



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

Final Decision

Applicant: The Stamford Hospital

Docket Number: 15-32020-CON

Project Title: Acquisition of a Single Photon Emission Computed Tomography/Computed Tomography Camera

Project Description: The Stamford Hospital (“Hospital” or “Applicant”) is seeking approval for the acquisition of a Single Photon Emission Computed Tomography-Computed Tomography (“SPECT-CT”) camera to replace a nuclear camera.

Procedural History: On August 17, 2015, 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 Advocate* (Stamford) on June 19, 20 and 21, 2015. The application was deemed complete on November 4, 2015. 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 Brancifort considered the entire record in this matter.

Findings of Fact and Conclusions of Law

1. The Hospital is a 305¹ bed not-for-profit general hospital located at 30 Shelburne Road, Stamford, Connecticut. Exhibit A, pp. 12, 195.
2. The Hospital currently operates five nuclear cameras, two at its main campus hospital, two at its Tully Health Center, located at 32 Strawberry Hill Court in Stamford, and one at Mill River Cardiology Imaging Center (“Mill River”), located at 80 Mill River Street in Stamford.

Provider and Location	Equipment	Hours of Operation	Utilization FY14
Stamford Hospital 30 Shelburne Road Stamford, CT 06902	Unit 1: GE Infinia Unit 2: GE Infinia Hawkeye – CT Slice 2	M-F 7 AM to 4 PM Emergency calls 7 days	1,308
Tully Health Center 32 Strawberry Hill Court Stamford, CT 06902	Unit 1: Philips Forte Unit 2: Philips Axis	M-F 7 AM to 4 PM	1,220
Mill River Cardiology Imaging Center 80 Mill River Street Stamford, CT 06902	Unit 1: GE Ventri (to be retired)	M-F 7 AM to 3:30 PM	704

Exhibit. A, p. 18.

3. The GE Ventri located at Mill River has been in operation since 2006 and is at the end of its useful life. The Applicant proposes disposing of the unit through the vendor and replacing it with a 4-slice GE Optima NM/CT 640 SPECT-CT. Exhibit A, pp. 13, 20.
4. The new SPECT-CT will be located in the Hospital’s new Heart and Vascular Institute (HVI) suite and will be dedicated solely to cardiac services. Exhibit A, p. 14.
5. The Hospital’s Community Health Needs Assessment identified cardiovascular disease to be among the leading causes of hospitalization and death in the Hospital’s service area. Exhibit A, p. 15, Stamford, *2013 Community Health Needs Assessment*, pp 35-38.
6. The Hospital’s goal is to create a “one-stop” environment that provides patients with integrated interventional and diagnostic cardiac services. The HVI will provide elective and emergency angioplasty procedures, pacemaker/defibrillator implantation, electrophysiology, as well as vascular and peripheral stenting. Exhibit A, pp. 13, 18.
7. Nuclear cardiology imaging has inherent limitations due to the variation and density of tissue within the body, which may result in shadows and attenuation artifacts in the resulting images. The GE Optima SPECT-CT will allow the hospital to provide patients with higher quality myocardial perfusion studies in the comprehensive diagnostic and

¹ Excludes 25 bassinets.

interventional HVI. To mitigate attenuation artifacts, the CT component of the proposed GE Optima camera will remove these artifacts, decreasing false positive results and eliminating unnecessary follow-up testing. Exhibit A, p. 16.

8. Currently, patients undergoing myocardial perfusion testing without attenuation correction are required to be scanned twice—initially in a supine position, then in a prone state, the latter of which can be uncomfortable and unstable for some patients. The proposed camera will provide superior image quality with shorter image acquisition times and thus, less radiation exposure to patients. Exhibit A, p. 17.
9. The new SPECT-CT will serve the same patient population as the existing camera. Exhibit A, p. 20.
10. Based on its actual historical utilization, the Hospital has conservatively projected stable utilization volume.

**TABLE 1
THE STAMFORD HOSPITAL'S HISTORICAL AND PROJECTED UTILIZATION
OF CARDIAC SPECT-CT CAMERAS****

	Actual				Projected		
	FY2012	FY2013	FY2014	FY2015*	FY2016	FY2017	FY2018
Proposed GE Optima	n/a	n/a	n/a	n/a	722	722	722
Existing GE Ventra	643	626	685	704	n/a	n/a	n/a
Total	649	626	685	704	722	722	722

*Annualized based on Sept. 2014 through May 2015 data

** Excludes two cameras in use in the Applicant's radiology department

Exhibit A, p. 21.

