

Office Of Health Care Access Certificate of Need Application

Final Decision

Applicants:	Eastern Connecticut Health Network, Inc. and Manchester Memorial Hospital
Docket Number:	08-31115-CON
Project Title:	Acquisition and Operation of a Fixed Positron Emission Tomography/Computed Tomography ("PET/CT")Scanner
Statutory Reference:	Sections 19a-638 and 19a-639 of the Connecticut General Statutes
Filing Date:	August 15, 2008
Public Hearing Date:	October 24, 2008
Decision Date:	November 13, 2008
Default Date:	November 13, 2008
Staff Assigned:	Steven W. Lazarus

Project Description: Eastern Connecticut Health Network, Inc. and Manchester Memorial Hospital ("MMH" or "Hospital") (together referred to as "Applicants") proposes to acquire and operate a positron emission tomography/computed tomography ("PET/CT") scanner, at a total capital cost of \$2,239,766.

Nature of Proceedings: On August 15, 2008, the Office of Health Care Access ("OHCA") received the Certificate of Need ("CON") application from the Applicants requesting authorization to acquire and operate a new PET/CT scanner at a total capital cost of \$2,239,766. The Hospital is a health care facility or institution as defined in 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 to file its CON application was published in the Journal Inquirer on April 12, 2008, pursuant to Sections

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19a-638 and 19a-639 of the Connecticut General Statutes ("C.G.S."). OHCA received no responses from the public concerning the Hospital's proposal. Pursuant to Sections 19a-638 and 19a-639, C.G.S., three individuals or an individual representing an entity with five or more people had until September 4, 2008, the twenty-first calendar day following the filing of the Hospital's CON application, to request that OHCA hold a public hearing on the Applicants' proposal. OHCA did not receive any requests to hold a public hearing.

Pursuant to Sections 19a-638 and 19a-639, C.G.S., a public hearing regarding the CON application was held on October 24, 2008. On October 9, 2008, the Applicants were notified of the date, time, and place of the hearing. On October 10, 2008, a notice to the public announcing the hearing was published in the Journal Inquirer. Commissioner Cristine A. Vogel served as Presiding Officer. The hearing was conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the Connecticut General Statutes) and Sections 19a-638 and 19a-639, C.G.S.

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

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. Eastern Connecticut Health Network, Inc. ("ECHN") is the parent corporation of Manchester Memorial Hospital ("Hospital" or "MMH") (together referred to as "Applicants") and Rockville General Hospital ("RGH"). MMH is an acute care hospital located at 71 Haynes Street, Manchester, Connecticut. (March 4, 2008. Letter of Intent, page 1)
- 2. Under Certificate of Need ("CON") Docket No.: 01-515, the Office of Health Care Access ("OHCA") authorized the Hospital, as part of a consortium to offer Positron Emission Tomography ("PET") service. (August 1, 2001, Office of Health Care Access, Final Decision under Docket No. 01-515)
- 3. MMH offers outpatient cancer treatment through Northeast Regional Radiation Oncology Network, Inc. ("NRRON"), specifically Community CancerCare ("CCC") also known as John DeQuattrro Cancer Center ("Center") located at 71 Haynes Street, Manchester, a joint venture between MMH, Rockville General Hospital, Johnson Memorial Hospital and Hartford Hospital.

(January 17, 1997, Office of Health Care Access, Agreed Settlement under Docket No.: 95-534)

- 4. The Hospital requests the following under this proposal:
 - (a) Acquisition of a fixed Positron Emission Tomography-Computed Tomography ("PET/CT") scanner to replace the Hospital's existing mobile part-time PET scanner; and
 - (b) To locate the proposed PET/CT scanner on its campus at the Center. (July 2, 2008, Initial CON Application page 13)
- 5. The Applicants provided the following as their service area for the PET/CT service:

Fable 1: ECHN's Total Service Area			
Primary Service Area	Andover, Ashford, Bolton, Coventry, East Windsor,		
("PSA") Towns	Ellington, Manchester, South Windsor, Tolland, Vernon,		
	Willington		
Secondary Service Area	Columbia, East Hartford, Glastonbury, Hebron, Mansfield,		
("SSA") Towns	Somers, Stafford and Union.		

