



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

October 6, 2011

**IN THE MATTER OF:**

An Application for a Certificate of Need filed  
Pursuant to Section 19a-638, C.G.S. by:

Notice of Final Decision  
Office of Health Care Access  
Docket Number: 11-31717-CON

**Lawrence & Memorial Hospital**

**Replacement of Nuclear Single Photon  
Emission Computed Tomography Camera  
with a Single Photon Emission Computed  
Tomography-Computed Tomography Camera**

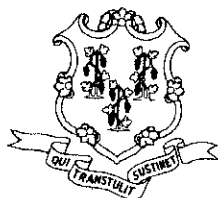
To: Shraddha Patel  
Director of Business Development & Planning  
Lawrence & Memorial Hospital  
365 Montauk Avenue  
New London, CT 06320

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 October 6, 2011, 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:pf



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

**Final Decision**

**Applicant:** Lawrence & Memorial Hospital

**Docket Number:** 11-31717-CON

**Project Title:** Replacement of Nuclear Single Photon Emission Computed Tomography Camera with a Single Photon Emission Computed Tomography-Computed Tomography Camera

**Project Description:** Lawrence & Memorial Hospital (“Applicant”) is proposing to replace a Single Photon Emission Computed Tomography (“SPECT”) camera with a Single Photon Emission Computed Tomography-Computed Tomography (“SPECT/CT”) camera to be located at 365 Montauk Avenue, in New London, Connecticut with an associated total capital expenditure of \$693,500.

**Procedural History:** On August 15, 2011, the Office of Health Care Access (“OHCA”) received a Certificate of Need (“CON”) application from the Applicant for the above-referenced project. The Applicant published notice of its intent to file the CON Application in *The Day*, on July 13, 14, 15, 2011. OHCA received no responses from the public concerning the Applicant’s proposal and no hearing requests were received from the public per General Statutes § 19a-639a (e).

**FINDINGS OF FACT**

1. The Applicant is a 308-bed acute care hospital located at 365 Montauk Avenue, in New London, Connecticut, and is proposing to replace an existing SPECT camera with a SPECT-CT camera. Ex. A, p. 16.
2. The SPECT camera is located on the main campus and is part of the Applicant’s full-service radiology department, which offers comprehensive imaging services to patients, including Computed Tomography (“CT”), Magnetic Resonance Imaging (“MRI”), Ultrasound, Digital Mammography and X-Ray, as well as Nuclear Medicine. Ex. A, p. 16.

3. The SPECT camera that the Applicant is proposing to replace is the oldest of the Applicant's nuclear imaging cameras. It was purchased in 2000 and has been in service for over ten years, and has reached the end of its useful life. The manufacturer no longer supports this equipment due to the age of the product and has exited the field of nuclear medicine. Ex. A, p. 16&19.
4. Nuclear medicine scans can be used to assess organ function and anatomical structure for diagnosis and treatment planning. The scans produced by a SPECT camera are particularly useful for cardiac, oncology and neurology patients, among others. Ex. A, p. 16.
5. During the scanning process, factors relating to different density tissue throughout the body can produce artifacts, which distort or degrade the image quality and can reduce the diagnostic accuracy of the results as well as possibly increase the risk of false positive studies. Ex. A, p. 16.
6. Attenuation correction reduces artifacts and improves image quality and specificity. Ex. A, p. 16
7. The existing SPECT camera has used Gadolinium-153 ("Gd-153") sources for attenuation correction since 2004. The Gd-153 method has been in use for many years and is being replaced by low-dose computed tomography based attenuation correction. Ex. A, p. 16.
8. CT generates high-quality attenuation maps due to higher photon flux, and CT-based attenuation correction offers improved image quality and higher sensitivity and specificity. Ex. A, p. 16.
9. The hybrid SPECT-CT modality offers enhanced attenuation correction and anatomic localization, among other benefits, resulting in improved image quality and diagnostic information. Ex. A, p. 16&17.
10. The hybrid SPECT-CT camera offers the following clinical benefits compared to the existing model:
  - Increased diagnostic quality and reduced false positives;
  - Improved lesion detection and lesion extension;
  - Reduced scanning time and radiation exposure for patients; and
  - Optimized image quality.Ex. A, p. 17.
11. While the proposed replacement camera is a hybrid SPECT-CT model, it does not include the configuration for standalone CT purposes. As a result, the equipment cannot be used as a standalone diagnostic CT scanner and will only be used for nuclear imaging SPECT scans. Ex. A, p. 17.

