

**STATE OF CONNECTICUT**  
DEPARTMENT OF PUBLIC HEALTH  
*Office of Health Care Access*

April 17, 2012

**IN THE MATTER OF:**

An Application for a Certificate of Need      Notice of Final Decision  
filed Pursuant to Section 19a-638, C.G.S. by:      Office of Health Care Access  
Docket Number: 11-31730-CON


**Lawrence & Memorial Hospital**

**Acquisition of a Fixed Positron Emission  
Tomography-Computed Tomography  
Scanner in Waterford, CT**

To: Ms. Shraddha Patel  
Director of Business Development & Planning  
Lawrence & Memorial Hospital  
365 Montauk Avenue  
New London, CT 06320

Dear Ms. Patel:

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-638, C.G.S. On April 13, 2012, 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.

  
Kimberly R. Martone  
Director of Operations

Enclosure  
KRM:swl



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

**Final Decision**

**Applicant:** Lawrence & Memorial Hospital

**Docket Number:** 11-31730-CON

**Project Title:** Acquisition of a Fixed Positron Emission Tomography-Computed Tomography Scanner in Waterford, CT

**Project Description:** Lawrence & Memorial Hospital ("Hospital") proposes to acquire a Positron Emission Tomography-Computed Tomography ("PET-CT") scanner at L&M Diagnostic Imaging ("Crossroads") at Crossroads in Waterford, Connecticut.

**Procedural History:** On January 17, 2012, the Office of Health Care Access ("OHCA") received a Certificate of Need ("CON") application from the Hospital for the above-referenced project. The Hospital published notice of its intent to file the CON Application in *The Day*, on September 30, 2011, and on October 1 and 2, 2011. OHCA received no responses from the public concerning the Hospital's proposal and no hearing requests were received from the public per General Statutes § 19a-639a (e).

## Findings of Fact

1. The Hospital is an acute care not-for-profit hospital located at 365 Montauk Avenue in New London, Connecticut. Ex. A, p. 14.
2. The Hospital proposes to acquire a PET-CT<sup>1</sup> scanner for the Hospital's outpatient imaging center known L&M Diagnostic Imaging at Crossroads ("Crossroads"), located at 196 Parkway South in Waterford. Ex. A, p. 14.
3. The proposed PET-CT scanner will replace a Computed Tomography ("CT<sup>2</sup>") scanner currently operating at Crossroads and a part-time mobile PET-CT scanner currently operating at the Hospital and at the Hospital's Pequot Health Center. Ex. A, p. 14.
4. Under Docket No.: 01-565, OHCA authorized the Hospital to offer a mobile PET scanner two days a week, which the Hospital offered one day a week at the L&M's main campus and one day a week at Pequot Health Center in Groton. Ex. A, p. 14.
5. The Hospital contracted with Alliance Imaging Inc. ("Alliance") to provide the mobile PET scanner. Ex. A, p. 14.
6. Under Report No.: 04-30262-DTR, OHCA determined that a CON was not required for Alliance to upgrade its previously authorized mobile PET scanner to a PET-CT scanner and upgrade its PET service to a PET-CT service at its previously authorized hospital locations including Crossroads. Ex. C, p. 237.
7. The Hospital's current CT and PET-CT service locations:

**Table 1: Current CT & PET-CT Service Locations**

	<b>Hospital</b> <i>(New London)</i>	<b>Pequot HC*</b> <i>(Groton)</i>	<b>MOB*</b> <i>(Old Saybrook)</i>	<b>Crossroads*</b> <i>(Waterford)</i>	<b>Walk-In Clinic*</b> <i>(Stonington)</i>
<b>Service</b>					
CT	Yes	Yes	No	Yes	No
PET-CT	Yes	Yes	No	No	No

\*Pequot HC=Pequot Health Center, MOB= Medical Office Building, Crossroads= L&M Diagnostic Imaging Center at Crossroads, Stonington Walk-In Clinic

<sup>1</sup> PET-CT PET/CT scan is a type of imaging test that combines positron emission tomography (PET) and computed tomography (CT) techniques. Combined PET/CT scans can be performed on any part of the body. They are frequently used to gather information about the heart, brain, and lungs. PET scans use a radioactive form of sugar (or other molecules) that is injected into your body to measure the cellular activity of the body part being scanned. A CT scan takes a large number of x-rays. These are analyzed by a computer to create a three-dimensional image of the body part being studied. When both tests are performed at the same time, the information about function and structure is integrated through computer models.

