

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

OFFICE OF COMMISSIONER

November 25, 2009

IN THE MATTER OF:

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

St. Vincent's Medical Center

Notice of Final Decision
Office of Health Care Access
Docket Number: 09-31327-CON

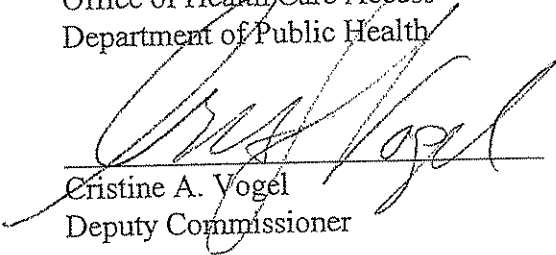
**Acquisition of Positron Emission
Tomography/Computed Tomography
Scanner**

To: Rachel Giliotti
Administrative Director
Department of Radiology
St. Vincent's Medical Center
2800 Main Street
Bridgeport, CT 06606

Dear Ms. Giliotti:

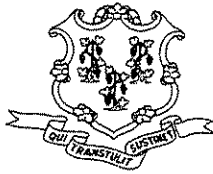
This letter will serve as notice of the Final Decision of the Office of Health Care Access in the above matter, as provided by Section 19a-639, C.G.S. On November 25, 2009, the Final Decision was rendered as the finding and order of the Office of Health Care Access. A copy of the Final Decision is attached hereto for your information.

By Order of the Division of
Office of Health Care Access
Department of Public Health


Cristine A. Vogel
Deputy Commissioner

CAV: rac:
Enclosure





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

Final Decision

Applicant: St. Vincent's Medical Center

Docket Number: 09-31327-CON

Project Title: Acquisition of Fixed Positron Emission Tomography Computed Tomography ("PET/CT") Scanner

Statutory Reference: Section 19a-639 of the Connecticut General Statutes

Filing Date: September 1, 2009

Public Hearing Date: October 27, 2009

Presiding Officer: Cristine A. Vogel, Deputy Commissioner

Intervenor: Robert D. Russo, M.D. and Associates Radiology, P.C.

Decision Date: November 25, 2009

Default Date: November 30, 2009

Staff: Ronald Ciesones and Steven Lazarus

Project Description: St. Vincent's Medical Center proposes to acquire a fixed positron emission tomography computed tomography ("PET/CT") scanner to replace its existing mobile PET/CT scanner on the Hospital's main campus. The proposed total capital expenditure of \$2,698,450 will be funded with donor contributions.

Nature of Proceedings: On September 1, 2009, the Office of Health Care Access ("OHCA") received the Certificate of Need ("CON") application of St. Vincent's Medical Center ("Hospital") seeking authorization to acquire a fixed positron emission tomography computed tomography ("PET/CT") scanner to replace its existing mobile PET/CT scanner on the Hospital's main campus. The proposed total capital expenditure of \$2,698,450 will be funded with donor contributions. The Hospital is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes ("C.G.S.").

Pursuant to Section 19a-639, C.G.S., a notice to the public concerning OHCA's receipt of the Hospital's Letter of Intent was published on March 26, 2009. Pursuant to Section 19a-639, C.G.S., three individuals or an individual representing an entity with five or more people had until July 29, 2009, the twenty-first calendar day following the filing of the Hospital's CON application, to request that OHCA hold a public hearing on the Hospital's proposal. OHCA received a response from the public concerning the Hospital's proposal on July 7, 2009.

On October 22, 2009, OHCA received a request for Intervenor status with full rights from the Robert D. Russo, M.D. and Associates Radiology, P.C. On October 26, 2009, OHCA granted Intervenor status with full rights to the Robert D. Russo, M.D. and Associates Radiology, P.C.

Pursuant to Section 19a-639, C.G.S., a public hearing regarding the CON application was held on October 27, 2009. On October 8, 2009 the Hospital were notified of the date, time, and place of the hearing. On October 8, 2009, a notice to the public announcing the hearing was published in *Connecticut Post*. Deputy Commissioner Cristine A. Vogel served as Presiding Officer. The hearing was conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the Connecticut General Statutes) and Section 19a-639, C.G.S.

