

Office Of Health Care Access Certificate of Need Application

Final Decision

Hospital: Middlesex Hospital

Docket Number: 04-30367-CON

Project Title: Expansion and Upgrade of Positron Emission

Tomography/Computed Tomography and Computed

Tomography Services

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

Filing Date: February 7, 2005

Decision Date: March 21, 2005

Default Date: May 8, 2005

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Project Description: Middlesex Hospital ("Hospital") proposes to acquire a fixed positron emission tomography/computed tomography ("PET/CT") scanner for the Hospital's Outpatient Center ("OP Center") and a 16-slice CT scanner for the Hospital itself. The PET/CT scanner will replace the existing mobile vendor-provided PET scanning service and replace the existing the OP Center's single slice CT scanner. The OP Center's single slice CT scanner will be moved to the Hospital. The proposal has a total capital cost of \$3,904,020.

Nature of Proceedings: On February 7, 2005, the Office of Health Care Access ("OHCA") received a completed Certificate of Need ("CON") application from Middlesex Hospital proposing to acquire a fixed PET/CT scanner for the Hospital's OP Center and a 16-slice CT scanner for the Hospital itself. The PET/CT scanner will replace the existing mobile vendor-provided PET scanning service and replace the existing single slice CT scanner. The OP Center's single slice CT scanner will be moved to the Hospital. The proposal has a total capital cost of \$3,904,020.

The Hospital is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes ("C.G.S.").

A notice to the public concerning OHCA's receipt of the Hospital's Letter of Intent was published on September 5, 2004, in the *Middletown Press* pursuant to Section 19a-639, C.G.S. OHCA received no comments from the public concerning the Hospital's proposal.

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. Middlesex Hospital ("Hospital") is a nonprofit acute care hospital located 28 Crescent Street, Middletown, Connecticut. Middlesex Hospital Outpatient Center ("OP Center") is located at 534 Saybrook Road, Middletown. (December 27, 2004, CON Application, page 139)
- 2. The Hospital's primary service area includes the following towns:

Chester	Clinton	Colchester
Cromwell	Deep River	Durham
East Haddam	East Hampton	Essex
Haddam	Killingworth	Madison
Marlborough	Middlefield	Middletown
Portland	Old Saybrook	Westbrook
(December 27,	2004, CON Application	n, page 6)

- 3. On August 1, 2001, the Office of Health Care Access ("OHCA") granted Certificate of Need ("CON") authorization under Docket Number 01-515 to InSight Health Services Corporation ("InSight"), Hartford Hospital, University of Connecticut John Dempsey Hospital, Middlesex Hospital, Manchester Memorial Hospital, and Windham Community Memorial Hospital to establish a mobile Positron Emission Tomography ("PET") scanning service at the campus of each hospital at a total capital expenditure of \$2,176,501. (August 1, 2001 OHCA Final Decision, Docket Number 01-515)
- 4. The Hospital's mobile vendor-provided PET scanning service is located at the OP Center. The Hospital proposes to replace the mobile PET scanner and the OP Center's single slice CT with a fixed PET/CT scanner. The OP Center's existing single slice CT scanner will be moved to the Hospital's main campus to provide backup during routine preventative maintenance of the Hospital's proposed new 16-slice CT scanner. (December 27, 2004, CON Application, page 1 to 3)

5. The Hospital's contract with InSight allows for termination of service if the Hospital elects to install its solely owned fixed PET system. The Hospital only needs to provide InSight 120 days notice of its intention to terminate the service. (February 7, 2005, Completeness Responses, page 2)

Positron Emission Tomography/Computed Tomography Scanner

- 6. The Hospital intends to acquire and operate a General Electric ("GE") Medical Systems Discovery ST 16-Slice fixed PET/CT scanner at a capital cost of \$2,300,115, which represents the estimated fair market value of the fixed PET/CT scanner to be leased. (February 7, 2005, Completeness Responses, page 14)
- 7. The Hospital listed several advancements and advantages of the proposed fixed PET/CT scanner over the mobile PET scanner:
 - By using the CT scan data for attenuation correction of the PET scan, a routine PET/CT scan may be completed in 20 to 30 minutes as opposed to the 50 or 60 minutes for a conventional PET only system;
 - The PET/CT imaging modality detects cancers that other modalities cannot detect; and
 - The simultaneous scanning of PET for the metabolic information and the CT for the anatomic information affords fusion imaging of the two data sets without having a patient scanned twice.