Note: According to the Hospital, these 19 towns define ECHN's service area towns in which majority of their patients originate. (July 2, 2008, Initial CON Application pages 18&19)

- 6. The Applicants' need assessment for the proposed PET/CT scanner was part of a larger, comprehensive assessment of the cancer program at MMH, which included the following:
 - (a) Patient data specific to the current cancer program was analyzed and compared to project market demands;
 - (b) Interviews with oncology care providers and other leaders within the cancer care community were performed to assess the overall program;
 - (c) Site visits were conducted to other comprehensive cancer centers in the state; and
 - (d) The qualitative evidence collected during the interviews and site visits combined with the projected market demand for oncology within the service area illustrated the need for PET/CT as an integral component of a comprehensive Cancer care program.
 (July 2, 2008, Initial CON Application page 14-15)
- 7. According to the Hospital, the proposal to acquire a fixed PET/CT will provide the following benefits:
 - (a) Meet the current standard of care for cancer patients;
 - (b) Capture PET/CT volume currently being referred out of the service area; and
 - (c) Provide the Hospital the ability to accommodate all outpatient CT simulations on the proposed PET/CT scanner, freeing the existing CT scanner located at the Hospital for inpatient use. (July 2, 2008, Initial CON Application pages 14-17)
- 8. According to the Hospital, the proposed PET/CT scanner will perform PET/CT scans for the diagnosis and staging of tumors in cancer patients, as well as CT simulations for developing radiation treatment plans for the cancer patients. (*July 2, 2008, Initial CON Application page 34*)

9. The Hospital reported the following historical PET volumes based on its operating schedule:

Table 2: Hospital's Historical PET Utilization						
	FY 2008					
# of Scans	462	463	467	440*		

*Actual FY 2008, PET volume provided as Late File.

The Hospital attributes the decline in PET scanning directly to the acceptance of PET/CT as the preferred standard of care for diagnosing and monitoring cancer in patients. (July 2, 2008, Initial CON Application pages 13&27 and October 31, 2008, Late File)

10. The Hospital provided the following capacity for the existing PET scanner, as well as for the proposed PET/CT scanner:

	Existing (FY 2008)	Proposed (FY 2010)
Type of Scanner	GE-PET	Siemens- PET/CT
Avg. # of hours/day scanner operates	8	4
Days/Week operational	1.5	5
Weeks/Year operational	52	52
Target utilization as % of capacity	100%	75%
Annual total capacity for scans in hours	624	1,040
Average scan time in hours	1	0.75
-		(45 minutes)
Average capacity-# scan/scanner	624	1,387
Projected actual # of scans	434	1,092
Percentage Total Capacity	69.6%	78.7%

Note: FY 2010 is the first full year of operation for the proposed PET/CT The Hospital testified that the proposed total capacity is based on the proposed 4 hours of operation for the proposed PET-CT scanner use.

(July 2, 2008, Initial CON Application page 29 and October 24, 2008, Public Hearing, Hospital Testimony)

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- 11. The Hospital projects the following PET/CT volume for the proposed scanner:

	FY 2009*	FY 2010	FY 2011	FY 2012
Number of PET/CT Scans	425	1,092	1,099	1,160
# of CT Simulations		520	650	780

Table 4: Hospital's Projected PET, PET/CT & CT Simulations

* FY 2009 is PET *Only* as FY 2010 is the first year of PET/CT scanner operation.

The proposed volume will operate 5 days per week and be able to accommodate an average of 20 patients per week.

The projections were based on the growth of the current PET patients base at MMH plus the growth in the volume of patients currently referred into Hartford by medical oncologist.

The Hospital projects to recapture 100% of the PET/CT imaging volume being referred to Hartford.

12. According to the Hospital, the following is the estimated market demand for PET and PET/CT in the total service area is:

Table 5: Total PET & PET/CT Exams in the Total Service Area

2005	2006	2007	2008	2009	2010	2011	2012
890	1,058	1,257	1,493	1,773	2,107	2,121	2,135

The Hospital based the PET & PET/CT demand on the following:

- (a) The demand for PET/CT was estimated using the Connecticut market use rates for 2005 and 2010 as provided by the Advisory Board's Outpatients Market Estimator Tool:
 - i. 2005 use rate = 3 (exams) per 1,000 persons
 - ii. 2010 use rate = 6 (exams) per 1,000 persons
- (b) The service use rates are consistent with the use rates calculated at the state level.
- (c) The market use rate for the years between 2005 and 2010 will increase incrementally at the average annual growth rate within each service area (PSA & SSA).
- (d) The market use rate for 2011 and 2012 will remain at the same 2010 use rate of 6 exams per 1,000.
- (e) MMH will maintain its projected 2009 share of the market equal to 24% through 2012 and accommodate the additional share of market currently referred outside of the service area by the Hospital medical oncologist, which totaled will account for 28% of the market through 2012. (*July 2, 2008, Initial CON Application, page 32*)
- 13. According to the Hospital, the medical oncologists based at MMH acknowledged that they refer eight to ten patients each week into Hartford to obtain a PET/CT scan. (July 2, 2008, Initial CON Application, page 21)

⁽July 2, 2008, Initial CON Application pages-24 25, August 15, 2008, Completeness Letter Responses, page 340)

- 14. Although the Hospital was unable to provide the actual number of patients referred during FY 2007 to Harford for a PET/CT scan, the Hospital extrapolated that during FY 2008, it referred 579 patients to Hartford for PET/CT imaging scans. (August 15, 2008, Completeness Letter Responses, pages 337-339)
- 15. According to the Hospital, the projected PET/CT volume during the first three years of the proposal will break down as follows:

Table 6: Projected PET/CT Volume by Source				
	2010	2011	2012	
MMH Current	504	508	511	
Patient Base				
Additional Medical-	587	591	595	
Oncologist Referrals				
Total PET/CT	1,092	1,099	1,106	

Avg. 21 scans per week, avg. 4 hours a day

- (July 2, 2008, Initial CON Application, page 32)
- 16. Additional capacity on the proposed PET/CT scanner will be utilized by the radiation oncologists to perform CT simulations, the Hospital is projecting the following for CT simulations:

Table 7: Projected CT Simulations

	2010	2011	2012
CT simulations per day	2.0	2.5	3.0
Total CT simulations	520	650	780

According to the Hospital, the anticipated growth in CT Simulations is a result of the relocated Center's acquisition of a second Linear Accelerator ("LinAc") which anticipates the number of patients on treatment at one time will increase to between 50 and 70 patients.

The demand for CT simulation, driven by increased number of patients on treatment will increase incrementally from 1.5 per day in 2008 to an estimated of a 3.0 by 2012. All outpatient CT simulation volume will be performed on the proposed PET/CT. (*July 2, 2008, Initial CON Application, page 33*)

- 17. According to the Hospital:
 - MMH is currently able to schedule and accommodate six to seven CT simulations per week on one of their two existing CT scanners located within the Hospital's Radiology Department;
 - MMH will be unable to accommodate the anticipated demand for CT simulation appointments beyond two per day without additional CT capacity; and
 - Growth in other areas of CT, including inpatient, emergent, diagnostic outpatient, and CT biopsy will contribute to challenges in providing additional scheduled time for CT simulations.

(July 2, 2008, Initial CON Application, pages 11&33)

18. Between 2005 and 2008, MMH experienced an average annual increase in inpatient CT volume of 12% and an average annual growth in Emergency Department CT volume of 17%. (*July 2, 2008, Initial CON Application, page 11*)

19. The Hospital reported the following historical CT imaging volume:

Patient Type	FY 2005	FY 2006	FY 2007	FY 2008	
Inpatient	3,896	4,466	4,573	5,211	
Emergency	3,902	4,961	6,054	6,707	
Total Inpatient &	7,798	9,427	10,627	11,928	
Emergency	7,790	9,427	10,027	11,920	
CT Simulation	346	341	371	385	
CT Biopsy	395	448	508	498	
All Other	8,244	8,615	7,923	7,921	
Total Outpatient	8,985	9,404	8,802	8,804	

Table 8: MMH's Historical Inpatient, Emergency & Outpatient CT Imaging Volume

FY 2008 Actual volume reported in the Hospital's Late File.

Total for Inpatient and Emergency was calculated by OHCA staff.