<sup>2</sup> A CT scan uses x-ray technology to take multiple cross-sectional views of the inside of the body. Compared to regular x-rays, a CT scan can take clearer images of organs, bone, soft tissue, blood vessels, and other areas of the body.

8. The proposed PET-CT scanner will be a fixed site scanner and will be located at Crossroads in Waterford. The fixed PET-CT scanner will be utilized for two purposes: general CT scanning and PET-CT scanning. Ex. A, p. 14.
9. The new PET-CT scanner will occupy space currently utilized by a CT scanner, including CT scan control and empty spaces that were planned for an additional CT scanner and MRI unit at the time of the original construction of the building. Ex. A, p. 37.
10. This proposal also involves renovation to approximately 2,700 gross square feet of existing space to accommodate the proposed PET-CT scanner and the required patient and support spaces. These spaces include the PET-CT treatment room, PET-CT equipment room, PET-CT control room, patient changing/injection rooms, patient holding room, patient toilets, hot lab, staff work area, clean supply and soiled holding and staff support spaces. Ex. A, p. 37.
11. The proposed PET-CT scanner will improve patient safety and care by allowing both a diagnostic CT and a PET-CT scan to be conducted in the same visit, which lowers the motion and movement between studies and decreases radiation doses. Ex. A, p. 16.
12. The current mobile PET-CT scanner does not have the capability to perform a PET-CT and diagnostic CT exam simultaneously. Ex. A, p. 20.
13. Under the current arrangement, patients requiring both exams must obtain two separate tests: a PET-CT exam on a mobile unit and then a diagnostic CT on a separate CT scanner, possibly during a second appointment if both cannot be scheduled on the same day. This is a more lengthy and cumbersome process for patients that exposes them to radiation during each exam. The proposed PET-CT scanner will allow patients to undergo both exams with a single scan in a single sitting, resulting in two images, a PET-CT and a diagnostic CT, acquired at the same time. Ex. A, p. 20.
14. The Hospital reported that between September 2010 and September 2011, 342 patients at the Hospital underwent separate PET-CT and diagnostic CT scans within 30 days of each other. Ex. A, p. 20.
15. The proposed PET-CT scanner will improve image quality through its ability to offer a 40-slice scan, an improvement upon the current CT scanner operating at Crossroads that provides an image with only a 16-slice scan. Ex. A, p. 37.
16. There will be reduced radiation to the patients and improved diagnostic accuracy as a result of fewer scans for the individual patient and improved technical capabilities (e.g. 16 vs. 40 slice) of the scanner. Ex. A, p. 37.

17. In addition to the increased slices per scan capability, the proposed PET-CT scanner will be able to perform new procedures that the older mobile PET scanner was unable to perform; these include rubidium cardiac scans and 18F Sodium Fluoride bone scans. Ex. C, p. 241.
18. The Hospital is projecting cardiac scans with rubidium at 60, 75 and 90 scans annually, for FYs 2013-2015. Ex. C, p. 241.
19. A new medical diagnostic test, 18F Sodium Fluoride PET-CT bone scan is used to identify skeletal metastases and has improved sensitivity and resolution over traditional nuclear medicine bone scans. Ex. C, p. 241.
20. 18F Sodium Fluoride PET-CT scans can better differentiate between benign and malignant lesions. This information is critical for physicians to determine the appropriate type and course of treatment. Although not listed separately due to little historical activity, the volume associated with the bone scans has been assumed in the Applicant's volume projections. Ex. C, p. 241.
21. Based on the factors mentioned in the findings above, this proposal will result in improvements in patient safety, clinical care and service for patients. Ex. A, p. 14.
22. The Hospital offers cancer services through its cancer program at the Hospital known as L&M Community Cancer Center ("Cancer Center"), which is an outpatient department at the Hospital. It's accredited by The Commission on Cancer ("CoC") of the American College of Surgeons as a Community Hospital Comprehensive Cancer Program. Services offered at the Hospital's Cancer Center include radiation oncology, medical oncology, and support services. Radiation therapy is provided through an affiliation with Yale-New Haven Hospital/Yale School of Medicine. Other cancer services include chemotherapy, social work, nutrition services, patient education seminars, support groups, healthy lifestyle programs, as well as tumor registry. Ex. C, p. 237-238.
23. The Cancer Center's historical radiation therapy and chemotherapy treatment utilization is illustrated in the table below: Ex. C, p. 237-238.