12. The need for the proposed equipment is based on the following:
  - The current Toshiba camera has reached the end of its useful life and is no longer supported by the vendor;
  - Nuclear medicine imaging plays a critically important role in the appropriate diagnosis and treatment planning for many patients including, but not limited to, cardiac, oncology, and neurology; and
  - The proposed replacement camera will offer superior image quality, less radiation, and faster scan times. Ex. A, p. 18.
13. The existing SPECT camera will be removed by the manufacturer and decommissioned. Ex. A, p. 17.
14. Replacing the SPECT with a SPECT-CT will improve the accessibility and quality of care provided to the Applicant's patients.
15. This proposal represents a replacement of an outdated SPECT camera with a new state-of-the-art SPECT-CT camera to serve the same patient population. As a result, it is not expected to have an effect on any existing providers and it will not result in a duplication of service. Ex. A, p. 22-23.
16. The following represents the Applicant's historical and current total nuclear medicine volume for inpatient, outpatient and Emergency Department patients at Lawrence & Memorial Hospital:

**Table 1: Historical and Current Nuclear Medicine Volume by Department**

	Actual Volume (Last 3 Completed FYs)			Actual Volume
	FY 2008*	FY 2009	FY 2010	FY 2011**
Inpatient	1,299	1,331	1,334	1,301
Outpatient	2,260	2,084	1,929	1,876
ED	33	37	35	38
<b>Total volume***</b>	<b>3,592</b>	<b>3,452</b>	<b>3,298</b>	<b>3,215</b>

\*Applicant's fiscal year runs from October 1<sup>st</sup> to September 30<sup>th</sup>.

\*\* Current fiscal year 2011 represents October 2010 to May 2011 (8 months) annualized.

\*\*\* The total volume represents cases scanned on all three cameras combined. Ex. A, p. 23.

17. The declining volumes for the SPECT camera between FY 2008 and FY 2010 are attributable to a worldwide shortage of radiopharmaceuticals resulting from the temporary closure of several nuclear reactors, and physicians practices (e.g. cardiologists) offering nuclear medicine scans in their offices. Ex. A, p. 25.
18. The Applicant conservatively projects that nuclear medicine volume will remain constant for the FY 2012 through FY 2014 at 3,215 scans per year. Ex. A, p. 23, 26.
19. Despite its conservative projections, the Applicant nonetheless expects that there will be an increase in nuclear medicine scans based upon the following:

- Additional clinical applications for nuclear medicine, such as new agents used to diagnose pulmonary embolisms and deep vein thrombosis, will contribute new volume to the modality.
- The projected growth and aging of the service area population will most likely result in a corresponding increase in demand for nuclear medicine scans in the coming years.
- The improved availability of radiopharmaceuticals will also have a positive impact on future nuclear medicine volume.
- The improved clinical benefits of SPECT-CT over SPECT are also expected to increase demand for SPECT-CT and provide an ongoing contribution to patient volume.
- Two cardiologists (Dr. Gaudio and Dr. Bagheri) recently joined Lawrence & Memorial Physicians, a multispecialty group affiliated with Lawrence & Memorial Hospital, and they will be utilizing the Hospital's service.  
Ex. A, p. 26.

20. The projected volumes are reasonable and achievable based upon the Applicant's historical volumes as well as the enhanced capabilities of the SPECT-CT.
21. The capital expenditure associated with the acquisition of the SPECT-CT is comprised of the following:

**Table 2: Proposal's Total Capital Expenditure**

Imaging Equipment	\$498,913
Construction/ Work-Renovation	194,587
<b>Total Capital Expenditure</b>	<b>\$693,500</b>

Ex. A, p. 30.

22. The Applicant will fund the project through Hospital equity.  
Ex. A, p. 32.
23. The Applicant projects the following incremental revenues and expenditures with the proposed project:

**Table 3: Projected Incremental Revenues and Expenditures**

Description	FY 2012	FY 2013	FY 2014
Incremental Revenue from Operations	\$0	\$0	\$0
Incremental Total Operating Expense	\$32,378	\$112,755	\$112,755
<b>Incremental Loss from Operations</b>	<b>(\$32,378)</b>	<b>(\$112,755)</b>	<b>(\$112,755)</b>

Ex. A, p. 34.

24. The projected incremental loss from operations is a result of the depreciation expense being incurred as the Applicant replaces an 11 year old nuclear camera with the proposed camera which will be depreciated over 5 years. Ex. A, p. 34.

