STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

February 20, 2014

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: 13-31845-CON
Yale-New Haven Hospital	**Acquisition of Two Single Photon Emission Tomography-Computed Tomography Cameras**

To:

Nancy Rosenthal
Senior Vice President-Health Systems Development
Yale-New Haven Hospital
20 York Street
New Haven, CT 06510

Dear Ms. Rosenthal:

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 February 20, 2014, 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: **Yale-New Haven Hospital**

Docket Number: **13-31845-CON**

Project Title: **Acquisition of Two Single Photon Emission Tomography-Computed Tomography Cameras**

Project Description: Yale-New Haven Hospital ("Hospital" or "Applicant") is seeking approval for the acquisition of two Single Photon Emission Computed Tomography-Computed Tomography ("SPECT-CT") cameras to replace a SPECT camera and two nuclear gamma cameras at the Hospital.

Procedural History: On June 18, 2013, the Office of Health Care Access ("OHCA") received the initial 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 New Haven Register* on March 18, 19 and 20, 2013. The application was deemed complete on September 5, 2013. OHCA received no responses from the public concerning the Hospital's proposal and no hearing requests were received from the public per Connecticut General Statutes § 19a-639a(e). In rendering her decision, Deputy Commissioner Davis considered the entire record in this matter.

To the extent the findings of fact actually represent conclusions of law, they should be so considered, and vice versa. *SAS Inst., Inc., v. S & H Computer Systems, Inc.*, 605 F.Supp. 816 (Md. Tenn. 1985).

Findings of Fact and Conclusions of Law

1. The Hospital is a 1,541[1] bed not-for-profit acute care teaching hospital located at 20 York Street, New Haven, Connecticut. Exhibit A, pp. 15, 642.

2. In January 2010, the Hospital acquired a Siemens Symbia T SPECT-CT camera to replace its 14-year-old Philips Axis SPECT camera in the Nuclear Medicine Department. Exhibit A, pp. 15-17.

3. In September 2011, the Hospital acquired a GE Discovery 570C SPECT-CT camera to replace two of its gamma cameras, which were over ten years old, in the Nuclear Cardiology Department. Exhibit A, pp.17-18.

4. The SPECT camera and the two gamma cameras have been removed and disposed of by the Hospital. Exhibit A, pp. 17-18.

5. Under Report Number 12-31807-DTR, OHCA determined that the Hospital was required to file a CON application for the acquisition of the above-mentioned SPECT-CT cameras. OHCA CON Determination, Report Number 12-31807-DTR.

6. Based upon Determination Report Number 12-31807-DTR, the Hospital is seeking CON authorization for the two SPECT-CT cameras. Exhibit A, pp. 15-18.

7. A nuclear medicine scan is used to assess organ function and internal anatomy for diagnosis and treatment for a broad range of patients, including cardiac, oncology and neurology patients. Exhibit A, p. 16.

8. The SPECT-CT camera in the Hospital's Nuclear Medicine Department can perform several different types of scans, including two- (planar) and three-dimensional imaging, SPECT, and SPECT-CT. Exhibit A, p. 16.

9. The camera's 2-slice CT component can be used to conduct bone, brain, pediatric neuroblastoma, whole body, liver, parathyroid and white blood cell scans as well as scan for Parkinson's disease (which can only be performed on a SPECT-CT). Exhibit A, pp. 16-17.

10. The SPECT-CT produces a three-dimensional image similar to SPECT, but the CT component adds clarity to the scan via attenuation correction, which removes shadows and artifacts which frequently can appear on images. Exhibit A, p. 16.

11. Images may be distorted due, in part, to the density of body tissue, which may result in low quality scans that appear cloudy or obstructed, and could provide false positives. The accompanying low dose CT scan can eliminate much of the distortion associated with tissue density. Exhibit A, pp. 16-17.