**Table 2: Historical Radiation & Chemotherapy Utilization**

	FY 2009	FY 2010	FY 2011
Radiation Therapy Treatments	11,675	11,179	10,443*
Chemotherapy Treatments	312	555	431

\*The Hospital typically operates 2 linear accelerators; however, in FY 2011, only one unit was in operation between 1/17/11 and 9/19/11 (8 months) due to the replacement of the second unit.

24. The Hospital is planning to relocate all its outpatient cancer services to a new comprehensive outpatient cancer center (“O/P Cancer Center”) in Waterford. It will be located approximately two miles from Crossroads and is projected to open in Fall of 2013. Ex. A, p. 19.
25. The availability of PET-CT services in close proximity to the O/P Cancer Center will be an important component in the O/P Cancer Center’s ability to deliver comprehensive, accessible care to its oncology patients. Ex. A, p. 14.
26. The O/P Cancer Center will provide comprehensive outpatient care for cancer patients such as radiation therapy, chemotherapy/infusion services, social work, nutrition services, patient education seminars, support groups, healthy lifestyle programs, tumor registry and a dedicated pharmacy and laboratory service in a comfortable, off-site environment. Ex. A, p. 19.
27. The O/P Cancer Center will also augment the Hospital’s existing oncology services with the addition of a second opinion clinic, multidisciplinary/subspecialty clinics, clinical trials, survivorship, genetic counseling, patient navigator services, and expanded public education sessions. Ex. A, p. 19.
28. The Hospital’s historical and projected CT utilization by location is as follows:

**Table 3: Historical and Projected CT Utilization**

	Patient Type	FY 2008	FY 2009	FY 2010	FY 2011*	FY 2012	FY 2013	FY 2014	FY 2015
<b>CT Scans</b>									
<b>L&amp;M Main Campus (2 CT Scanners)</b>									
	I/P	4,203	4,178	4,172	4,084	4,084	4,084	4,084	4,084
	O/P	4,546	5,391	5,033	4,570	4,570	4,570	4,570	4,570
	ED	11,666	11,874	12,038	11,919	11,919	11,919	11,919	11,919
<b>Pequot Health Center (1 CT Scanner)</b>									
	I/P	12	4	10	11	11	11	11	11
	O/P	6,744	5,342	4,521	4,872	4,872	4,872	4,872	4,872
	ED	9,739	8,022	7,720	8,419	8,419	8,419	8,419	8,419
<b>Crossroads (1 CT Scanner)</b>									
	O/P	0	0	1,737	2,309	2,662	3,025	3,399	3,784
<b>Total All Sites</b>									
	I/P	4,215	4,182	4,182	4,095	4,095	4,095	4,095	4,095
	O/P	11,290	10,733	11,291	11,751	12,104	12,467	12,841	13,226
	ED	14,649	14,550	15,227	15,455	15,455	15,455	15,455	15,455
	<b>Total</b>	<b>30,154</b>	<b>29,465</b>	<b>30,700</b>	<b>31,301</b>	<b>31,654</b>	<b>32,017</b>	<b>32,391</b>	<b>32,766</b>

\*2011 Projected. Ex. A, p. 29.