11. Studies have shown the benefits of a SPECT-CT over a SPECT camera in the evaluation of coronary artery disease. The enhanced attenuation correction of the SPECT-CT reduces the number of false-positive results, allowing for improved diagnostic accuracy as well as improved risk stratification of patients. Aju P. Pazhenkottil et. al, *Improved Outcome Prediction by SPECT Myocardial Perfusion Imaging After CT Attenuation Correction*, 52 J OF NUCL MED 196, 196-198 (2011). Exhibit C, p. 50.
12. The advancement of SPECT-CT cameras offers the opportunity to shorten acquisition time and provide accurate attenuation correction and fusion imaging. Additional advantages are represented by increased specificity and accurate depiction of localization of disease and of possible involvement of adjacent tissues. Moreover, SPECT-CT imaging is especially suited to support minimally invasive surgery, as well as to precisely define the diagnostic and prognostic profile of cardiovascular patients. Giuliano Mariani et. al., *A review on the clinical uses of SPECT/CT*, 37 J NUCL MED MOL IMAGING 1960 (2010). Exhibit C, p. 57.

13. A primary benefit of SPECT-CT cardiac imaging is the increased efficiency it provides. Recently developed myocardial perfusion cameras have come equipped with novel detector and collimator geometries that improve detection efficiency as well as improve spatial resolution for myocardial perfusion imaging. Youngho Seo et. al., *Technological Development and Advances in SPECT/CT*, 38 SEMIN NUCL MED 177, 12. Exhibit C, p. 106.
14. The costs related to the proposed project are associated with and included in \$450 million funding from the Hospital's previously approved Master Facility Plan CON (Docket #08-31284) and will be financed through a combination of debt, philanthropy and cash from operations.

**TABLE 2
THE STAMFORD HOSPITAL'S TOTAL CAPITAL EXPENDITURE**

Medical Equipment Purchase	\$539,308
Construction/Renovation	\$225,000
Total Capital Expenditure (TCE)	\$764,308

Exhibit A, pp. 26, 27.

15. Incremental losses are projected in each of the next three fiscal years (FY) due to other operating expenses and depreciation.

**TABLE 3
THE STAMFORD HOSPITAL'S PROJECTED INCREMENTAL REVENUES AND EXPENSES**

	FY 2016	FY 2017	FY 2018
Revenue from Operations	-	-	-
Total Operating Expenses*	\$44,000	\$125,000	\$125,000
Gain/(Loss) from Operations	(\$44,000)	(\$125,000)	(\$125,000)

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

16. Despite incremental losses, the Hospital projects overall operational gains from FY2016 through FY2018 following implementation of the proposal.

**TABLE 4
THE STAMFORD HOSPITAL'S PROJECTED REVENUES & EXPENDITURES WITH CON**

	FY 2016	FY 2017	FY 2018
Revenue from Operations	\$518,178	\$540,710	\$564,061
Total Operating Expenses*	\$468,886	\$503,051	\$521,290
Gain/(Loss) from Operations**	\$49,292	\$37,660	\$42,771

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.

** Decreases in operational gains from FY16 to FY18 are due to depreciation and the cost of renovating the space.

Exhibit A, pp. 29, 200.

17. No change in the patient population mix is projected by the Hospital.

**TABLE 5
THE STAMFORD HOSPITAL'S CURRENT & PROJECTED PAYER MIX**

Payer	Most Recently Completed FY 2014**		FY 2015**		FY 2016**		Projected			
	Volume	%	Volume	%	Volume	%	FY 2017**		FY 2018**	
							Volume	%	Volume	%
Medicare*	1,065	54%	1,073	54%	1,091	54%	1,091	54%	1,091	54%
Medicaid*	259	13%	242	12%	232	12%	232	12%	232	12%
CHAMPUS & TriCare	1	0%	0	0%	0	0%	0	0%	0	0%
Total Government	1,325	67%	1,315	66%	1,323	66%	1,323	66%	1,323	66%
Commercial Insurers	595	30%	640	32%	654	33%	654	33%	654	33%
Uninsured	52	3%	29	1%	30	1%	30	1%	30	1%
Workers Compensation	1	0%	0	0%	4	0%	4	0%	4	0%
Total Non- Government	648	33%	674	34%	689	34%	689	34%	689	34%
Total Payer Mix	1,973	100%	1,989	100%	2,012	100%	2,012	100%	2,012	100%

Exhibit. A, p. 28.