---

[1] Includes 134 bassinets

12. The SPECT-CT in the Nuclear Cardiology Department is used to perform stress perfusion exams, which are non-invasive tests that can detect heart disease. These tests are widely accepted and commonly used to stratify risk among patients prior to surgery and to evaluate the source of chest pain. Exhibit A, p. 18.

13. The Nuclear Cardiology SPECT-CT has a 64 slice CT component that can be used immediately after a SPECT scan to apply attenuation correction to remove shadows and artifacts distorted by overlying breast or adipose tissue that may appear as coronary defects. Use of the CT component allows for a high quality scan that can be interpreted with greater confidence, improved lesion detection, eliminate the need for unnecessary follow-up testing and decrease the risks of false positives. Exhibit A, pp. 17-19.

14. The CT component is also used to evaluate calcium scoring of the coronary arteries, providing physicians with additional information when interpreting perfusion scans and creating a more complete picture for treatment planning. Exhibit A, p. 18.

15. SPECT-CT scans can be performed with a lower dose of radioactive tracers and in less time than typical scans via a SPECT or gamma camera. Exhibit A, pp. 18-19, 22.

16. The SPECT-CT cameras cannot be used as standalone CT scanners for diagnostic imaging. Exhibit A, pp. 16, 18.

17. The Hospital's historical and projected SPECT-CT utilization in the Nuclear Medicine and Nuclear Cardiology Departments is as follows:

Table 1: Historical and Projected Utilization SPECT-CT Cameras

	Actual				Projected		
	FY2010	**FY2011**	**FY2012**	**FY2013**	**FY2014**	**FY2015**	**FY2016**
Nuclear Medicine	19	126	123	204	220	220	220
Nuclear Cardiology	n/a*	n/a*	599	845	845	845	845

Exhibit E.
*Although the SPECT-CT camera was acquired in 2010, the Hospital used only its planar imaging and SPECT functions until remodeling was completed in September 2012, when the Hospital became compliant with Occupational Safety and Health Administration regulations pertaining to accommodating the low-dose radiation associated with the CT component.

18. Based on its actual historical utilization, the Hospital has conservatively projected stable utilization volumes for FY2014 through FY2016.

19. The need for, and use of, SPECT-CT cameras, is supported by the following submissions:
    - *American Society of Nuclear Cardiology and Society of Nuclear Medicine Joint Position Statement: Attenuation Correction of Myocardial Perfusion SPECT Scintigraphy.* This article states that "incorporation of attenuation correction in addition to ECG gating with SPECT myocardial perfusion images will improve

image quality, interpretive certainty, and diagnostic accuracy. These combined results are anticipated to have a substantial impact on improving the effectiveness of care and lowering health care costs." Exhibit A, pp. 36, 460-461.

- *SPECT/CT.* This report notes the growing role of SPECT-CT in oncologic applications and its superiority over planar imaging or SPECT for benign and malignant skeletal diseases, thyroid or neuroendocrine cancer, parathyroid adenoma and sentinel lymph node mapping in the head, neck and pelvis. Exhibit A, pp. 36, 482-496.
- *SPECT/CT Imaging: Clinical Utility of an Emerging Technology.* This article explains the benefits of SPECT-CT and notes that "combining the functional imaging available with SPECT and the anatomic imaging of computed tomography has gained more acceptance and proved useful in many clinical situations [...] These attributes have proved useful in many cardiac, general nuclear medicine, oncologic, and neurologic applications in which SPECT results alone are inconclusive." Exhibit A, pp. 36-37, 497-514.
- *Clinical Applications of SPECT/CT; New Hybrid Nuclear Medicine Imaging System.* This article provides a summary of clinical applications such as thyroid cancer, adrenal tumors, neuroendocrine tumors, lymphoma, bone scintigraphy, cerebral masses and various cardiac images. Exhibit A, pp. 37, 516-576.

20. Since the two SPECT-CT cameras replaced an existing SPECT camera and existing gamma cameras, no impact on existing providers is expected. Exhibit A, p. 27.

