

M. JODI RELL
GOVERNOR

STATE OF CONNECTICUT
OFFICE OF HEALTH CARE ACCESS

CRISTINE A. VOGEL
COMMISSIONER

September 3, 2009

IN THE MATTER OF:

An Application for a Certificate of
Need filed pursuant to Sections
19a-638 and 19a-639, C.G.S. by:

Notice of Final Decision
Office of Health Care Access
Docket Number: 08-31256-CON

Norwalk Hospital

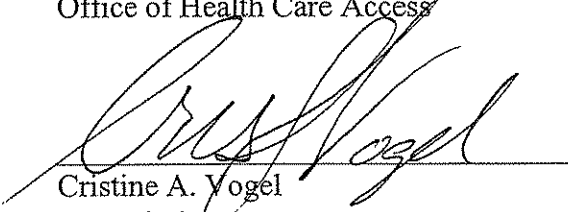
**Proposal to Establish a Fixed-Based PET/CT
Service from a Mobile-Based PET/CT Service
that will be Located at the Norwalk Radiology
and Mammography Center in Norwalk, CT**

To: Lisa Brady
Vice President, Planning and Business Development
Norwalk Hospital
34 Maple Street
Norwalk, CT 06856

Dear Ms Brady:

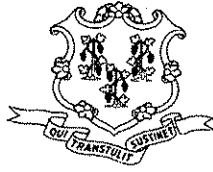
This letter will serve as notice of the Final Decision of the Office of Health Care Access in the above matter as provided by Sections 19a-638 and 19a-639, C.G.S. On September 3, 2009, the Final Decision was rendered as the finding and order of the Office of Health Care Access. A copy of the Final Decision is attached hereto for your information.

By Order of the
Office of Health Care Access



Cristine A. Vogel
Commissioner

CAV: jah



Office of Health Care Access Certificate of Need Application

Final Decision

Applicant: Norwalk Hospital

Docket Number: 08-31256-CON

Project Title: Proposal to Establish a Fixed-Based PET/CT Service from a Mobile-Based PET/CT Service that will be located at the Norwalk Radiology and Mammography Center in Norwalk, Connecticut

Statutory Reference: Sections 19a-638 & 19a-639 of the Connecticut General Statutes

Filing Date: June 5, 2009

Decision Date: September 3, 2009

Default Date: September 3, 2009

Staff Assigned: Jack A. Huber

Project Description: Norwalk Hospital proposes to establish a fixed-based positron emission tomography/computed tomography ("PET/CT") service from an existing mobile-based PET/CT service through the addition of a new PET equipment module to an existing 16-slice CT scanner, located at the office of Norwalk Radiology and Mammography Center, at 148 East Avenue in Norwalk, Connecticut. The total capital expenditure for the proposal is \$1,444,285.

Nature of Proceedings: On June 5, 2009, the Office of Health Care Access ("OHCA") received the Certificate of Need ("CON") application from the Norwalk Hospital ("Hospital") seeking authorization to establish a fixed-based positron emission tomography/computed tomography ("PET/CT") service from an existing mobile-based PET/CT service through the addition of a new PET module to an existing 16-slice CT scanner, located at the office of Norwalk Radiology and Mammography Center, at 148 East Avenue in Norwalk, Connecticut. The total capital expenditure for the proposal is

\$1,444,285. The Hospital is a health care facility or institution as defined in Section 19a-630 of the Connecticut General Statutes (“C.G.S.”).

Pursuant to Sections 19a-638 and 19a-639, C.G.S., a notice to the public concerning OHCA’s receipt of the Hospital’s Letter of Intent to file its CON application was published by The Hour Publishing Company on November 1, 2008. OHCA received no responses from the public concerning the Hospital’s proposal. Pursuant to Sections 19a-638 and 19-639, C.G.S., three individuals or an individual representing an entity with five or more people had until June 26, 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 did not receive any requests to hold a public hearing.

OHCA’s authority to review and approve, modify or deny the CON application is established by Sections 19a-638 and 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 of the Proposal on the Hospital’s Current Utilization Statistics Proposal’s Contribution to the Quality of Health Care Delivery in the Region Proposal’s Contribution to the Accessibility of Health Care Delivery in the Region

1. It is found that Norwalk Hospital Association d/b/a/ Norwalk Hospital (“Hospital”) is a general acute care hospital located at 34 Maple Street in Norwalk, Connecticut. *(October 22, 2008, Letter of Intent, page 1)*
2. On June 11, 2001, under Docket Number (“DN”): 00-509, the Office of Health Care Access (“OHCA”) granted a Certificate of Need (“CON”) for the establishment of a mobile-based, positron emission tomography (“PET”) scanning service to a six hospital consortium known as the Fairfield County Mobile PET Collaborative (“Collaborative”). The Hospital has been providing PET services since 2002. *(February 19, 2009, Initial CON submission, pages 8 & 11 and June 11, 2001, Final Decision and Order regarding DN: 00-509 for the Fairfield County Mobile PET Collaborative)*
3. It is found that current Collaborative members are Norwalk Hospital, Stamford Hospital, St. Vincent’s Medical Center and Bridgeport Hospital. *(June 5, 2009, CON Completeness Responses, page 572)*
4. On August 11, 2003, under DN: 02-584, OHCA approved a CON that granted the Collaborative the lease of a second mobile scanning unit and an upgrade of the mobile-based service scanners from a PET to a positron emission tomography/computerized tomography (“PET/CT”) configuration. *(February 19, 2009, Initial CON submission, pages 11 & 12; June 5, 2009 and August 11, 2003, Final Decision and Order regarding DN: 02-584 for the Fairfield County Mobile PET Collaborative)*