(December 27, 2004, CON Application, page 2)

- 8. The current technological level of the mobile PET scanner allows one patient per hour to be completed in a normal day. The mobile vendor provides the service two days per week. The proposed PET/CT scanner will be able to accommodate approximately two patients per hour and will be used five days or more per week. It is estimated that two hours per day, or 20% of available time, will be needed to complete the daily PET/CT volume. During the remaining time, CT scans will be performed on the PET/CT scanner. (February 7, 2005, Completeness Responses, page 2)
- 9. The Hospital's actual PET scan volumes for Fiscal Years ("FY") 2002 through 2004 are given in the following table:

Table 1: Actual PET Scan Volumes by Fiscal Year

Fiscal Year	Number of PET Scans
2002	441
2003	484
2004	545

(February 7, 2005, Completeness Responses, page 1)

10. Much of the growth in the Hospital's PET scan volume has been related to the increasing number of PET procedures being approved by the Centers for Medicare and Medicaid Services as clinically appropriate. (*December 27, 2004, CON Application, page 1*)

- 11. The Hospital estimates that the proposed PET/CT scanning services will commence operation on July 1, 2005, subsequent to the completion of the Hospital's related facility renovations and installation of the proposed PET/CT scanner. (February 7, 2005, Completeness Responses, page 2)
- 12. The Hospital's projected PET/CT scan volumes for FY 2005, FY 2006, and FY 2007 are 645, 780, and 1,040 scans respectively. The projected volume for the existing mobile PET service is 630 scans. The projected PET/CT volumes are conservatively based on a 5% growth rate for the first year and a marginal growth rate of 1% for the following two years. Growth of PET/CT volumes is expected to increase in demand due to the additional procedure approvals from CMS and demand by the Radiation Oncology Department for cancer treatment planning. (December 27, 2004, CON Application, page 5 and February 7, 2005, Completeness Responses, page 5)
- 13. The Hospital will initially provide its PET/CT scanning services five days per week on Monday through Friday from 6:00 a.m. to 7:00 p.m., and the days and hours of operation would be expanded if patient demand increases. (*December 27, 2004, CON Application, page 4*)
- 14. There are no other providers of PET or PET/CT scanning within the Hospital's service area. The Hospital does not expect that the proposal will affect any existing providers of CT services in the area. (*December 27, 2004, CON Application, page 4*)
- 15. The Hospital will apply for accreditation with the American College of Radiology for the PET/CT service once the service is implemented (*December 27, 2004, CON Application, page 6*)

Computer Tomography Scanner

- 16. The Hospital proposes to purchase a GE Lightspeed Pro 16 CT Scanner System. The 16-slice CT scanner has a purchase price of \$1,000,405. GE will acquire the Hospital's existing CT scanner in trade as part of the purchase agreement. (December 27, 2004, CON Application, page 217 and February 7, 2005, Completeness Responses, page 3)
- 17. The Hospital's single slice CT scanner has been in service for over six years. The system has experienced downtime of 110 hours during the past year. When the scanner is not available, critical emergency room patients and inpatients must be transported by ambulance to another facility when a CT scan is needed. (*December 27*, 2004, CON Application, page 2)

18. The Hospital's actual CT scan volume for FYs 2002, 2003, and 2004 are presented in the following table:

Table 2: Actual CT Scan Volume by Fiscal Year

		Fiscal Year		
Location		2002	2003	2004
Hospital		11,177	13,432	14,411
OP Center		4,773	4,984	5,392
	Total	15,950	18,416	19,803

(February 7, 2005, Completeness Responses, page 1)

19. The Hospital projects the following CT volumes by location for FYs 2005, 2006, and 2007: (December 27, 2004, CON Application, page 5)

Table 3: Projected CT Scan Volume by Location

	Fiscal Year		
Location	2005	2006	2007
Hospital ¹	15,131	15,887	16,681
OP Center	5,483 ²	$5,757^3$	5,814 ²
Total	20,614	21,644	22,495

¹ 5% growth per year.

20. The OP Center will utilize the CT scanner within the PET/CT scanner to perform scans on patients. The new CT scanner will be able to accommodate four patients per hour. The current single-slice CT scanner can only perform two scans per patient per hour. The new 16-slice CT scanner will conservatively perform four scans per patient per hour or 32 patients in an eight-hour period. (February 7, 2005, Completeness Responses, page 2)

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

- 21. The CON proposal's total capital cost of \$3,900,405 includes \$2,300,115 for the fair market value of the fixed PET/CT scanner, \$1,000,405 for the 16-slice CT scanner, and \$603,500 for facility renovations. (December 27, 2004, CON Application, page 10)
- 22. The total capital cost for the CON proposal will be financed with funded depreciation in the amount of \$1,603,905 and by lease financing through GE Capital Corporation that has a monthly payment of \$35,375, an interest rate of 7.07%, and a lease term of 5 years. (December 27, 2004, CON Application, pages 13 and 14)

² Marginal growth only.