OHCA's authority to review and approve, modify or deny this proposal is established by Section 19a-639, C.G.S. The provisions of this section as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were fully considered by OHCA in its review.

Findings of Fact

Clear Public Need

Impact on the Hospital's Current Utilization Statistics Contribution of the Proposal to the Accessibility and Quality of Health Care Delivery in the Region

1. It is found that St. Vincent's Medical Center ("Hospital" or "Medical Center") is a non-profit acute care general hospital, whose main campus is located at 2800 Main Street in Bridgeport, Connecticut. (*March 11, 2009, Letter of Intent, page 1*)
2. A Certificate of Need ("CON") was initially granted by the Office of Health Care Access ("OHCA") on June 11, 2001, under Docket Number ("DN") 00-509 to Bridgeport Hospital, Danbury Hospital, Greenwich Hospital, Norwalk Hospital, Saint Vincent's Medical Center and Stamford Hospital ("six Hospitals") for the establishment of positron emission tomography ("PET") scanning services at the six Hospitals through the leasing of one mobile PET scanner. (*June 11, 2001, CON Final Decision, Docket Number 00-509 and August 11, 2003, CON Final Decision, Docket Number 02-584*)
3. On August 11, 2003, under DN 02-584, OHCA authorized a CON approval for the six Hospitals, together known as the Fairfield County Mobile PET Collaborative, to upgrade the mobile unit from a PET modality to a combined positron emission tomography computed tomography ("PET/CT") modality and to provide mobile PET/CT services as part of a consortium. (*August 11, 2003, CON Final Decision, Docket Number 02-584, page 19*)
4. On April 20, 2007, under DN 06-30823-CON, OHCA authorized approval for the Hospital to undertake a master facility project, which included the expansion of the

Emergency Department (“ED”), construction of a new ambulatory cancer center, reorganization of outpatient services, construction of an ambulatory procedures area and cardiovascular center, construction of a new parking garage, and other infrastructure and facility improvements. *(April 20, 2007, CON Final Decision, Docket Number 06-30823)*

5. The Hospital also proposes a reconfiguration that includes moving a 64-slice CT scanner to the ED in December, 2009 and leaving a 16-slice CT scanner in the Medical Center’s Radiology Department. *(July 8, 2009, Initial CON Application, page 11)*
6. The Hospital indicates that the current mobile PET/CT scanner offers services one day a week, on Thursdays from 8:00 a.m. to 4:30 p.m. with the option to add a half day on Monday as needed, which are provided on the main campus through a contractual arrangement with Alliance Imaging. *(July 8, 2009, Initial CON Application, pages 9, 12 & 13)*
7. The Hospital contends that the following table identifies the historical increase in PET scan volume through fiscal year 2009. *(September 1, 2009, Completeness Response, page 336)*

Table 1: Hospital’s Current PET and/or PET/CT Scans

	FY 2006	FY 2007	FY 2008	FY 2009*
PET & PET/CT Scans	299	353	366	375
Annual % Increase	**	18.1%	3.7%	1.9%

*The FY 2009 amount is the year to date volume through June 2009 annualized by the hospital.

** Data not provided.

8. In April 2009, the Centers for Medicare and Medicaid Services initiated PET diagnostic testing for two new cancers; ovarian and myeloma. *(July 8, 2009, Initial CON Application, pages 10)*
9. The Hospital contends that the FY 2010 projection includes 10% growth from the FY 2009 volume. The Hospital attributes this growth to the opening of the new Cancer Center plus an additional sixty procedures annually for two additional cancers that have been approved for PET diagnostics (ovarian and myeloma). *(September 1, 2009, Completeness Response, pages 336 & 337 and July 8, 2009, Initial CON Application, page 11)*

Table 2: Hospital’s Projected PET and/or PET/CT Scans

	FY 2010	FY 2011	FY 2012
PET and/or PET/CT Scans	470	493	509
Annual % Increase	26.0%	4.9%	3.2%

(September 1, 2009, Completeness Response, page 336)

10. The Hospital contends that PET/CT scans for FYs 2010 through FY 2012 are projected to return to more conservative growth rates of approximately 3% to 5% as the initial growth impact of the new Cancer Center levels off. *(September 1, 2009, Completeness Response, pages 336 & 337)*
11. OHCA finds that the Applicant’s projections appear to be reasonable and achievable for PET/CT scans.

