



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

December 8, 2010

IN THE MATTER OF:

An Application for a Certificate of Need
filed Pursuant to Section 19a-639, C.G.S. by:

Notice of Final Decision
Office of Health Care Access
Docket Number: 10-31614-CON

Saint Francis Hospital and Medical Center

**Acquisition of a Single Photon Emission
Computed Tomography-Computed
Tomography Camera**

To:

Christopher Hartley
Senior Vice President, Planning & Facilities Development
Saint Francis Hospital and Medical Center
114 Woodland Street
Hartford, CT 06105

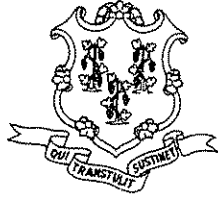
Dear Mr. Hartley:

This letter will serve as notice of the Final Decision of the Office of Health Care Access in the above matter, as provided by Sections 19a-639, C.G.S. On December 8, 2010, 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.

A handwritten signature in black ink, appearing to read "Kimberly R. Martone", written over a horizontal line.

Kimberly R. Martone
Director of Operations

KRM: cgc
Enclosure



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

Final Decision

Applicant: Saint Francis Hospital and Medical Center

Docket Number: 10-31614-CON

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

Project Description: Saint Francis Hospital and Medical Center (“Applicant”) is proposing to acquire a Single Photon Emission Computed Tomography – Computed Tomography camera (“SPECT-CT”) to be located at 114 Woodland Street, in Hartford, Connecticut with an associated total capital expenditure of \$774,000.

Procedural History: On November 10, 2010, the Office of Health Care Access (“OHCA”) received a Certificate of Need (“CON”) application for the above-referenced project.

A notice to the public concerning OHCA’s receipt of the Applicant’s CON application was published in *The Hartford Courant*, on May 25, 2010. OHCA received no responses from the public concerning the Applicant’s proposal. Pursuant to Public Act 09-3 § 10, three individuals or an individual representing an entity with five or more people had until December 1, 2010, the twenty-first calendar day following the filing of the Applicant’s CON Application, to request that OHCA hold a public hearing on the Applicant’s proposal. OHCA received no hearing requests from the public.

OHCA’s authority to review, approve, modify, or deny this proposal is established by Public Act 09-3 § 10. The provisions of this section, as well as the principles and guidelines set forth in Public Act 08-14 §1, were fully considered by OHCA in its review.

FINDINGS OF FACT

1. The Applicant is a tertiary level academic facility located at 114 Woodland Street, in Hartford, Connecticut, and is proposing to acquire a SPECT-CT to replace its SPECT¹ camera. *(August 11, 2010, CON application, pages 3, 4 and 5)*
2. The SPECT camera provides cardiac SPECT imaging on bariatric patients greater than 300 pounds and imaging for brain applications as well as other body imaging applications where high imaging quality resolution and accurate anatomic localization is critical. *(August 11, 2010, CON application, page 5)*
3. The SPECT camera is 13 years old and at the end of its useful life. The manufacturer is no longer able to offer full service support to the SPECT camera due to the unavailability of parts and difficulty in training staff on this particular piece of equipment. *(August 11, 2010, CON application, page 4, Attachment 1, page 21)*
4. The target population includes, but is not limited to, bariatric patients hospitalized with chest pain. *(August 11, 2010, CON application, page 7)*
5. The Applicant's bariatric patients are currently imaged on a small nuclear medicine gamma camera that is not capable of attenuation correction. *(August 11, 2010, CON application, page 7)*
6. Existing patients sometimes experience an increased length of time in the hospital due to lack of CT anatomic localization particularly on bariatric cardiac patients. Without CT attenuation correction, these patients must be administered higher doses of radiotracer and imaged over two days. *(August 11, 2010, CON application, pages 7, 14-15)*
7. Additionally, the studies on the SPECT camera are not as detailed in image quality making accurate interpretations difficult. *(August 11, 2010, CON application, page 14)*
8. The downtime and technical issues with the SPECT camera have resulted in a high volume of cardiac studies being done on the other two cardiac capable cameras in the department, Cardio MD 1 and Cardio MD 2. Shifting the volumes to the other cameras, however, has caused difficulty in coordinating studies of hospitalized patients and resulted in increased lengths of stay. *(August 11, 2010, CON application, page 9)*
9. SPECT-CT cameras have been in service for over half a decade, are being used routinely, and represent an evolution from the current SPECT-only capable gamma camera. *(August 11, 2010, CON application, page 5)*

¹ Single Photon Emission Computed Tomography (SPECT) is a variation of computed tomography in which the ray sum is defined by the collimator holes on the gamma ray detector rotating around the patient. SPECT units usually consist of large crystal gamma cameras mounted on a gantry that permits rotation of the camera around the patient. Multiple detectors are used to reduce the imaging time. *(Moby's Medical Dictionary. Missouri: Mosby, Inc., 2006. Print)*