³ 5% growth due to expanded service hours, increased patient throughput, and shifting of all outpatient scans from Hospital to the OP Center.

23. The following table summarizes the Hospital's projected incremental revenues and expenses with the proposal for FYs 2005, 2006, and 2007:

Table 4: Summary of Incremental Projected Revenues and Expenses

Description	FY 2005	FY 2006	FY 2007
Incremental Revenue from Operations	\$37,638	\$834,253	\$1,931,441
Incremental Total Operating Expense	34,434	228,504	452,208
Incremental Gain from Operations	\$ 3,203	\$605,749	\$1,479,233

(February 7, 2005, Completeness Responses, page 4)

- 24. The cost for the mobile PET scanning service in Fiscal Year 2004 was \$407,750. It is expected that with increased volume the yearly lease expense of \$424,500 will be equivalent to, or less than, what would be paid to the mobile vendor in FY 2005. (December 27, 2004, CON Application, page 3)
- 25. Renovations to the OP Center will encompass approximately 700 square feet of existing space. The PET/CT scanner will be placed where the single slice CT scanner is currently located. Two patient holding rooms will be constructed adjacent to the existing room. (December 27, 2004, CON Application, page 11)
- 26. Renovations to the Hospital will encompass approximately 750 square feet of existing space in order to locate the single slice CT scanner being removed from the OP Center. The 16-slice CT scanner will be installed in an existing simulator room that was vacated in 2002 when the Radiation Oncology Department was relocated to the OP Center. (December 27, 2004, CON Application, page 11)
- 27. Lead shielding will be provided and infrastructure modifications will be made as necessary to the OP Center as well as the Hospital. (*December 27, 2004, CON Application, page 11*)
- 28. The proposal's renovation costs are summarized in the following table:

Table 5: Summary of Renovation Costs

Description	Cost
Building Work	\$423,100
Architecture and Engineering Costs	92,875
Contingency Costs	57,350
Inflation Adjustment	30,175
Total Costs	\$603,500

(December 27, 2004, CON Application, page 11)

29. The Hospital's current payer mix and the projected payer mix for each of the three years following implementation of the proposal are given in the following table:

Table 6: Hospital's Current and Projected Payer Mix with the CON Proposal

Description	Payer Percent ¹
Medicare	39.5
Medicaid	6.6
TriCare (CHAMPUS)	0.2
Total Government	46.3
Commercial Insurers	48.8
Self-Pay	0.6
Workers Compensation	4.3
Total Non-Government	53.7
Uncompensated Care	0
Total Payer Mix	100

¹Based on net patient revenue.

(December 27, 2004, CON Application, pages 14 and 15)

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

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

- 30. There is no State Health Plan in existence at this time. (*December 27, 2004, CON Application, page 2*)
- 31. The Hospital has adduced evidence that the proposal is consistent with the Hospital's long-range plan. (December 27, 2004, CON Application, page 2)
- 32. The Hospital has improved productivity and contained costs by undertaking energy conservation, group purchasing and activities involving the application of new technology. (*December 27, 2004, CON Application, page 22*)
- 33. The proposal will not result in any significant change to the Hospital's teaching and research responsibilities. (*December 27, 2004, CON Application, page 23*)
- 34. There are no distinguishing or unique characteristics of the Hospital's patient/physician mix related to the proposal. (December 27, 2004, CON Application, page 23)
- 35. The Hospital has sufficient technical, financial and managerial competence and expertise to provide efficient and adequate service to the public. (*December* 27, 2004, *CON Application, Attachment* 11, page 458 498)
- 36. The Hospital's rates are sufficient to cover the capital and operating costs associated with the proposal. (February 7, 2005, Completeness Response, page 24))

Rationale

The Office of Health Care Access ("OHCA") approaches community and regional need for the proposed services on a case by case basis. Certificate of Need ("CON") applications do not lend themselves to general applicability due to a variety of complexity 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 proposed services.