5. Formed in 1986, Norwalk Radiology and Mammography Center is a joint venture entity comprised of S.W.C. Corporation, also known as Southwest Connecticut Corporation, a for-profit affiliate of the Hospital and NRC Equipment Associates, LLC, a subsidiary of Norwalk Radiology Consultants, P.C. Norwalk Radiology Consultants serve as the Hospital's radiologist consultants. *(February 19, 2009, Initial CON submission, page 8 and June 5, 2009, CON Completeness Responses, page 569)*
6. The Hospital claims that the joint venture parties of NRMC will work together through a purchase service agreement to provide the proposed fixed-based PET/CT service. The parties currently have a similar service agreement for the provision of magnetic resonance imaging services. *(June 5, 2009, CON Completeness Responses, page 569)*
7. It is found that while the proposal calls for the PET/CT service to move from the Hospital's campus to NRMC's office location, the proposed fixed-based PET/CT service will remain the responsibility of the Hospital. *(June 5, 2009, CON Completeness Responses, page 569)*
8. It is found that the Hospital will handle the technical billing for the fixed-based PET/CT service, while NRMC radiologists will bill for the professional component of the service. *(June 5, 2009, CON Completeness Responses, page 570)*
9. The Hospital contends that its Whittingham Cancer Center ("WCC") offers the following oncology services and programs: medical oncology and hematology; radiation oncology; surgical oncology; Smilow Family Breast Health Center; clinical research programs; departments of Radiology and Pathology Services; prevention and screening programs; genetic counseling; tumor registry; nutritional counseling; patient, professional and community educational services; patient and family counseling and support services; and complementary medicine including art/music therapy, reiki and massage services. *(February 19, 2009, Initial CON submission, page 27 and Exhibit F, pages 399 through 405)*
10. The Hospital claims that the proposal's intended target population is the same as the current population requiring PET/CT services. The mobile-based service's current population is comprised of outpatients referred to the Hospital and NRMC by physicians who practice primarily in the towns of Norwalk, Westport, Wilton, New Canaan, Weston, and Darien. *(February 19, 2009, Initial CON submission, page 23)*
11. The Hospital claims that for fiscal year ("FY") 2008, 85% of its actual PET/CT volume was generated from patients coming from the towns of Norwalk, Westport, Wilton, New Canaan, and Weston with 4% coming from the towns of Fairfield, Darien, Ridgefield and Stamford. *(February 19, 2009, Initial CON submission, pages 22 through 25)*
12. The Hospital claims that nearly all its mobile PET/CT scans are performed for the benefit of its oncology patients. *(February 19, 2009, Initial CON submission, Exhibit H, pages 410 and 411 and June 5, 2009, CON Completeness Responses, page 576)*

13. The Hospital provided the following oncology service statistics for fiscal years (“FYs”) 2006 through 2008:

Table 1: Oncology Service Statistics

Description	FY 2006	FY 2007	FY 2008
Medical Oncology Patient Treatments*	1,977	1,639	1,896
New Patients Treated**	778	733	658
Patients Receiving Radiation Therapy***	290	295	303

Source: * Norwalk Medical Group, Oncology Resource Consultants & Hospital’s Finance Department
** Norwalk Hospital Tumor Registry Analytic and Non-Analytic Cases
*** WCC Radiation Oncology Report
(June 5, 2009, CON Completeness Responses, pages 574 and 575)

14. OHCA finds that based on the oncology utilization data provided by the Hospital, the number of patients it treats for cancer has remained stable between FYs 2006 through 2008.
15. The Hospital provided the actual number of mobile-based PET/CT scans performed for FYs 2006 through 2008 as follows:

Table 2: Actual Mobile-Based PET/CT Volume

Fiscal Year	PET/CT Scans	Increase in the Number of Scans	Annual % Increase in PET/CT Volume
2006	376	-	-
2007	420	44	11.7%
2008	476	56	13.3%

Note: The number of actual scans reflects a fiscal year’s combined inpatient and outpatient activity.
(February 19, 2009, Initial CON Application, page 16 and Exhibit D, page 197)

16. OHCA finds that the Hospital demonstrated actual growth in the number of PET/CT scans performed in FYs 2007 and 2008.
17. In the first seven months of FY 2009 (i.e. October 1, 2008 through April 30, 2009) the Hospital claims that it performed 359 PET/CT scans as compared to 277 PET/CT scans over the same time period for FY 2008. The projected-actual number of scans for FY 2009, based on annualizing the 359 PET/CT year-to-date scans, is estimated to be 615 PET/CT scans. (June 5, 2009, CON Completeness Responses, pages 579 & 580, Attachment 5, page 611 and Attachment 5, page 612, from Patient Census Report #7, published by the Connecticut Hospital Association, April 2009 vs. 2008)
18. OHCA finds that the Hospital demonstrated actual growth in the number of PET/CT scans performed in the first seven months between FY 2008 (277 scans) and FY 2009 (359 scans) to be approximately 30%.