12. The Hospital asserts that the location of the fixed PET/CT scanner will promote enhanced accessibility and utilization for both inpatients and outpatients.
13. The Hospital identified the following providers in the proposed service area:

Table 3: PET and PET/CT Providers Located in the Proposed Service Area

Provider Name & Location	Type of Service	Affiliated Physicians	Hours and Days of Operation	Utilization
HealthCenter Imaging LLC 999 Silver Lane Trumbull, CT 06611	Cardiac PET/CT	Yohan Bragg, MD	Unknown	CON for Cardiac PET/CT use only, over \$400,000 threshold <u>Docket Number</u> 08-25546-MDF
Russo Radiology 2660 Main Street Bridgeport, CT 06606	PET	Robert Russo, MD & Members of Robert D. Russo and Associates, PC	Unknown	CON for PET only acquired below \$400,000 threshold <u>Docket Numbers</u> 06-30865-VST for investigative proceedings 06-30781-DTR for CON DTR
Advanced Radiology 15 Corporate Drive Trumbull, CT 06611	PET	Alan Kaye, MD Physician members of Advanced Radiology Consultants	Unknown	CON acquired below \$400,000 threshold <u>Docket Number</u> 04-30381-DTR
Bridgeport Hospital 267 Grant Street Bridgeport CT 06610 through Alliance Imaging	PET/CT	Unknown	2 pm – 6 pm Mondays only	PET/CT Scans - 180 CY 2008
Milford Hospital 300 Seaside Ave. Milford CT 06460 through Alliance Imaging	PET/CT	Unknown	7 am – 12 pm Sundays only	PET Only Scans - 60 PET/CT Scans - 36 CY 2008
Norwalk Hospital Maple Street Norwalk CT 06856 through Alliance Imaging	PET/CT	Unknown	8 am – 2 pm Every other Tuesday 8 am- 5 pm Every Thursday	PET/CT Scans - 476 CY 2008

(July 8, 2009, Initial CON Application, pages 13 & 14 and September 1, 2009, Completeness Response, page 338)

14. The Hospital indicates that it currently operates the following CT scanners: *(September 1, 2009, Completeness Response, page 336)*

Table 4: Existing CT Scanners at St. Vincent's Medical Center

GE 16 Slice Lightspeed	Located in main imaging department	Hours: Monday - Sunday 8 a.m. - 11:30 p.m.
GE VCT 64 Slice Lightspeed	Located in main imaging department	Hours: Monday - Sunday 24 hrs - 7 days per week
Sim 4 Slice Lightspeed RT/CT	Located in radiation oncology department	Hours: Monday - Friday 8:00 a.m. - 4:30 p.m.

15. The Hospital contends that its CT scanner service volumes have increased steadily. The stand-alone CT scans for all patients including inpatient, outpatient and emergent patients is illustrated below: *(September 1, 2009, Completeness Response, page 337)*

Table 5: St. Vincent's Medical Center's Stand-alone CT Scans

	FY2006	FY2007	FY2008	FY2009*
Inpatient CT	11,660	15,484	16,684	16,624
Outpatient CT	9,891	12,791	11,954	12,539
ED CT	2,757	3,287	3,154	3,305
Total	24,308	31,562	31,792	32,468

*FY 2009 amount is year to date volume through June 2009 annualized by the Hospital.

16. Joseph Gagliardi, MD testified to the high demand of inpatient and emergent CT scans as well as for CT-guided interventional procedures and that this proposal will improve patient access to CT scan imaging services throughout the hospital. *(October 22, 2009 prefiled testimony of Joseph Gagliardi, page 370)*

**Financial Feasibility of the Proposal and its Impact on the Hospital's
Rates and Financial Condition
Impact of the Proposal on the Interests of Consumers of Health Care
Services and Payers for Such Services
Consideration of Other Section 19a-637, C.G.S. Principles and Guidelines**