Middlesex Hospital ("Hospital") proposes to acquire a fixed PET/CT scanner for the Hospital's Outpatient Center ("OP Center") and a 16-slice CT scanner for the Hospital itself. The PET/CT scanner will replace the existing mobile vendor-provided PET scanning service and replace the OP Center's existing single slice CT scanner. The OP Center's single slice CT scanner will be moved to the Hospital.

The Hospital provided several advantages of the proposed fixed PET/CT scanner over the mobile PET scanner. By using the CT scan data for attenuation correction of the PET scan, a routine PET/CT scan may be completed in 20 to 30 minutes as opposed to the 50 or 60 minutes for a conventional PET only system. The PET/CT imaging modality detects cancers that other modalities cannot detect. The simultaneous scanning of PET for the metabolic information and the CT for the anatomic information affords fusion imaging of the two data sets without having a patient scanned twice. In addition, the PET/CT scanner may be used as a stand-alone CT scanner. The proposed PET/CT scanner will be used to provide CT images of patients at the OP Center. The proposed PET/CT scanner will be an enhancement over the current single slice CT scanner that the OP Center has been utilizing.

The Hospital projects PET/CT scan volume of 645 scans in FY 2005, 780 in FY 2006, and 1,040 in FY 2007. In addition, the PET/CT scanner is projected to perform 5,483 CT scans in FY 2005, 5,757 in FY 2006, and 5,814 in FY 2007. The new 16-slice CT scanner to be purchased for the Hospital is expected to perform 15,131, 15,887, and 16,681 CT scans in FYs 2005, 2006, and 2007, respectively. These volumes projections appear to be reasonable and achievable based on the Hospital's historical scan volumes and allowing for increases in demand for both PET/CT scans and CT scans. Based on the foregoing reasons, OHCA finds that there is a clear public need for the CON proposal, and that the proposed scanners will improve both the quality and accessibility to PET/CT and CT services in the Middlesex area.

The CON proposal's total capital cost of \$3,904,020 will be financed through funded deprecation and a capital lease for the PET/CT scanner. The Hospital projects incremental gains from operations of \$3,203 in FY 2005, \$605,749 in FY 2006, and \$1,479,233 in FY 2007 associated with the CON proposal. The Hospital's volume projections and the financial projections upon which they are based appear to be reasonable and achievable. Therefore, OHCA finds that the CON proposal is both financially feasible and cost effective.

Based upon the foregoing Findings and Rationale, the Certificate of Need application of Middlesex Hospital to replace its existing mobile vendor-provided PET/CT scanner and a 16-slice CT scanner, at a total capital cost of \$3,904,020 is hereby GRANTED.

Order

Middlesex Hospital ("Hospital") is hereby authorized to acquire a fixed positron emission tomography/computed tomography ("PET/CT") scanner and a multi-slice CT scanner for the Hospital's Outpatient Center at a total capital cost of \$3,904,020 subject to the following conditions:

- 1. This authorization shall expire on March 21, 2006. Should the Hospital's fixed PET/CT scanner acquisition 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 cost of \$3,904,020. In the event that the Hospital learns of potential cost increases or expects that final project costs will exceed those approved, the Hospital shall file with OHCA a request for approval of the revised CON project budget.
- 3. The Hospital shall terminate the contract for the mobile PET scanner after the fixed PET/CT scanner has commenced operation. Furthermore, the Hospital shall provide evidence to OHCA of the termination of the contract for the mobile PET scanner by no later than two months after the fixed PET/CT scanner has commenced operation.
- 4. The Hospital is authorized to relocate the Outpatient Center's existing CT scanner to the Hospital's main campus at 28 Crescent Street, Middletown.
- 5. This authorization requires the removal of the Hospital's existing CT scanner for certain disposition such as sale or salvage. The Hospital shall provide evidence to OHCA of the disposition of the Hospital's existing CT scanner by no later than two months after the relocated CT scanner has commenced operation.
- 6. The Hospital shall file with OHCA utilization statistics for the fixed PET/CT scanner on a quarterly basis for two full years of operation. 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 fixed PET/CT scanner commenced operation. The quarterly reports shall include the following information:
 - a. Total number of scans scheduled for the fixed PET/CT scanner;
 - b. Total number of scans performed by the fixed PET/CT scanner;
 - c. Average patient waiting time from the scheduling of the scan to the performance of the scan;
 - d. Number of scans by patient zip code;

Middlesex Hospital March 21, 2005 Final Decision, Docket Number 04-30367-CON page 10 of 10

- e. Hours and days of operation for each week and in total; and
- f. 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

March 21, 2005

Signed by Cristine A. Vogel Commissioner

CAV: lkg