21. The proposal's total capital expenditure is itemized as follows:

Table 2: Total Capital Expenditure -- Nuclear Medicine

Imaging Equipment (SPECT-CT Scanner)	$465,000
Construction/Renovation	$61,000
Total Capital Expenditure	**$526,000**

Exhibit A, p. 39.

Table 3: Total Capital Expenditure -- Nuclear Cardiology

Imaging Equipment (SPECT-CT Scanner)	$1,354,443
Total Capital Expenditure	**$1,354,443**

Exhibit A, pp. 39-40.

22. The SPECT-CT camera acquisitions were fully funded by the Hospital's equity. Exhibit A, p. 40.

23. As shown in **Tables 4** and **5**, the projected gains derived from Nuclear Cardiology more than offset the losses projected from Nuclear Medicine and result in a net gain for the overall proposal.

Table 4: Historical/Projected Incremental Revenues and Expenditures (Nuclear Medicine)

	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
Revenue from Operations	$192,974	$197,776	$152,974	$203,710	$209,821	$216,116
Total Operating Expenses*	$143,514	$375,146	$372,154	$381,204	$390,525	$400,126
Gain/(Loss) from Operations	**$49,460**	**($177,369)**	**($219,180)**	**($177,494)**	**($180,704)**	**($184,010)**

Note: figures are in thousands.
*Operating expenses include salaries/fringe benefits, supplies/drugs and depreciation/amortization.
Exhibit E.

Table 5: Historical/Projected Incremental Revenues & Expenditures (Nuclear Cardiology)

	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
Revenue from Operations	$1,358,459	$1,627,495	$1,464,291	$1,493,577	$1,523,449	$1,553,918
Total Operating Expenses*	$897,046	$948,402	$818,989	$843,559	$868,866	$894,932
Gain/(Loss) from Operations	**$461,413**	**$485,601**	**$451,810**	**$456,526**	**$461,091**	**$465,494**

Note: figures are in thousands.
*Operating expenses include salaries/fringe benefits, supplies/drugs and depreciation/amortization.
Exhibit E.

24. With the proposal, the Hospital projects operational gains of $79.2M in FY 2014, $90.3M in FY 2015 and $98.0M in FY 2016.

Table 6: Yale-New Haven Hospital Projected Revenues & Expenditures with CON

	FY 2014	FY 2015	FY 2016
Revenue from Operations	$2,484,520	$2,601,094	$2,730,762
Total Operating Expenses*	$2,405,291	$2,510,778	$2,632,774
Gain/(Loss) from Operations	**$79,229**	**$90,316**	**$97,988**

Note: figures are in thousands.
*Operating expenses include salaries/fringe benefits, professional/contracted services, supplies/drugs, bad debts, other operating expenses, depreciation/amortization, interest expense and lease expense.
Exhibit B, pp.718-719.

25. As shown in **Tables 7** and **8**, no change in the patient population mix is projected by the Hospital:

Table 7: Current and Projected Payer Mix (Nuclear Medicine)

Description	FY2012	FY2013	FY2014	FY2015	FY2016
Medicare*	32.9%	32.9%	32.9%	32.9%	32.9%
Medicaid*	11.7%	11.7%	11.7%	11.7%	11.7%
CHAMPUS & TriCare	0.6%	0.6%	0.6%	0.6%	0.6%
Total Government	**45.2%**	**45.2%**	**45.2%**	**45.2%**	**45.2%**
Commercial Insurers*	52.8%	52.8%	52.8%	52.8%	52.8%
Uninsured	1.5%	1.5%	1.5%	1.5%	1.5%
Workers Compensation	0.6%	0.6%	0.6%	0.6%	0.6%
Total Non-Government	**54.8%**	**54.8%**	**54.8%**	**54.8%**	**54.8%**
Total Payer Mix	**100%**	**100%**	**100%**	**100%**	**100%**

* Includes managed care activity.

