	100%

^a based on 250 days/year, 8 hours/day *(December 13, 2002, CON Application, page 13)*

27. The Hospital states that the methodology shows that a fixed PET-CT scanner would be fully utilized by the third year of operation. *(December 13, 2002, CON Application, page 14)*
28. The number of PET-CT scans to be performed by type is given in the following table:

Table 5: PET-CT Scans by Type Performed at the Hospital of Saint Raphael

Type of Scan	Year 1	Year 2	Year 3
Oncology	1,148	1,416	1,988
Cardiac	100	200	250
Other	10	50	80
Total Scans	1,258	1,666	2,318

(December 13, 2002, CON Application, page 33)

**Financial Feasibility of the Proposal and its Impact on the Applicants' Rates
and Financial Condition
Impact of the Proposal on the Interests of Consumers of Health Care Services
and Payers for Such Services**

29. The total capital expenditure for this proposal is \$3,414,796 which includes:

Table 6: Type and Amount of Capital Expenditures for Proposal

Type of Capital Expenditure	Amount
Fixed Equipment (Lease (FMV))	\$3,127,883
Nonmedical Equipment (Purchase)	49,500
Construction/Renovation	237,413
Total Capital Expenditures	\$3,414,796

(December 13, 2002, CON Application, page 22)

30. The cost of the fixed equipment consists of the following components:

Table 7: Components and Cost of Fixed Equipment

Item	Cost
PET-CT (basic) scanner	\$3,009,383
Software for CT perfusion for Lightspeed Operator Console	59,250
Software for 3D package for Lightspeed QX/I Operator Console	59,250
Total Cost	\$3,127,883

(December 13, 2002, CON Application, page 23)

31. The Hospital proposes to fund the total capital expenditure of \$3,414,796 through an equity contribution from operating funds of \$237,413 and an operating lease of \$3,177,383. The monthly lease payments will be \$63,273 for a term of 60 months. *(December 13, 2002, CON Application, page 25)*

32. The Hospital is projecting the following incremental revenue related to the proposal:

Table 8: Revenue Projections by Fiscal Year

Fiscal Year	Revenue Dollars
2003	\$(70,331)
2004	373,407
2005	1,372,351

(December 13, 2002, CON Application, page 32)

33. The Hospital will incur a termination penalty for the discontinuance of the mobile service. The penalty will be \$3,000 per day for the one day per week of contracted on-site scanning; the annual penalty will be \$156,000 per year. *(December 13, 2002, CON Application, page 32)*

34. The projected payer mix associated with the CON proposal is as follows:

Table 9: Payer Type and Mix by Percent

Type of Payer	Payer Mix (%)			
	Current	Year 1	Year 2	Year 3
Medicare	32	32	32	32
Medicaid	1	1	1	1
TriCare	-	-	-	-
Commercial Insurers	67	67	67	67
Self-Pay	-	-	-	-
Workers Compensation	-	-	-	-
Uncompensated Care	-	-	-	-
Total	100%	100%	100%	100%

(December 13, 2002, CON Application, page 25)

35. The Hospital anticipates that four weeks after receiving CON approval the proposal will be initiated; ten weeks after approval, the scanner will be ready for use. *(December 13, 2002, CON Application, page 24)*

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

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

36. There is no State Health Plan in existence at this time. *(December 13, 2002, CON Application, page 2)*
37. The Hospital has adduced evidence that this proposal is consistent with their long-range plans. *(December 13, 2002, CON Application, page 2)*
38. The Hospital has improved productivity and contained costs through energy conservation, group purchasing, reengineering, and the application of technology. *(December 13, 2002, CON Application, page 20)*
39. The proposal will not result in changes to the Hospital's current teaching and research responsibilities. *(December 13, 2002, CON Application, page 21)*
40. There are no distinguishing characteristics of the patient/physician mix of the Hospital. *(December 13, 2002, CON Application, page 21)*
41. The Hospital has sufficient technical, financial and managerial competence to provide efficient and adequate service to the public. *(December 13, 2002, CON Application, Attachment 5)*

Rationale

The Hospital of Saint Raphael (“Hospital”) proposes to acquire fixed Positron Emission Tomography and Computerized Tomography (“PET-CT”) scanning equipment and perform the associated renovations at a total proposed capital expenditure of \$3,414,796. The fixed PET-CT scanner will replace the current mobile PET service that the Hospital offers two days a week.