25. Despite the incremental losses, the Applicant projects overall operating gains of \$21,587,000, \$21,507,123 and \$21,507,000 for fiscal years 2012 through 2014, respectively. Ex. A, p. 34.
26. This proposal will positively affect the strength of the state's health care system by replacing an outdated nuclear medicine camera with a more advanced model that utilizes contemporary technology and can be supported by its vendor if necessary. The improved accuracy and image quality and faster throughput provided by the new camera will result in more cost-effective, efficient care. Ex. A, p. 32.

## 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 Applicant is an acute care hospital located in New London, Connecticut, that is proposing to replace an existing SPECT camera with a SPECT-CT camera. FF1. The Applicant's current SPECT camera is over 10 years old and at the end of its useful life. FF3. The manufacturer no longer supports this equipment due to the age of the product and has exited the field of nuclear medicine. FF3. Nuclear medicine scans are used to assess organ function and anatomical structure for diagnosis and treatment planning and are particularly useful for cardiac, oncology and neurology patients. FF4. During the scanning process, factors relating to different density tissue throughout the body can produce artifacts, which distort or degrade the image quality and can reduce the diagnostic accuracy of the results as well as possibly increase the risk of false positive studies. FF5. Attenuation correction reduces artifacts and improves image quality and specificity. FF 6. Currently, the existing SPECT camera has used Gadolinium-153 for attenuation correction which is being replaced by low-dose computed tomography based attenuation correction. FF7. CT generates high-quality attenuation maps due to higher photon flux and it offers improved image quality and higher sensitivity and specificity. FF8.

The proposed SPECT-CT will enhance the attenuation correction and anatomic localization capabilities of SPECT studies, resulting in improved diagnostic information. FF9. The SPECT-CT also will reduce the number of false positive studies, improve lesion detection and lesion extension, reduced scanning time and radiation exposure for patients. FF10. While the proposed replacement camera is a hybrid SPECT-CT model, it does not include the configuration for standalone CT purposes. Therefore, the equipment cannot be used as a

standalone diagnostic CT scanner and will only be used for nuclear imaging SPECT scans. FF11. Accordingly, OHCA finds that the replacement of the SPECT camera with a SPECT-CT will improve the accessibility and quality of health care delivery for the Applicant's patients.

Although the improved clinical benefits of SPECT-CT over SPECT are expected to increase demand for SPECT-CT, the Applicant conservatively projects that nuclear medicine scan volumes will remain constant at 3,215 scans for FY 2012 through FY 2014. FF 18-19. OHCA finds the projected volumes to be achievable and reasonable based upon the Applicant's historical volumes and the enhanced capabilities of the SPECT-CT.

The total capital expenditure associated with this proposal is \$693,500. FF21. Despite incremental losses associated with the proposal, the Applicant is projecting overall operating gains of \$21,587,000, \$21,507,123 and \$21,507,000 for FY 2012 through FY 2014. FF 23-25. This proposal will positively affect the strength of the state's health care system by replacing an outdated nuclear medicine camera with a more advanced model that utilizes contemporary technology and can be supported by its vendor if necessary. The improved accuracy and image quality and faster throughput provided by the new camera will result in more cost-effective, efficient care. FF26. Accordingly, OHCA finds that the project is financially feasible.

Based upon the foregoing, OHCA concludes that the Applicant has demonstrated a need to replace its SPECT camera with a SPECT-CT.

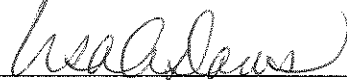
## Order

Based upon the foregoing Findings and Discussion, the Certificate of Need application of Lawrence & Memorial Hospital to replace a SPECT camera with a SPECT-CT camera to be located at 365 Montauk Avenue, in New London, Connecticut with an associated total capital expenditure of \$693,500, is hereby GRANTED.

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

10/6/11  
Date

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

  
Lisa A. Davis, MBA, BSN, RN  
Deputy Commissioner  
RWJ Executive Nurse Fellow Alumni

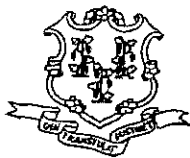
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STATE OF CONNECTICUT  
DEPARTMENT OF PUBLIC HEALTH  
OFFICE OF HEALTH CARE ACCESS

FAX SHEET

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DATE: 10/11/11 TIME: 1:45 pm  
NUMBER OF PAGES: 9  
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Comments:

11-31717-CON FINAL DECISION