Exhibit A, p. 41.

Table 8: Current and Projected Payer Mix (Nuclear Cardiology)

Description	FY2012	FY2013	FY2014	FY2015	FY2016
Medicare*	34.6%	34.6%	34.6%	34.6%	34.6%
Medicaid*	22.0%	22.0%	22.0%	22.0%	22.0%
CHAMPUS & TriCare	0.2%	0.2%	0.2%	0.2%	0.2%
Total Government	**56.8%**	**56.8%**	**56.8%**	**56.8%**	**56.8%**
Commercial Insurers*	41.0%	41.0%	41.0%	41.0%	41.0%
Uninsured	2.1%	2.1%	2.1%	2.1%	2.1%
Workers Compensation	0.1%	0.1%	0.1%	0.1%	0.1%
Total Non-Government	**43.2%**	**43.2%**	**43.2%**	**43.2%**	**43.2%**
Total Payer Mix	**100%**	**100%**	**100%**	**100%**	**100%**

* Includes managed care activity.
Exhibit A, p. 41.

29. OHCA is currently in the process of establishing its policies and standards as regulations. Therefore, OHCA has not made any findings as to this proposal's relationship to any regulations adopted by OHCA. (Conn .Gen. Stat. § 19a-639(a)(1))

30. This CON application is consistent with the overall goals of the State Health Care Facilities and Services Plan. (Conn. Gen. Stat. § 19a-639(a)(2))

31. The Applicant has established that there is a clear public need for its proposal. (Conn. Gen. Stat. § 19a-639(a)(3))

32. The Applicant has satisfactorily demonstrated that its proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4))

33. The Applicant has satisfactorily demonstrated that its proposal would improve the accessibility and quality of health care delivery in the region and it has satisfactorily demonstrated a potential improvement in cost effectiveness. (Conn. Gen. Stat. § 19a-639(a)(5))

34. The Applicant has shown that there will be no change in access to the provision of health care services to the relevant populations and payer mix. (Conn. Gen. Stat. § 19a-639(a)(6))

35. The Applicant has satisfactorily identified the population to be served and has satisfactorily demonstrated that this population has a need as proposed. (Conn. Gen. Stat. § 19a-639(a)(7))

36. The Applicant's historical provision of treatment in the service area supports this proposal. (Conn. Gen. Stat. § 19a-639(a)(8))

37. The Applicant has satisfactorily demonstrated that the proposal will not result in an unnecessary duplication of existing services in the area. (Conn. Gen. Stat. § 19a-639(a)(9))

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). The Applicant bears the burden of proof in this matter by a preponderance of the evidence. *Jones v. Connecticut Medical Examining Board, 309 Conn. 727 (2013).*

Yale-New Haven Hospital, a 1,541 bed not-for-profit acute care teaching hospital in New Haven, is seeking authorization for the acquisition of two SPECT-CT cameras, which were acquired to replace a SPECT camera and two gamma cameras. *FF1-3.* Under Determination Report Number 12-31807-DTR, OHCA determined that the acquisition of the two SPECT-CT cameras required CON approval, although the Hospital has been operating them without CON authorization since 2010/2011. *FF2-5.*

The Hospital's Nuclear Medicine Department uses the SPECT-CT camera to assess organ function and internal anatomy for diagnosing and treating cardiac, oncology and neurology patients, among others. *FF7.* The camera, which can perform two- and three-dimensional imaging, SPECT, and SPECT-CT, has a 2-slice CT component which is used to conduct bone, brain, pediatric neuroblastoma, whole body, liver, parathyroid and white blood cell scans as well as scan for Parkinson's disease. *FF8-9.* The SPECT-CT produces a three-dimensional image similar to SPECT, but its CT component eliminates distortion and adds clarity to the scan via attenuation correction. This CT capability removes shadows and artifacts which frequently appear on images, thus reducing low quality, cloudy or obstructive scans and the potential for false positives. *FF10-11.*