29. The Hospital projects the Inpatient and Emergency Department CT utilization to remain the same and the outpatient to increase overall by approximately 3%, for the first three years of this proposal. Additionally, the Hospital expects the overall increased outpatient volume will be accommodated at Crossroads. Ex. A, p. 33
30. The Hospital is projecting an annual average 12% increase for the first three years of this proposal for its CT utilization at Crossroads as a result of its 16-Slice CT scanner being replaced with the proposed PET-CT scanner, offering 40-Slice CT scan capability. Ex. A, p. 29 & 36.
31. The Hospital's historical and projected PET-CT utilization is as follows:

**Table 4: Historical and Projected PET-CT Utilization**

	Patient Type	FY 2008	FY 2009	FY 2010	FY 2011*	FY 2012	FY 2013	FY 2014	FY 2015
<b>PET-CT Scans</b>									
<b>L&amp;M Main Campus</b>									
	I/P	5	0	4	2	0	0	0	0
	O/P	297	154	237	0	0	0	0	0
	<b>Total</b>	<b>302</b>	<b>154</b>	<b>241</b>	<b>2***</b>	<b>0***</b>	<b>0**</b>	<b>0**</b>	<b>0**</b>
<b>Pequot Health Center</b>									
	O/P	380	389	269	434	218	0**	0**	0**
<b>Crossroads</b>									
	O/P	0	0	0	0	218	496	555	570
<b>Total All Sites</b>									
	I/P	5	0	4	2	0	0	0	0
	O/P	677	543	506	434	436	496	555	570
	<b>Total</b>	<b>682</b>	<b>543</b>	<b>510</b>	<b>436</b>	<b>436</b>	<b>496</b>	<b>555</b>	<b>570</b>

\*2011 Projected. \*\*Due to the Replacement PET-CT. \*\*\*Due to construction at the Hospital. Ex. A, p. 29

32. The Hospital's outpatient volume was negatively impacted in FY 2011 due to the need to move the entire mobile PET-CT service to the Pequot Health Center in order to perform construction at the Hospital's main campus. The construction at the Hospital is expected to be completed by November (2011), at which point the mobile PET-CT service will resume at the Hospital one day per week, until replaced with the proposed Fixed PET-CT scanner at Crossroads. Ex. A, p. 32.
33. A fixed site Magnetic Resonance Imaging ("MRI") scanner will be installed at the Crossroads location, which was authorized by OHCA under Docket No.: 11-31682-CON. Ex. A, p. 37.
34. Patient access will be enhanced, as Crossroads offers ample parking in a building that houses the offices of several physicians on the Hospital's staff. Ex. A, p. 20.

35. The following physician practices are currently located at Crossroads:  
 a New London Cancer Center (3 medical oncologists and 2 APRNs); and  
 b Eastern Connecticut Cardiology Group, P.C. (8 cardiologists).  
 Ex. C, p. 237-238.
36. The following physician offices are located in the service area of the proposal and are expected to be potential referral sources for the proposed PET-CT scanner service:

**Table 5: Affiliated Physician Offices in the Area**

Practice	Location	Specialty
Oncology & Hematology Associates	New London	4 medical oncologists 1 physician assistant
Lawrence & Memorial Physician Association Cardiology	New London	2 cardiologists
Gold Coast Pulmonary & Sleep Associates, LLC	New London	2 pulmonologists
William G. Crawford, M.D	New London	1 thoracic surgeon
Shoreline Pulmonology	New London	1 pulmonologist
Southeastern Pulmonary Associates	New London	2 pulmonologists 1APRN
Neurological Group	New London	1 neurologist
Oncology Hematology Associates	Westerly, RI	2 medical oncologists
Thames Urology Center	New London	3 urologists
Mystic Medical Center	Mystic	1 urologist
Yale School of Medicine at L&M Community Cancer Care	New London	1 attending radiation oncologist 1 resident radiation oncologist

Ex. C, p. 237-238.

