

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: St. Vincent's Medical Center
2800 Main Street
Bridgeport, Connecticut 06606

Docket Number: 15-32056-CON

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

Project Description: St. Vincent's Medical Center ("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 December 24, 2015, the Office of Health Care Access ("OHCA") received the initial 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 Connecticut Post* (Bridgeport) on November 4, 5 and 6, 2015. The application was deemed complete on March 21, 2016. 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). Deputy Commissioner Brancifort considered the entire record in this matter.



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Findings of Fact and Conclusions of Law

1. The Applicant is a 473¹ bed not-for-profit general hospital located at 2800 Main Street, Bridgeport, Connecticut. Exhibit A, p. 42.
2. The Applicant currently operates one nuclear camera at its main hospital campus.

Provider and Location	Equipment	Hours of Operation	Utilization FY15
St. Vincent's Medical Center 2800 Main St. Bridgeport, CT 06606	GE Millennium MPR/MPS SPECT	M-F 7 AM to 5 PM Sat., Sun. and evenings on call	910

Exhibit. A, pp. 5, 17, 19.

3. The GE Millennium, located at the Applicant's main hospital campus, is more than nine years old and nearing the end of its useful life. The Applicant proposes replacing it with a 4-slice GE Optima NM/CT 640 SPECT-CT. Exhibit A, pp. 5, 6, 24.
4. There are no other cameras with similar CT-capabilities located in the Applicant's service area, which includes Bridgeport, Fairfield, Easton, Monroe, Trumbull, Shelton and Stratford. Exhibit A, pp. 8, 9.
5. The proposed SPECT-CT will offer a more reliable way to accurately diagnose functional abnormalities. Exhibit A, p. 6.
6. A SPECT-CT camera will allow for faster diagnosis, more accurate anatomical localization and attenuation correction while decreasing radiation exposure, leading to improved quality of patient care. A study comparing the benefits of a SPECT-CT over a SPECT resulted in decreased false positives (21% vs. 58%) and increased true positive results (63% vs. 22%). Exhibit A, pp. 8, 11; Nicholas Patchett, et. al., New Generation General-Purpose SPECT/CT Myocardial Perfusion Imaging Improves Diagnostic Accuracy and Reduces Radiation Exposure Compared to Traditional SPECT, Section of Cardiovascular Medicine. Exhibit A, p. 93.
7. SPECT-CT increases image accuracy while decreasing the need for additional exams in different test locations, thus reducing patient wait times, travel and out of network costs. Exhibit A, p. 11; Exhibit C, p. 195.
8. SPECT, in combination with CT, enables a direct correlation of anatomic information and functional information, resulting in better localization and definition of scintigraphic findings and a reduction in indeterminate findings. The superiority of SPECT-CT over SPECT has been demonstrated for the imaging of benign and malignant skeletal diseases, thyroid cancer, neuroendocrine cancer, parathyroid adenoma and mapping of sentinel lymph nodes in the head, neck and pelvic region. SPECT-CT in cardiac imaging improves upon diagnosis as well as illustrative visualization. Furthermore, it may be beneficial in identifying candidates for more intensive prevention or risk factor modification strategies

¹ Excludes 47 bassinets.

and those who would benefit from coronary angiography and revascularization. Andreas K. Buck, et. al., *SPECT/CT*, J NUCL MED 49, 8. Exhibit A, pp. 95-106.

9. The proposed SPECT-CT will serve the oncology, cardiology and the gastroenterology departments, as well as provide diagnostics for conditions such as thyroid disorders, brain disorders and inflammations and infections. Exhibit A, p. 8.
10. The Hospital's Community Health Needs Assessment identified cardiovascular disease and cancer to be among the leading causes of death in the Hospital's service area Exhibit A, p. 9.
11. The Hospital's primary service area includes Bridgeport, the state's most impoverished and diverse urban center. The Statewide Health Care Facilities and Services Plan notes that Black non-Hispanics and Hispanics are more likely than non-Hispanics to have a potentially preventable hospitalization or avoidable ED visit. As the leading causes of emergency department admissions are heart and digestive diseases, the proposed SPECT-CT will allow the area's underserved minority population access to clinical testing that may prevent hospitalizations or ED visits through providing more accurate diagnoses. Exhibit A, pp. 8-9.
12. Despite a decline in volume since FY2013, the Applicant projects volume to level off with the acquisition of the SPECT-CT, due to its improved image quality.

**TABLE 1
APPLICANT'S HISTORIC AND PROJECTED UTILIZATION**

	Actual			Projected			
	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019
Proposed GE Optima	n/a	n/a	n/a	n/a	900	900	900
Existing GE Millennium	1154	1090	910	900	n/a	n/a	n/a
Total	1154	1090	910	900	900	900	900

Volume has declined due to the age of the existing equipment along with diminished quality in imaging. Exhibit A, pp. 19, 26.

13. The cost for diagnostic imaging for patients will remain the same as on the existing camera. Exhibit A, p. 11.
14. The costs related to the proposed project have been approved by the Applicant's capital committee to fully fund the project with capital dollars. Additional funding through fundraising, the incurring of debt or through current operations will not be necessary.

**TABLE 3
APPLICANT'S CAPITAL EXPENDITURE**

Medical Equipment Purchase	\$547,797
Construction/Renovation	\$204,552
Total Capital Expenditure (TCE)	\$752,349

Exhibit A, pp. 12, 18; Exhibit C, p. 197.

15. Incremental losses are projected in each of the three fiscal years (FY) following implementation of the proposal, due to depreciation.