17. The Hospital's proposed total capital expenditure of \$2,698,450 will be for the purchase of medical equipment for a GE Discovery VCT fixed 64-slice PET/CT scanner. *(March 11, 2009, Letter of Intent, page 5 and July 8, 2009, Initial CON application, pages 9 & 19)*
18. The Hospital contends that the proposal has been developed to capture the financial benefit of philanthropic donations and to move toward providing optimal clinical care for its patients. *(July 8, 2009, Initial CON Application, page 10)*
19. The Hospital indicates that donors will provide funding through financial contributions that will generate the equity funds to be used to purchase the proposed fixed 64-slice PET/CT scanner, with any remainder to be utilized for costs associated with the area within the Medical Center where the equipment will be located. *(September 1, 2009, Completeness Response, page 335)*
20. The Hospital has provided evidence from the donors and the Medical Center stating that the donors agree to make contributions specifically to be utilized for the purpose of purchasing the fixed 64-slice PET/CT scanner for the Hospital. *(September 1, 2009, Completeness Response, page 335 and Attachment 1, pages 342 through 345)*
21. The Hospital contends that the proposed fixed 64-slice PET/CT scanner will allow for inpatients to be scanned without the Medical Center having to pay a per scan fee to Alliance Imaging, while also being able to obtain reimbursement for inpatients that fall under a DRG. *(July 8, 2009, Initial CON application, page 23)*

22. The Hospital testified that the fixed PET/CT scanner proposal is a more financially prudent and cost-effective model over the current per scan fee agreement with Alliance Imaging since the Hospital would own the equipment and generate approximately \$250,000 in net cash due to depreciation. *(July 8, 2009, Initial CON application, page 24 and public hearing testimony of John Gleckler October 26, 2009)*
23. The Hospital's incremental projections of its gains/(losses) from operations with the project in the first four years of operation of the proposal for net patient revenue, operating expenses, and gains/(loss) from operations for FY 2010 through FY 2013 are presented below:

Table 6: Projected Hospital Incremental Gains/(Losses) from Operations

	FY 2010	FY 2011	FY 2012	FY 2013
Revenue from Operations	\$0	\$0	\$0	\$0
Operating Expenses	(\$93,000)	(\$26,000)	\$5,000	(\$1,000)
Gains/(loss) from Operations	\$93,000	\$26,000	(\$5,000)	\$1,000

(July 8, 2009, Initial CON application, page 328)

24. The Hospital's projected gains from operations with the CON project in the first four years of the proposal for net patient revenue, operating expenses, and gains/(losses) from operations for FY 2010 through FY 2013 are presented below:

Table 7: Projected Total Hospital Gain/(Loss) from Operations with the CON Project

	FY 2010	FY 2011	FY 2012	FY 2013
Revenue from Operations	\$367,648,000	\$385,071,000	\$404,319,000	\$427,253,000
Operating Expenses	\$357,173,000	\$372,082,000	\$388,565,000	\$408,594,000
Gain/(loss) from Operations	\$ 10,475,000	\$ 12,989,000	\$ 15,754,000	\$ 18,659,000

(July 8, 2009, Initial CON application, page 328)

25. The Hospital provided the following current and three-year projected payer mix for the proposed fixed PET/CT scanner service:

Table 8: Current and Three-year Hospital Projected Payer Mix

Payer	Current FY 2009	Projected FY 2010	Projected FY 2011	Projected FY 2012
Medicare	48.78%	48.78%	48.78%	48.78%
Medicaid	14.34%	14.34%	14.34%	14.34%
TriCare (CHAMPUS)	0.0%	0.0%	0.0%	0.0%
Total Government	63.12%	63.12%	63.12%	63.12%
Commercial Insurers	30.84%	30.84%	30.84%	30.84%
Uninsured	4.72%	4.72%	4.72%	4.72%
Workers Compensation	1.32%	1.32%	1.32%	1.32%
Total Non-Government	36.88%	36.88%	36.88%	36.88%
Total Payer Mix	100.00%	100.00%	100.00%	100.00%

(July 8, 2009 Initial CON Application, page 22)

26. The Hospital expects that its current payer mix will not change as a result of this proposal. *(July 8, 2009, Initial CON Application, page 22)*
27. There is no State Health Plan in existence at this time. *(July 8, 2009, Initial CON application, page 9)*