The use of PET-CT images provides clinicians with the ability to find cancers that would not have been detected through other non-invasive imaging exams. Through the use of the PET-CT scanner, a patient’s cancer care and treatment is significantly enhanced. The introduction of the PET technology to the Hospital was made available through a mobile unit that provided service one day a week. Although the unit now performs scans on patients two days a week, the demand for PET imaging continues to grow. The acquisition of a fixed scanner, located on site, will provide timely and consistent access to necessary services that have been proven vital to the improvement of patient outcomes in the diagnosis and treatment of cancer. OHCA finds that the CON proposal will improve both the quality and accessibility of the Hospital’s PET scanning services.

The Hospital’s volume projections are 1,598, 1,758 and 1,934 for FY 2003, FY 2004 and FY 2005, respectively. The Hospital projects incremental increases in operating revenues relating to this project after the first year of operation. The scan projections and the financial projections relating to the operational aspects of this project appear reasonable and achievable.

Based on the foregoing Findings and Rationale, the Certification of Need application of The Hospital of Saint Raphael to acquire a fixed Positron Emission Tomography – Computer Tomography scanner at 1450 Chapel Street, New Haven, is hereby **GRANTED**.

Order

The request of The Hospital of Saint Raphael to acquire a fixed Positron Emission Tomography-Computerized Tomography scanner, non-medical equipment and associated renovations is approved subject to the following conditions:

1. The authorization shall expire February 11, 2004. Should the Hospital's project not be completed by that date, The Hospital of Saint Raphael must seek further approval from OHCA to complete the project beyond that date.
2. The Hospital of Saint Raphael shall not exceed the approved capital cost of \$3,414,796. In the event that The Hospital of Saint Raphael learns of potential cost increases or expects that the final project costs will exceed those approved, The Hospital of Saint Raphael shall file with OHCA a request for approval of the revised project budget.
3. Authorization for the mobile PET service will cease two months after the fixed PET-CT scanner has been put into operation. The Hospital will provide evidence to OHCA that the service has terminated.
4. The Hospital of Saint Raphael shall file utilization statistics for the PET-CT 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 PET-CT scanning service commenced operation. The quarterly reports shall include the following:
 - Total number of scans scheduled for the PET-CT scanning service;
 - Total number of scans performed by the PET-CT scanning service;
 - Average patient waiting time from the scheduling of the scan to the performance of the scan;
 - Number of scans by patient zip code;
 - Hours and days of operation for each week and in total; 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:
February 11, 2003

Signed by:
Mary M. Heffernan
Commissioner

Table Descriptions

Table 2, page 5:

Table 2 lists the conservative estimate of the Hospital's PET-CT scan volume that was based on the Hospital's Tumor Registry. The list is broken down by type of cancer, i.e. breast, lung, lymphoma, breast and gives the annualized number of cases for each in FY 2002. The annualized number of cases was based on nine months of actual data. Using an estimate of percent of usage for new cases by type of cancer and an estimate of PET-CT scans that would be applicable to recurring cases, the Hospital estimates for FY 2002 that 1,453 PET-CT scans could have been performed. For example: The four highest listed new cancer types were breast, lung, lymphoma and lung nodules with 447, 391, 217 and 195 cases, respectively. The percent estimate of usage of PET-CT scans for new cases of lung, lung nodules and lymphoma is 90%, and the estimates of scans for recurrent cases was 45%. Applying the 90% to each of the 391 cases for lung, 217 for lymphoma, and 195 for lung nodules, results in 352, 176 and 195 scans. Adding another 45% of each resulting number brings the estimate of the number of scans to 510, 255 and 283. For breast cancer, the estimate of usage for new cases is 45%, and remains at 45% for recurrent cases, resulting in an estimate of the number of scans to be 292.

Table 4, page 6

Table 4 lists the number of projected scans by each of the three methodologies for FY 2003, FY 2004, and FY 2005. The Tumor Registry, or conservative method, estimates 1,598, 1,758, and 1,934 for the three years. The Solucient methodology, or aggressive method, estimates 918, 1,575, and 2,701 for the three years. The averages of the estimates are 1,258, 1,666, and 2,318 for FY 2002, FY 2003 and FY 2004, respectively. The average number of scans per day are estimated to be 5, 7, and 9 for FY 2002, FY 2003, and FY 2004, respectively. The percent utilization, based on 250 days per day and 8 hours per day, is estimated to be 50%, 69%, and 100% for FY 2002, FY 2003, and FY 2004, respectively.

Table 5, page 6

Table 5 lists the type of PET-CT scans that will be performed for the first three years of operation. In Year 1, the number of scans are 1,148 for oncology, 100 for cardiac, and 10 other types of scans. In Year 2, the number of scans are 1,416 for oncology, 200 for cardiac, and 50 for other types of scans. In Year 3, the number of scans are 1,988 for oncology, 250 for cardiac, and 80 for other types of scans. The total number of scans are 1,258, 1,666, and 2,381 for the three years.