The SPECT-CT in the Nuclear Cardiology Department is used to perform stress perfusion exams that can detect heart disease, which are widely accepted and commonly used to stratify risk among patients prior to surgery and to evaluate the source of chest pain. *FF12.* The Nuclear Cardiology SPECT-CT has a 64 slice CT component that can be used immediately after a SPECT scan to apply attenuation correction to remove shadows and artifacts distorted by overlying breast or adipose tissue that may appear as coronary defects. The CT component is also used to evaluate calcium scoring of the coronary arteries, providing physicians with additional information when interpreting test results and creating a more complete picture for treatment planning. *FF13-14.* Its use allows for a high quality scan that can be interpreted with greater confidence and improved lesion detection, thus eliminating the need for unnecessary follow-up testing and decreasing the risks of false positives. *FF13.*

The Applicant provided numerous clinical studies and articles that support the need for, and use of, SPECT-CT cameras and which substantiate SPECT-CT's impact on the quality of care and its potential for lowering health care costs. *FF19.* Both SPECT-CTs replaced equipment that was more than ten years old. *FF2-3.* The quality of the scans produced by the SPECT-CT cameras are significantly superior to the outdated SPECT and gamma cameras they replaced, due in part to the ability of the CT component to provide attenuation correction. Moreover, these scans can be performed with a lower dose of radioactive tracers and in less time than typical scans via a

SPECT or gamma camera. *FF15.* Specifically, in order to perform a nuclear medicine scan, a small amount of radioactive isotope is first injected into a patient. This radioactive tracer is then detected by nuclear camera to create pictures of internal organs based on the distribution of the isotope. A nuclear medicine scan can be used to assess organ function and internal anatomy for diagnosis and treatment purposes, and can be useful in a broad range of patients, including but not limited to cardiac, oncology, and neurology patients. According to the Hospital, at times the image produced may be distorted, due in part to the density of tissue within the body. This may result in low quality scans that appear cloudy or obstructed and could produce false positive results. To correct these imperfections, a nuclear medicine scan that is performed with a SPECT camera may be accompanied by low dose CT, which provides attenuation correction. *Exhibit A, pp.16-17.*

The two SPECT-CT cameras replaced existing equipment and the Hospital stated that it is not aware of any providers in its service area that offer SPECT-CT nuclear imaging services. *FF20;Exhibit A, pp. 23, 27.* As such, there is no duplication of services in the service area and no impact on existing providers. The Hospital projects that there will be no change in the payer mix as a result of the acquisition. *FF25.* The Applicant has projected stable utilization for FY2014 and FY2016. *FF18.* Based on the actual historical utilization, the projections appear reasonable and achievable.

The total capital expenditure for the Nuclear Medicine Department SPECT-CT, $526,000, and the Nuclear Cardiology Department SPECT-CT, $1,354,443, was fully funded by the Hospital's equity. *FF21.* While there is an overall loss from operations projected for FY2014-2016 in the Nuclear Medicine Department, it is more than offset by projected gains from operations in the Nuclear Cardiology Department. Moreover, the Hospital projects operational gains of $79.2M, 90.3M and $98.0M, respectively, for FY2014-2016. *FF24.* Therefore, the Applicant has demonstrated that its proposal is financially feasible.

The Applicant has demonstrated clear public need for the acquisition of the two SPECT-CT cameras due to the overall clinically superior care it offers. Additionally, the Applicant has satisfactorily shown that access to care will be maintained, quality of care will be improved and the combined results of the quality improvements may have a potential impact on cost effectiveness. *FF19.*

Order

Based upon the foregoing Findings of Fact and Discussion, the Certificate of Need application of Yale-New Haven Hospital for the acquisition of two SPECT-CT cameras is hereby **approved.**

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

3/20/14
Date

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