37. The nearest providers of CT, PET and PET scanning services are The William W. Backus Hospital which offers all these services at its main campus in Norwich and CT scanning services at its Norwich outpatient center. Additionally, The Westerly Hospital in Westerly, RI provides CT scanning services at its main campus and at an outpatient center, both in Westerly, RI. Ex. A, p. 28
38. The proposal's total capital expenditure is itemized as follows:

**Table 6: Project Total Capital Expenditure**

Imaging Equipment (PET-CT Scanner)	\$2,168,286
Medical Equipment Purchase	\$161,450
Non-Medical Equipment	\$296,179
Construction/Renovation	\$600,000
<b>Project Total Capital Expenditure</b>	<b>\$3,225,915</b>

Ex. A, p. 36.

39. This proposal will be fully funded by the Hospital's equity. Ex. A, p. 38.



40. Ending FY2011, the Hospital reported having total current assets of \$189,459,218. This included \$39,933,255 in current assets and \$105,904,042 in cash on hand. OHCA's FY2011, Hospital Financial Reporting.
41. The Hospital is projecting the following annual gains in operations incremental to the proposal:

**Table 7: Projected Incremental Revenues and Expenditures**

	<b>FY 2012</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>
<b>Revenues from Operations</b>	\$105,900	\$363,120	\$512,618	\$555,548
<b>Total Operating Expenses (Increase/Decrease)</b>	\$(1,834)	\$222,150	\$228,312	\$230,490
<b><i>Gain from Operations</i></b>	<b>\$107,734</b>	<b>\$140,970</b>	<b>\$284,306</b>	<b>\$325,058</b>

Note: The positive \$1,834 in operating expense results from expenses for Salaries & Wages and Fringe Benefits being prorated for FY2012 (the first year of operation).  
 x. A, p. 219-220.

42. This proposal will result in a reduction in the operating expenses<sup>3</sup> per scan for providing CT and PET-CT services on the same scanner and is therefore a more cost efficient model of care. Ex. A, p. 38.
43. The proposed PET-CT scanner will be cost effective, as it will cost less to operate a single scanner than operating the two current scanners. Ex. A, p. 14.

<sup>3</sup> Incremental Operating Expense/Projected Annual Volume=Cost per Scan. FY2013:222,150/423=\$525, FY2014:228,312/493=\$463 & FY2015:230,499/519=\$444.

## Discussion

CON applications are decided on a case by case basis and do not lend themselves to general applicability due to the uniqueness of the facts in each case. In rendering its decision, OHCA considers the factors set forth in General Statutes § 19a-639(a) and the Applicant bears the burden of proof in this matter by a preponderance of the evidence. *Goldstar Medical Services, Inc., et al. v. Department of Social Services*, 288 Conn. 790 (2008); *Swiller v. Commissioner of Public Health*, No. CV 95-0705601 (Sup. Court, J.D. Hartford/New Britain at Hartford, October 10, 1995); *Bridgeport Ambulance Serv. v. Connecticut Dept. of Health Serv.*, No. CV 88-0349673-S (Sup. Court, J.D. Hartford/New Britain at Hartford, July 6, 1989); *Steadman v. SEC*, 450 U.S. 91, 101 S.Ct. 999, *reh'g den.*, 451 U.S. 933 (1981); *Bender v. Clark*, 744 F.2d 1424 (10th Cir. 1984); *Sea Island Broadcasting Corp. v. FCC*, 627 F.2d 240, 243 (D.C. Cir. 1980).

The Hospital proposes to acquire a fixed PET-CT scanner for the Crossroads location in Waterford. FF2. The proposed fixed PET-CT scanner will replace the Hospital's existing part-time mobile PET-CT scanner, currently offering PET-CT services one day a week at the Hospital's main campus and one day a week at its Pequot Health Center in Groton. FF4. Additionally, the proposed PET-CT scanner will also replace the Hospital's current 16-Slice CT scanner operating at Crossroads. FF14.

