

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner



Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Health Care Access

Certificate of Need Final Decision

Applicant: Yale-New Haven Hospital

Docket Number: 16-32124-CON

Project Title: Acquisition of Two Single Photon Emission Computed 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 two existing SPECT cameras.

Procedural History: The Applicant published notice of its intent to file a Certificate of Need (“CON”) application in The New Haven Register on November 21, 22 and 23, 2016. On December 29, 2016, the Office of Health Care Access (“OHCA”) received the CON application from the Applicant for the above-referenced project and deemed the application complete on March 17, 2017. OHCA received no responses from the public concerning the proposal and no hearing requests were received from the public per Connecticut General Statutes (“Conn. Gen. Stat.”) § 19a-639a(e). In rendering the decision, Deputy Commissioner Addo considered the entire record in this matter.



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Findings of Fact and Conclusions of Law

1. The Hospital is a 1,541¹ bed not-for-profit acute care teaching hospital located at 20 York Street, New Haven, Connecticut. Exhibit A, pp. 19, 51.
2. As shown in the table below, the Hospital currently operates 10 SPECT cameras and one SPECT-CT camera.

**TABLE 1
EXISTING EQUIPMENT OPERATED BY THE APPLICANT**

Provider Name/Address	Service	Days/Hours of Operation	Utilization (FY16)
YNHH HVC, 111 Goose Lane, Guilford, CT	SPECT	M-F, 7am-5pm	887
YNHH HVC, 1450 Chapel St. New Haven, CT	SPECT	M-F, 7am-5pm	231
YNHH HVC, 1450 Chapel St. New Haven, CT	SPECT	M-F, 7am-5pm	491
YNHH HVC, 1450 Chapel St. New Haven, CT	SPECT	M-F, 7am-5pm	492
YNHH HVC, 2 Divine Street, North Haven, CT	SPECT	M-F, 7am-5pm	915
YNHH HVC, 79 Wawecus Street, Norwich, CT	SPECT	M-F, 7am-5pm	776
YNHH HVC, 20 York Street, New Haven, CT	SPECT-CT	M-F, 8am-5pm	660
YNHH HVC, 20 York Street, New Haven, CT	SPECT	M-F, 8am-5pm	484
YNHH HVC, 20 York Street, New Haven, CT	SPECT	M-F, 8am-5pm	193
YNHH HVC, 20 York Street, New Haven, CT*	SPECT	M-F, 8am-5pm	0
YNHH ED, 20 York Street, New Haven, CT	SPECT	M-F, 8am-8pm	984

Exhibit A, p. 43.

* This camera is used mostly for multiple gated acquisition studies and does not perform myocardial perfusion studies. However it may be used once a year to perform a myocardial perfusion study if a patient is not able to lie flat or exceeds the weight limit of the table for the other cameras.

3. The GE MyoSite SPECT camera at 111 Goose Lane in Guilford was purchased in 2005 and is at the end of its useful life. The Siemens Symbia SPECT camera at 1450 Chapel Street (St. Raphael Campus) was purchased in 2014 and is not able to produce superior images like a SPECT-CT. The Applicant proposes replacing these two cameras with 4-slice GE Optima 640 SPECT-CT cameras. Exhibit A, pp. 18-19.
4. Under Report Number 16-32124-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 16-32124-DTR.