(July 2, 2008, Initial CON Application, page 11, 22-23 and October 31, 2008, Hospital's Late File)

20. According to Connecticut Hospital Association's ("CHA") Patient Census Report ("PCR"), the following is the PET related data reported by Connecticut hospitals between August 2008 vs. 2007:

Hospital	2008	2007	Net Change	% Change
Bridgeport	166	128	38	29.7
Greenwich	906	856	50	5.8
Norwalk	443	398	45	11.3
St. Vincent	343	322	21	6.5
Griffin	239	212	27	12.7
MidState	455	500	-45	-9.0
St. Raphael	2,069	2,197	-128	-5.8
Backus	694	720	-26	-3.6
Day Kimball	171	210	-39	-18.6
L&M	657	677	-20	-3.0
Middlesex	600	621	-21	-3.4
Windham	82	86	-4	-4.7
Bristol	504	564	-60	-10.6
Hartford	1,596	1,635	-39	-2.4
HCC	319	281	38	13.5
JDH	513	473	40	8.5
Johnson	132	154	-22	-14.3
Manchester	388	425	-37	-8.7
St. Francis	1,547	1,448	99	6.8
C. Hungerford	143	123	20	16.3
Danbury	680	616	64	10.4
New Milford	256	286	-30	-10.5
Connecticut Grand Total	12,903	12,932	-29	-0.2

Table 9: PET Data as Reported in CHA's August PCR

(Connecticut Hospital Association's August Patient Census Report)

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- 21. The Hospital indicated there are no providers of PET/CT imaging service within its service area, with the closest providers located in Hartford. Although, the Hospital recognizes that Saint Francis Hospital and Medical Center may experience a decrease in volume as patients within ECHN community continue their care at the proposed PET/CT scanner, the impact to their volume will be temporary as the demand for these services will inevitability grow within their immediate service area. (July 2, 2008, *Initial CON Application, pages18,19& 31*)
- 22. The proposed hours of operation for the new and relocated scanner will be Monday through Friday (five days). Four hours a day will be scheduled for PET-CT imaging and an additional four hours will be reserved for NRRON to perform CT simulations. (*July 2, 2008, Initial CON Application, page 21*)
- 23. The Hospital testified to the following at the public hearing:
 - a. The current mobile PET scanner will no longer be available, as a matter of fact, this is the last remaining mobile PET scanner in the state;
 - b. The medical office building where the proposed PET-CT scanner will be housed is not designed to accommodate a mobile scanner;
 - c. The Hospital utilizes its current 16-Slice to mostly accommodate emergency department and inpatient patients and the Hospital utilizes its Single-Slice CT scanner to accommodate CT biopsies; therefore, CT Simulations are a currently performed on the scanner which is available at that moment;
 - d. The Hospital will shift approximately 400-500 CT scans to its Tolland Imaging Center; however, the additional capacity will be utilized mostly by the Hospital's emergency department or inpatient population. This was taken into account in this proposal,
 - e. The Hospital projects between 750-800 annual PET-CT scans to be the financial breakeven point for this proposal,
 - f. The proposed PET-CT scanner is expensive but it's a better alternative to operating two separate machines and then coming back with another proposal for a PET-CT scanner in a couple of years.
 - g. If approved, according to the Hospital, the proposed PET-CT scanner will be the first in the state of Connecticut to be utilized both PET-CT applications as well as CT Simulations,
 - h. The Hospital based their projections on national data rather than local data, and
 - i. The Hospital was unable to respond to the flat or no growth in PET-CT utilization in Connecticut for the past year. (October 24, 2008, Public Hearing, Hospital's Testimony)

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

24. The total capital cost of the project is \$2,239,766. The costs are itemized as follows:

Table 10: Project Cost Itemization	
Description	Component Cost
Medical Equipment (Purchase)	\$45,000
Major Medical Equipment (Purchase)	\$1,979,766
Non-Medical Equipment (Purchase)	\$15,000
Construction/Renovation	\$200,000
Total Capital Expenditure	\$2,239,766

(August 15, 2008, Completeness Letter Responses, pages 341)

- 25. The project will be financed through a conventional loan. (July 2, 2008, Initial CON Application, pages 46)
- 26. The Hospital provided OHCA a Commitment Letter from De Lage Landen Financial Services for the proposed PET-CT scanner. (October 30, 2008, Hospital's Late File)
- 27. The Hospital projects incremental revenue from operations, total operating expense and losses/gains from operations associated with the CON proposal for FY 2010 through FY 2012 as follows:

Table 11 Incremental Financial Projections for FYs 2010-2012					
FY 2008	FY 2009	FY 2010			
\$887,866	\$946,906	\$1,005,771			
\$249,340	\$551,441	\$530,723			
\$638,625	\$395,465	\$475,048			
	FY 2008 \$887,866 \$249,340	FY 2008FY 2009\$887,866\$946,906\$249,340\$551,441			

(July 2, 2008, Initial CON Application, page 318)