The Hospital's current mobile PET-CT scanner is limited in its capability, for example, it cannot perform a PET-CT and a diagnostic CT at the same time. FF12. Under the current process, patients requiring a PET-CT and a diagnostic CT exam have to obtain two separate tests, a PET-CT scan on the mobile PET-CT unit and a diagnostic CT on a separate CT scanner. The proposed PET-CT will provide the Hospital with the ability to scan the patient once on the proposed scanner and perform a CT and a PET-CT at the same time. FF13. The Hospital reported that between September 2010 and September 2011, there were 342 patients that underwent separate PET-CT and diagnostic CT scans within 30 days of each other. FF14. Furthermore, patients receiving a diagnostic CT scan on the proposed scanner will have the advantage of receiving a 40-slice image compared to a 16-slice image on the existing CT scanner. This will not only aid in improving the image quality and diagnostic accuracy but the replacement of two scans by one will also lead to reduced radiation to the patients. FF15-16. The proposed PET-CT scanner will provide with the Hospital the ability to offer its patients two new procedures, rubidium cardiac scans and 18F Sodium Fluoride bone scans. These are new procedures that the current mobile PET-CT scanner is not able to perform. FF17-18. Taking into these factors, it appears that the acquisition of the proposed PET-CT scanner will result in improvements in patient safety, clinical care and services to patients. FF17-21.

Additionally, the Hospital is planning to relocate all its outpatient cancer services to a new comprehensive outpatient Cancer Center two miles away from Crossroads in Waterford. FF24. The availability of PET-CT services in close proximity to the Cancer Center will be an important component of the Cancer Center's ability to deliver comprehensive, accessible care to its oncology patients. FF25. In addition to the multitude of Hospital services in the area, the

Hospital has affiliated physician practices such as New London Cancer Center and Eastern Connecticut Cardiology Group, P.C. located at Crossroads and approximately 11 other Hospital affiliated physician practices in the greater New London area, all of which are expected to be potential referral sources for the proposed PET-CT scanner. FF33-34. Accordingly, OHCA finds that the acquisition of a fixed PET-CT scanner will positively impact the quality and accessibility of health care delivery for patients in the Hospital's service area.

Based on the proposed PET-CT scanner's updated technology and ability to perform improved imaging, greater slices per scan, new procedures, establishment of the Hospital's new freestanding Cancer Center in close proximity of Crossroads and existing and new physician base at Crossroads and in the service area, it appears that the Hospital's PET-CT and CT scan volumes appear to be reasonable. FF12- 30. Therefore, OHCA finds that the Hospital has demonstrated a need for the acquisition of a fixed PET-CT scanner at Crossroads.

The total capital expenditure associated with the proposal is \$33,225,915. FF35. There will be incremental gains from operations associated with the proposal for the first three full fiscal years of operation. FF37. Additionally, acquisition of the proposed PET-CT scanner will be cost effective, as it will cost less to operate a single scanner than operating the two current scanners. FF43.

## Order

Based upon the foregoing Findings and Discussion, the Certificate of Need application of Lawrence & Memorial Hospital for the acquisition and operation of a fixed positron emission tomography-computed tomography ("PET-CT") scanner to be located at the L&M Diagnostic Imaging Center at Crossroads in Waterford to replace its existing part-time mobile PET-CT and a fixed CT scanner at a total capital expenditure of \$3,225,915 is hereby **approved**; with the following conditions:

1. The Hospital will notify OHCA of the date of the termination of services and the disposition of the current mobile PET-CT scanner within 30 days of the beginning of the operation of the new PET-CT scanner .
2. The Hospital will notify OHCA of the actual date and disposition of the current CT scanner being replaced at L&M Diagnostic Imaging Center at Crossroads within 30 days of the beginning of the operation of the new PET-CT scanner

All of the foregoing constitutes the final order of the Office of Health Care Access in this matter.

By Order of the  
Department of Public Health  
Office of Health Care Access

4/16/12  
Date

Lisa A. Davis  
Lisa A. Davis, MBA, BSN, RN  
Deputy Commissioner