¹ Includes 134 bassinets

5. The Determination Request noted five SPECT cameras in line for replacement, but due to the need to allocate capital resources efficiently, the hospital will replace only two SPECT cameras with SPECT-CT cameras at this time. Exhibit A, p. 19
6. The new SPECT-CT cameras will be replacing one existing camera in Guilford and one of the three cameras operating at 1450 Chapel Street in New Haven. Exhibit A, pp. 19-20.
7. YNHH Heart and Vascular Center (HVC) treats heart and vascular patients and offers various cardiac imaging technology, including echocardiography, ultrasound, molecular nuclear medicine imaging, cardiac magnetic resonance imaging, positron emission topography, and computed tomography to evaluate a variety of cardiac issues such as chest pain, congestive heart failure and valve disease. Exhibit A, pp. 19-20
8. These cameras will be used to perform myocardial perfusion studies, non-invasive imaging tests showing how well blood flows through the heart muscle. A radioactive tracer is injected into a patient and a nuclear camera is used to capture images of the heart after exercise, rest, or both to show areas with either blocked arteries or injury in the heart tissue. Exhibit C, p. 220
9. There are certain limitations to this type of scan due, in part, to variation in density of various tissues within the body. Overlying breast tissue and/or adipose tissue can create shadows or artifacts especially in obese patients, which cloud the image and may result in an erroneous appearance of coronary defects. Exhibit A, p. 20
10. The SPECT-CT camera has a CT component that adds clarity to the scan via attenuation correction, which removes shadows and artifacts that frequently can appear on images as coronary defects. Exhibit A, pp. 20, 26.
11. Use of the CT component provides a higher quality of scan, improves lesion detection, eliminates the need for unnecessary follow-up testing and decreases the risk of false positives. Exhibit A, pp. 20, 26.
12. The proposed cameras will provide superior image quality within a shorter image acquisition time and less radiation exposure to patients. Exhibit A, p. 17.
13. Studies have shown the benefits of a SPECT-CT over a SPECT camera in the evaluation of coronary artery disease. Incorporation of attenuation correction in addition to ECG gating² 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. *American Society of Nuclear Cardiology and Society of Nuclear Medicine Joint Position Statement: Attenuation Correction of Myocardial Perfusion SPECT Scintigraphy*. Exhibit A, pp. 22, 80-87.

² Gating techniques are used to improve temporal resolution and minimize imaging artifacts caused by cardiac motion.

14. Based on actual historical utilization, the Hospital has projected stable utilization volume.

**TABLE 2
HISTORICAL AND PROJECTED UTILIZATION SPECT-CT CAMERAS**

Location	Historical			Projected			
	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020
Guilford	816	912	887	887	887	887	887
New Haven	281	233	231	231	231	231	231

Exhibit A, pp. 30, 35, Exhibit C, p. 223

15. The new SPECT-CT will serve the same patient population as the existing camera including Medicaid and indigent persons. Exhibit A, pp. 20, 26-27, 30.
16. No change in the payer mix is projected by the Hospital.

**TABLE 3
THE HOSPITAL'S CURRENT & PROJECTED PAYER MIX**

Payer	FY 2016		Projected							
			FY 2017		FY 2018		FY2019		FY 2020	
	Scans	%	Scans	%	Scans	%	Scans	%	Scans	%
Medicare*	414	46.7	414	46.7	414	46.7	414	46.7	414	46.7
Medicaid*	38	4.3	38	4.3	38	4.3	38	4.3	38	4.3
CHAMPUS & TriCare	1	0.1	1	0.1	1	0.1	1	0.1	1	0.1
Total Government	453	51.1	453	51.1	453	51.1	453	51.1	453	51.1
Commercial Insurers	429	48.4	429	48.4	429	48.4	429	48.4	429	48.4
Uninsured/Self Pay	2	0.2	2	0.2	2	0.2	2	0.2	2	0.2
Workers Compensation	3	0.3	3	0.3	3	0.3	3	0.3	3	0.3
Total Non-Government	434	48.9	434	48.9	434	48.9	434	48.9	434	48.9
Total Payer Mix	887	100	887	100	887	100	887	100	887	100

Exhibit A, p. 36, Exhibit B, p. 224.

17. There will be no gap in services during the cameras' installation period. Installation will take one week and during that time patients will continue to have access to myocardial perfusion testing with other SPECT cameras located in New Haven, North Haven and Norwich. Exhibit C, p. 220-221

18. The construction cost is the same for both locations. This cost is based on the installation of a new footprint and bed for both machines. No major construction expenses are required for either site. The proposal’s total capital expenditure is itemized as follows:

**TABLE 4
TOTAL CAPITAL EXPENDITURE – GUILFORD LOCATION**

Imaging Equipment (SPECT-CT Scanner)	\$453,931
Construction/Renovation	\$10,000
Total Capital Expenditure	\$463,931

Exhibit A, p. 34, Exhibit C, p.221

**TABLE 5
TOTAL CAPITAL EXPENDITURE – NEW HAVEN LOCATION**

Imaging Equipment (SPECT-CT Scanner)	\$453,931
Construction/Renovation	\$10,000
Total Capital Expenditure	\$463,931

Exhibit A, p. 34, Exhibit C, p. 221

19. This proposal will be funded through available capital.
Exhibit A, p. 28.
20. Diagnostic imaging performed on the replacement SPECT-CT cameras will have the same cost to the patient as imaging on the older equipment. Exhibit A, p. 25.
21. Incremental losses are projected in each of the next three fiscal years (FY) due to depreciation expense.