17. 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))
18. This CON application is consistent with the Statewide Health Care Facilities and Services Plan. (Conn. Gen. Stat. § 19a-639(a)(2))
19. The Applicant has established that there is a clear public need for its proposal. (Conn. Gen. Stat. § 19a-639(a)(3))
20. The Applicant has satisfactorily demonstrated that its proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4))
21. The Applicant has satisfactorily demonstrated that access to services will be maintained and quality of health care delivery in the region as well as cost effectiveness will be improved. (Conn. Gen. Stat. § 19a-639(a)(5))
22. 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))
23. 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))

24. The Applicant's historical utilization in the service area supports this proposal. (Conn. Gen. Stat. § 19a-639(a)(8))
25. 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))
26. The Applicant has satisfactorily demonstrated that the proposal will not result in a reduction or change in access to services for Medicaid recipients or indigent persons. (Conn. Gen. Stat. § 19a-639(a)(10))
27. The Applicant has satisfactorily demonstrated that the proposal will not result in a negative impact on the diversity of health care providers in the area. (Conn. Gen. Stat. § 19a-639(a)(11))
28. The Applicant has satisfactorily demonstrated that its 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 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).

The Stamford Hospital (“Hospital” or “Applicant”), a 305-bed not-for-profit general hospital in Stamford, is seeking authorization for the acquisition of a 4-slice GE Optima NM/CT 640 SPECT-CT camera to replace its 2006 GE Ventri nuclear camera that is at the end of its useful life. *FF1*, 3. The Hospital currently operates five nuclear cameras at its main campus and off-site locations. *FF2*.

Acquiring the SPECT-CT and locating it within the new Heart and Vascular Institute (HVI) suite will facilitate the Hospital’s goal of creating a “one-stop” environment with integrated interventional and diagnostic cardiac services. *FF4*, 6. A one-stop model will help increase speed of diagnosis and treatment, facilitate the development of clinical pathways and foster collaboration between interventional cardiologists and their non-interventional colleagues. The HVI will provide elective and emergency angioplasty procedures, pacemaker/defibrillator implantation, electrophysiology, as well as vascular and peripheral stenting. *FF6*.

The CT component of the proposed GE Optima Camera delivers attenuation correction for myocardial perfusion imaging studies, which improves diagnostic accuracy. Nuclear cardiology imaging has inherent limitation due to the variation and density of tissue within the body. Variations in tissue can create shadows and attenuation artifacts in the resulting images. *FF7*. The CT component of the proposed GE Optima camera will remove such artifacts, decreasing false positive results and eliminating unnecessary follow-up testing. *FF7*. Additionally, patients who undergo myocardial perfusion testing without attenuation correction are required to be scanned twice—initially in a supine position and then in the prone state, which may be uncomfortable and unsteady for some patients and produce unclear images that necessitate additional scans. *FF8*. The proposed camera will provide superior image quality in less time and reduce the number of required scans and, in turn, reduce patients’ radiation exposure. *FF8*. Based on the foregoing, the proposal will result in improved quality of care.

The Applicant provided numerous scholarly articles that support the benefits of a SPECT-CT camera over a SPECT camera in the evaluation of coronary artery disease. The quality of scans produced by the SPECT-CT cameras is significantly superior to the SPECT camera. The SPECT-CT’s enhanced attenuation correction allows for improved diagnostic accuracy and risk stratification. *FF11*. Moreover, SPECT-CT imaging is suited to precisely define the diagnostic and prognostic profile of cardiovascular patients. *FF12*. With increased accuracy comes increased efficiency that the SPECT-CT provides. Recent advances in SPECT-CT have allowed perfusion cameras to come equipped with novel detector and collimator geometries that improve detection efficiency as well as improve spatial resolution for myocardial perfusion imaging. *FF13*. The SPECT-CT camera will enable the most at-risk patients to be identified more quickly.

Based on historical utilization, the Applicant has conservatively projected stable utilization from FY2016 to FY2018. *FF10*. There is no expected change in the patient population as the Applicant is upgrading old existing imaging equipment and there will be no change in the patient population mix. The Applicant will continue to provide the same access to care to Medicaid patients. *FF9,17*.

The SPECT-CT acquisition cost was included in \$450 million funding from the Hospital's previously approved 2008 Master Facility Plan CON and will be financed through a combination of debt, philanthropy and cash from operations. *FF14*. Despite incremental losses, the Applicant projects overall operational gains of \$49,292,000, \$37,660,000 and \$42,771,000 in FY16, FY17 and FY18, respectively, with the declining gains attributable to depreciation and other operating costs. *FF15,16*. Therefore, OHCA finds the proposal is financially feasible.

The Applicant has satisfactorily demonstrated clear public need for this proposal as access to care will be maintained and quality of care will be improved. These two benefits are consistent with the Statewide Health Care Facilities and Services Plan.

Order

Based upon the foregoing Findings of Fact and Discussion, the Certificate of Need application of The Stamford Hospital for the acquisition of a SPECT-CT camera 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

December 15, 2015
Date

Janet M. Brancifort
Janet M. Brancifort, RRT, MPH
Deputy Commissioner