10. The SPECT-CT utilizes a CT scanner for attenuation correction and anatomic localization which help improve diagnostic accuracy. *(August 11, 2010, CON application, page 7)*
11. An “attenuation map” of the patient is created using a CT scanner that is mated to the SPECT camera that obtains a CT image at low dose. The data is then used to correct for overlying attenuation abnormalities providing a more accurate myocardial perfusion image than the SPECT camera alone. *(August 11, 2010, CON application, page 15)*
12. The proposed SPECT-CT will provide the following benefits to the Applicant and the patients:
 - Support patients weighing up to 500 pounds;
 - Enhance the attenuation correction and anatomic localization capabilities of the SPECT studies;
 - Increase the accuracy of myocardial perfusion imaging which in turn will reduce the number of false positive studies;
 - Allow for faster performance of a myocardial perfusion study with a lower dose of radiotracer administered to the patient. *(August 11, 2010, CON application, pages 5 and 15, and Attachment 9-Vendor's Quote, page 263)*
13. The SPECT-CT also allows for the accurate determination of the location in the body of the administered radiotracer, which is necessary for minimally invasive surgical procedures and therapies, and the accurate localization of sentinel lymph nodes, parathyroid gland, thyroid nodules, and metastases in the body, which eliminates the necessity for large exploratory procedures. *(August 11, 2010, CON application, pages 15-16)*
14. Replacing the SPECT with a SPECT-CT will improve the accessibility and quality of care provided to the Applicant's patients.
15. The Applicant performed approximately 2,953 cardiac nuclear medicine tests in FY 2010 on its Cardio MD 1 and Cardio MD 2, and 50% of these patients met the definition of a patient suitable for SPECT-CT imaging. *(August 11, 2010, CON application, page 7, Attachment 2, page 24)*

16. The following represents the Applicant's historical and current total nuclear medicine department volume by scanner:

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

Camera Equipment	Actual Volume (Last 3 Completed FYs)			Actual Volume
	FY 2007	FY 2008	FY 2009	FY 2010
Cardio MD 1	1,672	1,846	1,677	1,331
Cardio MD 2	1,734	1,852	1,669	1,298
Total Cardio MD 1 & 2	3,406	3,698	3,349	2,629
SPECT	793	779	759	760
Other*	1,955	2,265	2,282	2,372
Total volume	6,514	6,742	6,390	5,761

Source: GE ImageCAST (Radiology/Imaging Information System)

Note: The Applicant's fiscal year runs from Oct 1st through Sept 30th.

*Other represents volume from the following cameras: Argus, Solus 1, and Solus 2.

(August 11, 2010, CON application, pages 9-10, and Attachments 2 and 3, pages 24 and 26, and Completeness Responses, September 9, 2010, Attachment 11, page 298)

17. The declining volumes for the SPECT camera between FY 2008 and FY2010 are attributable to the increase in downtime which results in the shift of volume to other cameras to accommodate patient care requirements and to the global shortage of radioisotope material. (August 11, 2010, CON application, page 10, and November 10, Completeness Responses, page 302)
18. The following represents the Applicant's total projected nuclear medicine department volume by scanner:

Table 3: Projected Nuclear Medicine Department Volume by Scanner

Camera Equipment	Projected Volume (First 3 Full years of Operations)		
	FY 2011	FY 2012	FY 2013
Cardio MD 1	712	719	726
Cardio MD 2	717	724	731
Total Cardio MD 1 & 2	1,429	1,443	1,457
SPECT-CT	2,235	2,258	2,280
Other*	2,543	2,568	2,594
Total	6,207	6,269	6,331

Source: GE ImageCAST (Radiology/Imaging Information System)

*Other represents volume from the following cameras: Argus, Solus 1, and Solus 2

(November 10, 2010, Completeness Responses, Attachment 12, page 303)

19. The Applicant will shift some volume from its cardio cameras as some studies will be better suited for the new SPECT-CT, particularly bariatric cardiac patients. (August 11, 2010, CON application, page 9)

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 4: Proposal's Total Capital Expenditure

Imaging Equipment	\$614,000
Building Work-Renovation	160,000
Total Capital Expenditure	\$774,000

(August 11, 2010, CON application, page 17, and Attachments 9 and 10, pages 255 and 294)

22. The Applicant will fund the project through funded depreciation.
(August 11, 2010, CON application, page 18)
23. The Applicant's FY 2009 Audited Financial Statements on file with OHCA indicates that their total income from operations for FY 2009 is \$17.9 million.
(August 11, 2010, CON application, page 17, and Saint Francis Hospital and Medical Center FY 2009 Audited Financial Statements)
24. The Applicant projects the following incremental gains:

Table 5: Financial Projections Incremental to the Project

Description	FY 2011	FY 2012	FY 2013
Incremental Revenue from Operations	\$1,125,990	\$1,267,816	\$1,425,486
Incremental Total Operating Expense	132,696	204,692	211,734
Incremental Gain from Operations	\$993,294	\$1,063,124	\$1,213,752

(November 10, 2010, Completeness Responses, Financial Attachment 1, page 305)

25. The Applicant reported the following payer mix based on patient population as follows:

Table 6: Current & Three-Year Projected Payer Mix

Payer	Current FY 2010	FY2011	FY2012	FY2013
Medicare*	37.9%	37.9%	37.9%	37.9%
Medical Assistance**	20.0%	20.1%	20.1%	20.1%
CHAMPUS & TriCare	0.3%	0.3%	0.00%	0.00%
Total Government	58.3%	58.3%	58.3%	58.3%
Commercial Insurers*	39.2%	39.3%	39.3%	39.3%
Uninsured	1.5%	1.5%	1.5%	1.5%
Workers Comp.	1.0%	1.0%	1.0%	1.0%
Total Non-Government	41.7%	41.7%	41.7%	41.7%
Total Payer Mix	100.0%	100.00%	100.00%	100.00%

*Includes managed care activity

**Includes Medicaid, Medicaid Managed care and SAGA

(August 11, 2010, CON application, page 284, and September 9, 2010, Completeness Responses, page 296)

26. The proposal is financially feasible based upon the Applicant's projections with respect to incremental operating gains.
27. The proposal is consistent with the Applicant's long-range plan to continue to be a high quality health care institution by developing a model of better care where the patients' entire healthcare needs are provided and coordinated over time from the patient's point of view. (*August 11, 2010, CON application, page 20*)

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 Public Act 08-14 §1, 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 a tertiary level academic facility located in Hartford, Connecticut, that is proposing to acquire a SPECT-CT to replace its SPECT camera. FF1. The target population includes, but is not limited to, bariatric patients hospitalized with chest pain. FF4. The Applicant's current SPECT camera is 13 years old and at the end of its useful life. FF3. The manufacturer will no longer be able to offer full service support to the SPECT camera due to the unavailability of parts and difficulty in training staff on this particular piece of equipment. FF3. The Applicant's bariatric patients are currently imaged on a small nuclear medicine gamma camera that is not capable of attenuation correction. FF5. Without the CT attenuation correction, these patients must be administered a higher dose of radiotracer and imaged over two days. FF6. The studies on the SPECT camera are also not as detailed in image quality making accurate interpretations difficult. FF7.

In addition to having the capability to support patients weighing up to 500 pounds, the proposed SPECT-CT will enhance the attenuation correction and anatomic localization capabilities of SPECT studies, will reduce the number of false positive studies and will allow the applicant to perform a myocardial perfusion study faster with a lower dose of radiotracer administered to the patient. FF12. The SPECT-CT also allows for the accurate determination of the location in the body of the administered radiotracer, which is necessary for minimally invasive surgical procedures and therapies, and the accurate localization of sentinel lymph nodes, parathyroid gland, thyroid nodules, and metastases in the body, which eliminates the necessity for large exploratory procedures. FF13. 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.

The technical issues with the SPECT camera have resulted in high volume of cardiac studies being done on the other two cardiac capable cameras in the department, Cardio MD 1 and Cardio MD 2. FF8. The Applicant performed approximately 2,953 cardiac nuclear medicine tests in FY 2010 on its Cardio MD 1 and Cardio MD 2, and 50% of these patients met the definition of a patient suitable for SPECT-CT imaging. FF15. The Applicant will shift some volume from its cardio cameras as some studies will be better suited for the new SPECT-CT, particularly bariatric cardiac patients. FF19. 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 \$774,000. FF21. The Applicant's FY 2009 Audited Financial Statements indicates that their total income from operations for FY 2009 is \$17.9 million. FF23. The Applicant is projecting incremental gains for this proposal. FF24. Accordingly, OHCA finds that the project is financial feasible.

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

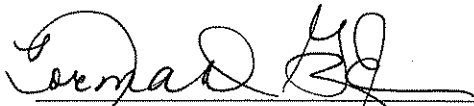
Order

Based upon the foregoing Findings and Discussion, the Certificate of Need application of Saint Francis Hospital and Medical Center for the acquisition of a SPECT-CT Camera to be located at 114 Woodland Street, in Hartford, Connecticut with an associated total capital expenditure of \$774,000, is hereby GRANTED.

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

By Order of

12.8.10
Date


Norma D. Gyle, R.N., Ph.D.
Deputy Commissioner
Office of Health Care Access