- 28. There is no State Health Plan in existence at this time. (July 2, 2008, Initial CON Application, page 13)
- 29. The Hospital has adduced evidence that the proposal is consistent with its long-range plan. (July 2, 2008, Initial CON Application, page 13)
- 25. The Hospital has improved productivity and contained costs by undertaking energy conservation measures, employing group purchasing practices in its procurement of supplies and equipment, by participating in activities involving the application of new technologies and through reengineering efforts. (November July 2, 2008, Initial CON Application, page 38)
- 26. The proposal will not result in any change to the Hospital's teaching and research responsibilities. (July 2, 2008, Initial CON Application, page 39)

60.4

38.3

1.3

0.0%

100.00%

39.6

Payer Mix	Current PET	Year 1 PET/CT	Year 2 PET/CT	Year 3 PET/CT
Medicaid	2.4%	2.4%	2.4%	2.4%

60.4

38.3

1.3

0.0%

39.6

100.00%

60.4

38.3

1.3

0.0%

100.00%

39.6

60.4

38.3

1.3

0.0%

39.6

100.00%

(July 2, 2008, Initial CON Application, page 4)

Total Government

Commercial Insurers

Total Payer Mix

Workers Compensation

Total Non-Government

Uninsured

- 28. The Hospital indicates the proposal will not result in any change its patient/physician mix. (*July 2, 2008, Initial CON Application, page 39*)
- 29. The Hospital possesses sufficient technical, financial and managerial competence and expertise to provide efficient and adequate service to the public. (*July 2, 2008, Initial CON Application, page 37 and Appendix 5D*)
- 30. The Hospital's rates are sufficient to cover the proposed capital and operating costs associated with the proposal. (*July 2, 2008, Initial CON Application, page 318*)

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Rationale

The Office of Health Care Access ("OHCA") approaches community and regional need for the proposed service on a case by case basis. Certificate of Need ("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 proposed services.

Eastern Connecticut Health Network, Inc. is the parent corporation of Manchester Memorial Hospital ("MMH" or "Hospital") (together referred herein as "Applicants"). MMH is an acute care hospital located in Manchester, CT. The Applicants are proposing to acquire a fixed Positron Emission Tomography-Computed Tomography ("PET/CT") scanner to replace the Hospital's existing mobile part-time PET scanner and to locate the proposed fixed PET/CT scanner on its campus at the John DeQuattrro Cancer Center ("Center").

The Applicants assert the need for the acquisition of the proposed fixed PET/CT scanner is based on the comprehensive assessment of the cancer program at MMH. The Applicants provided evidence that the need of a fixed PET/CT scanner is part-time and propose to use it approximately 20 hours per week. These projections are based on a 100% recapture assumption. The Applicants' volume projections are questionable in light of the fact that PET utilization statewide over the past year has remained flat. Further, the Hospital based its volume projections on national data rather than local data and was unable provide a response to no growth in PET/CT utilization in Connecticut over the past year. As a matter of fact, if the Applicants recapture 100% of the volume currently referred to Hartford, specifically to St. Francis Hospital and Medical Center ("SFHMC"), it would impact SFHMC by reducing its PET/CT volume by almost one third. This appears to be a shift of PET/CT patient volume from one provider to another, possibly leading to excess capacity in the service area.

The Hospital is proposing to utilize the proposed PET/CT scanner on part-time basis for PET/CT scans and part-time for CT Simulations. The Applicants provided evidence that CT Simulations are likely to continue to increase from approximately 1.5 per day to 3.0 per day and stated that such capacity does not exist on the Hospital's two existing CT scanners. The Applicants also testified at the public hearing that approximately 400-500 CT scans will be shifted to its Tolland Imaging Center. OHCA questions the Applicants' claim regarding CT capacity at the Hospital since Tolland Imaging Center became operational in September, 2008 and its impact on the Hospital CT volume is too premature to determine.

Since OHCA cannot conclude definitively that need exists for the proposed fixed PET/CT scanner, OHCA is unable to evaluate the financial feasibility of the proposal.

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Order

Based upon the foregoing Findings and Rationale, the Certificate of Need application of Eastern Connecticut Health Network, Inc. and Manchester Memorial Hospital, for the acquisition of a full-time fixed PET/CT scanner at a total capital cost of \$2,239,866, is hereby **Denied**.

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

Signed by Commissioner Vogel on November 13, 2008

Date

Cristine A. Vogel Commissioner

CAV:swl