**TABLE 6
YALE NEW HAVEN HOSPITAL’S PROJECTED INCREMENTAL REVENUES AND EXPENSES**

	FY 2018	FY 2019	FY 2020
Revenue from Operations	-	-	-
Total Operating Expenses*	\$66,276	\$66,276	\$66,276
Gain/(Loss) from Operations	(\$66,276)	(\$66,276)	(\$66,276)

*Operating expenses represent the change in depreciation amount, which is a non-cash expense.
Exhibit A, pp. 29, 200. Exhibit B, pp. 227

22. Despite incremental losses, the Hospital projects overall operational gains from FY2018 through FY2020 following implementation of the proposal.

TABLE 7
YALE NEW HAVEN HOSPITAL'S PROJECTED REVENUES & EXPENDITURES WITH CON

	FY 2018	FY 2019	FY 2020
Revenue from Operations	\$2,815,465	\$2,866,019	\$2,922,450
Total Operating Expenses	\$2,715,990	\$2,765,774	\$2,820,230
Gain/(Loss) from Operations	\$99,475	\$100,245	\$102,219

Note: figures are in thousands.
Exhibit A, pp. 29, 200.

23. 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 not yet adopted by OHCA. (Conn. Gen. Stat. § 19a-639(a)(1)).
24. The proposal is consistent with the Statewide Health Care Facilities and Service Plan. (Conn. Gen. Stat. § 19a-639(a)(2)).
25. The Applicant has established that there is a clear public need for the proposal. (Conn. Gen. Stat. § 19a-639(a)(3)).
26. The Applicant has demonstrated that the proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4)).
27. The Applicant has satisfactorily demonstrated that the proposal will improve quality, and maintain accessibility and cost effectiveness of health care delivery in the region. (Conn. Gen. Stat. § 19a-639(a)(5)).
28. The Applicant has shown that there would be no change in the provision of health care services to the relevant populations and payer mix, including access to services by Medicaid recipients and indigent persons. (Conn. Gen. Stat. § 19a-639(a)(6)).
29. The Applicant has satisfactorily identified the population affected by this proposal. (Conn. Gen. Stat. § 19a-639(a)(7)).
30. The Applicant's historical provision of services in the service area supports this proposal. (Conn. Gen. Stat. § 19a-639(a)(8)).

31. The Applicant has satisfactorily demonstrated that this proposal would not result in an unnecessary duplication of existing services in the area. (Conn. Gen. Stat. § 19a-639(a)(9)).
32. The Applicant has demonstrated that there will be no reduction in access to services by Medicaid recipients or indigent persons. (Conn. Gen. Stat. § 19a-639(a)(10)).
33. The Applicant has demonstrated that the proposal will not negatively impact the diversity of health care providers and patient choice in the region. (Conn. Gen. Stat. § 19a-639(a)(11)).
34. The Applicant has satisfactorily demonstrated that the proposal will not result in any consolidation that would affect health care costs or access to care. (Conn. Gen. Stat. § 19a-639(a)(12)).

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 Conn. Gen. Stat. § 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 to replace two of its ten existing SPECT cameras with SPECT-CT cameras. The new SPECT-CT cameras, which will be located in Guilford and New Haven, will be used to evaluate and diagnose a variety of cardiac and vascular issues such as chest pain, congestive heart failure and valve disease. The quality of scans produced by SPECT-CT cameras is significantly superior to the SPECT camera as its CT component delivers attenuation correction for myocardial perfusion imaging studies, improving diagnostic accuracy. The SPECT-CT provides better image quality in less time with a lower chance of false positive results, reducing the need for follow-up testing and additional radiation exposure. *FF1-13*

As both SPECT-CT cameras will be replacing existing equipment, the Applicant will be serving the same patient population, including Medicaid and indigent patients, and no change to the payer mix is projected. Access to care will be maintained and the proposal will not affect the cost to patients. All these benefits are consistent with the Statewide Health Care Facilities and Services Plan. *FF15, 16*.

Order

Based upon the foregoing Findings and Discussion, the Certificate of Need application requesting authorization to acquire two SPECT-CT cameras at the Yale-New Haven Hospital, Connecticut, 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



6/7/2017
Date

Yvonne T. Addo, MBA
Deputy Commissioner