28. The Hospital has adduced evidence that this proposal is consistent with its long-range plan. *(July 8, 2009, Initial CON application, page 9)*
29. The Hospital contends that it has improved productivity and contained costs by participating in activities involving the application of new technology and employing group purchasing practices in its procurement of supplies and equipment. *(July 8, 2009, Initial CON application, pages 17)*
30. The Hospital contends that the proposal will not result in any change to the Hospital's teaching and research responsibilities. *(July 8, 2009, Initial CON application, page 17)*
31. The Hospital contends that the proposal will not result in any change in its patient/physician mix. *(July 8, 2009, Initial CON application, page 17)*

Rationale

The Office of Health Care Access ("OHCA") approaches community and regional need for Certificate of Need ("CON") proposals on a case-by-case basis. CON applications do not lend themselves to general applicability due to a variety of factors, which may affect any given proposal; e.g., the characteristics of the population to be served, the nature of the existing services, the specific types of services proposed to be offered, the current utilization of services and the financial feasibility of the proposal.

St. Vincent's Medical Center ("Hospital" or "Medical Center") is a non profit acute care hospital located at 2800 Main Street in Bridgeport, Connecticut. The Hospital proposes to establish a fixed-based positron emission tomography/computed tomography ("PET/CT") service. The Hospital currently operates a mobile-based PET/CT service through a 6-hospital consortium known as the Fairfield County Mobile PET Collaborative. The proposed fixed-based PET/CT service will be offered in the newly integrated cancer center being built on the main campus of the Medical Center.

The Applicant testified at the hearing as to the high demand for inpatient and emergent CT scans as well as for CT-guided interventional procedures and that this proposal will improve patient access to CT scan imaging services throughout the hospital. Further, the proposed PET/CT service will enable the Hospital to move a 64-slice Computed Tomography ("CT") scanner to the Emergency Department ("ED") where it can be dedicated to ED patients to improve patient flow and expedite the delivery of care to ED patients. The Hospital reports gradual annual increases in PET scan volume and projects larger increases in upcoming years because the Center for Medicare and Medicaid Services ("CMS") approved the use of PET and PET/CT for two additional cancer diagnoses.

With respect to the financial feasibility and cost effectiveness of the proposal, the total capital expenditure for the CON project is \$2,698,450 which will be financed through a donor contribution. The Hospital projects incremental gains from operations of \$93,000 and \$26,000, in FY 2010 and FY 2011, an incremental loss of \$5,000 in FY 2012 and an incremental gain of \$1,000 in FY 2013. The Hospital's volume and financial projections upon which they are based appear to be reasonable. Therefore, OHCA finds that the CON proposal is financially feasible, cost effective and will improve availability to quality PET/CT scanning services to Hospital patients.

Order

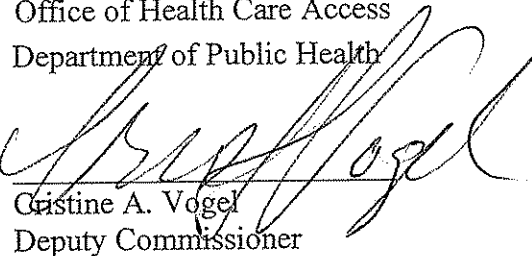
Based upon the foregoing Findings and Rationale, the Certificate of Need application of St. Vincent's Medical Center ("Applicant") for the acquisition of a Fixed Positron Emission / Computed Tomography ("PET/CT") Scanner at a total capital expenditure of \$2,698,450, is hereby **GRANTED**, subject to the following conditions.

1. The Applicant shall not exceed \$3 million in replacement fair market value or capital expenditure for the proposed equipment. In the event that the Applicant learn of potential cost increases or expect that final project costs will exceed those approved, the Applicant shall notify OHCA in writing.
2. Should the Applicant propose any change in the array of health care services offered or a change in its complement of existing imaging equipment, the Applicant shall file with OHCA appropriate documentation regarding its change, including either a Certificate of Need Determination Request or a Certificate of Need Letter of Intent.

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

By Order of the

Office of Health Care Access
Department of Public Health



Cristine A. Vogel
Deputy Commissioner

11-25-09
Date