**TABLE 4
APPLICANT'S PROJECTED INCREMENTAL REVENUES AND EXPENSES**

	FY 2017	FY 2018	FY 2019
Revenue from Operations	-	-	-
Total Operating Expenses*	\$123,000	\$123,000	\$123,000
Gain/(Loss) from Operations	(\$123,000)	(\$123,000)	(\$123,000)

*Operating expenses represent the change in depreciation amount, which is a non-cash expense. Exhibit A, p. 193; Exhibit C, p. 197.

16. The new SPECT-CT will serve the same patient population as the SPECT camera being replaced. Exhibit A, p. 9.
17. No change in the patient population mix is projected by the Applicant.

**TABLE 6
APPLICANT'S CURRENT & PROJECTED PAYER MIX**

Payer	Most Recently Completed FY 2015		Projected							
			FY 2016		FY 2017		FY 2018		FY 2019	
	Volume	%	Volume	%	Volume	%	Volume	%	Volume	%
Medicare	418	46%	405	45%	405	45%	405	45%	405	45%
Medicaid	218	24%	207	23%	207	23%	207	23%	207	23%
CHAMPUS & TriCare	0	0%	0	0%	0	0%	0	0%	0	0%
Total Government	636	70%	612	68%	612	68%	612	68%	612	68%
Commercial Insurers	228	25%	243	27%	243	27%	243	27%	243	27%
Uninsured	41	4.5%	40	4.5%	40	4.5%	40	4.5%	40	4.5%
Workers Compensation	5	0.5%	5	0.5%	5	0.5%	5	0.5%	5	0.5%
Total Non-Government	274	30%	288	32%	288	32%	288	32%	288	32%
Total Payer Mix	910		900		900	100%	900	100%	900	100%

Exhibit. A, p. 20; Exhibit C, p. 195.

18. There will be no gap in service as the SPECT-CT will be housed in a new location within the Radiology Department, allowing the current SPECT camera to be utilized during construction. Exhibit A, pp. 6, 9, Exhibit C, p. 195.

19. 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))
20. This CON application is consistent with the Statewide Health Care Facilities and Services Plan. (Conn. Gen. Stat. § 19a-639(a)(2))
21. The Applicant has established that there is a clear public need for the proposal. (Conn. Gen. Stat. § 19a-639(a)(3))
22. The Applicant has satisfactorily demonstrated that the proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4))
23. 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))
24. 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, including access to services by Medicaid recipients and indigent persons. (Conn. Gen. Stat. § 19a-639(a)(6))
25. The Applicant has satisfactorily identified the population to be served and that this population has a need for the proposal. (Conn. Gen. Stat. § 19a-639(a)(7))
26. The Applicant's historical utilization in the service area supports this proposal. (Conn. Gen. Stat. § 19a-639(a)(8))
27. 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))
28. 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))
29. The Applicant has satisfactorily demonstrated that the proposal will not negatively impact the diversity of health care providers in the area. (Conn. Gen. Stat. § 19a-639(a)(11))
30. 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 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).

St. Vincent's Medical Center ("Hospital" or "Applicant"), a 473-bed not-for-profit general hospital in Bridgeport, is seeking authorization for the acquisition of a 4-slice GE Optima NM/CT 640 SPECT-CT camera to replace its nuclear camera that is at the end of its useful life. *FF1,3*. The Hospital currently operates one nuclear camera at its main campus. *FF2*. There are no other cameras within the Applicant's service area that offer the capabilities of a SPECT-CT. *FF4*.

The SPECT-CT will enable direct correlation of anatomic and functional information, resulting in a reduction in indeterminate findings. *FF8*. It will also allow for more reliable and faster diagnosis, more accurate anatomical localization and provide attenuation correction, while decreasing radiation exposure. *FF5,6*. SPECT-CT increases image accuracy while decreasing the need for additional exams in different test locations, thus reducing patient wait times, travel and out of network costs. *FF7*. The superiority of SPECT-CT over SPECT has been demonstrated for the imaging of skeletal diseases, cancer, parathyroid adenoma and sentinel lymph nodes mapping. Additionally, it may further benefit patients by identifying candidates for more extensive prevention or risk factor modification strategies or those needing coronary angiography. *FF8*.

The proposed SPECT-CT will serve the oncology, cardiology and the gastroenterology departments. *FF9*. The Hospital's Community Health Needs Assessment identified cardiovascular disease and cancer to be among the leading causes of death in the Hospital's service area. *FF10*. The Applicant's primary service area includes Bridgeport, the state's most impoverished and diverse urban center. The Statewide Health Care Facilities and Services Plan notes that Black non-Hispanics and Hispanics are more likely than non-Hispanics to have a potentially preventable hospitalization or avoidable ED visit. As the leading causes of emergency department admissions are heart and digestive diseases, the proposed SPECT-CT will allow the area's underserved minority population access to clinical testing that may prevent hospitalizations or ED visits through providing more accurate diagnoses. *FF11*. Patient outcomes may be improved by enabling more accurate identification and treatment of diseases, thus preventing long term hospitalization as well as lowering the potential for ED visits. Together, these multiple advantages will improve the quality of care delivered to patients in the area.

The SPECT-CT will serve the same patient population and no change in the patient population mix, including Medicaid patients, is projected by the Applicant. *FF16,17*. Additionally, the cost for diagnostic imaging for patients will remain the same as on existing equipment. *FF13*. As a result, the proposal will have no negative impact on access to or the cost of care to patients.

While the Applicant anticipates incremental losses of \$123,000 in FY17, FY18 and in FY19, these losses are attributable to depreciation and costs associated with renovating the SPECT-CT space. *FF15*. The costs related to the proposed project have been approved by the Applicant's capital committee to fully fund the project with capital dollars. Additional funding through fundraising, the incurring of debt or through current operations will not be necessary. *FF14*. Therefore, OHCA finds the proposal 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 St. Vincent's Medical Center 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

5/20/2016
Date

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