19. To project the number of fixed-based PET/CT scans for the first three years of operating the proposed service, the Hospital used as its base the actual number of mobile PET/CT scans performed for FYs 2006 through 2008. The Hospital's projections for the proposed fixed-based service are as follows:

Table 3: Projected Fixed-Based PET/CT Volume

Fiscal Year	PET/CT Scans	Increase in the # of Scans	Annual % Increase in PET/CT Volume
2009	503	27	5.6%
2010	531	28	5.6%
2011	584	53	10%
2012	642	58	10%

(February 19, 2009, Initial CON submission, page 31 and Exhibit D, page 198)

20. OHCA finds that the Applicant provided evidence to support the 5.6% and the 10% annual percentage increases in PET/CT volume from its historical PET/CT utilization statistics.
21. The Hospital contends that the following itemization depicts its actual FY 2008 outpatient mobile-based PET/CT scans by disease type and its projected FYs 2010 through 2012 outpatient fixed-based PET/CT scans by disease type.

Table 4: Outpatient PET/CT Scans by Disease Type

Disease Type	FY 2008 Scans	FY2008 % of Total	FY 2010 Scans	FY 2011 Scans	FY 2012 Scans
Cancer Cases					
Oral	4	1%	5	5	6
Digestive	50	11%	60	66	72
Respiratory	114	26%	137	150	165
Skin	7	2%	8	9	10
Breast	85	19%	102	112	123
Male Reproductive	6	1%	7	8	9
Lymphoma	96	22%	115	126	139
Other Cases					
Lung	35	8%	42	46	50
Chest	17	4%	20	22	24
Swelling/Mass/Lump	30	7%	36	40	43
TOTAL O/P Scans	444	100%	531	584	642

Note: *Cases reflect FY'08 actual outpatient activity only & assumes consistent distribution of cancer cases across the fiscal years. (June 5, 2009, CON Completeness Responses, page 576)

22. The Hospital contends that since 2005 and up to March 6, 2009, it has been providing the mobile-based PET/CT services on campus every Thursday from 8 a.m. to 5 p.m. (February 19, 2009, Initial CON Application, pages 8 & 18 and June 5, 2009, Completeness Responses Letter, page 580)
23. The Hospital contends that since March 6, 2009, it has added an additional mobile-based PET/CT service day every other week, based on the Hospital's existing demand for PET/CT services. (June 5, 2009, Completeness Responses Letter, page 580)

24. The Hospital claims that a fixed-based service would allow for greater service accessibility than the current on-campus van arrangement; provide improved availability for patients requiring such scans; provide improved oversight and direction for the service's quality assurance process; and would be the more cost effective alternative of the two options considered. *(June 5, 2009, CON Completeness Responses, page 573)*
25. The existing providers of PET/CT services within the Fairfield County area are as follows:

Table 5: Existing PET/CT Providers in the Fairfield County Area

Service Description	Provider Name	Days and Hours of Operation	PET/CT Volume*	
			FY '07	FY '08
Mobile PET Scanner	Norwalk Hospital**	Thursdays, 8 – 5	422	487
Mobile PET/CT Scanner	Stamford Hospital***	Saturdays, 7 – 5	unavailable	unavailable
Mobile PET/CT Scanner	St. Vincent's Medical Center	Thursdays, 7 – 5	353	364
Mobile PET/CT Scanner	Bridgeport Hospital	Mondays, 8 – 5	138	177
Fixed PET/CT Scanner	Greenwich Hospital	Monday – Friday 8 – 4	936	986
Fixed PET/CT Scanner	Danbury Hospital	Monday – Friday 8 - 3	664	703

Notes: * Number of scans performed for the most recent 12 month period.
 ** Service has been expanded to a second day each alternating week.
 *** Stamford Hospital utilization statistics are unavailable.
(PET/CT Volume from OHCA's Hospital Reporting System, Report 450)

**Financial Feasibility and Cost Effectiveness 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 the Payers for Such Services and
 Consideration of Other Section 19a-637, C.G.S. Principles and Guidelines**

26. The project's total capital expenditure is \$1,444,285. It is comprised of the following: \$1,005,493 for the proposed GE Discovery STE 8/16 PET scanner equipment add-on; \$290,990 for building work associated with the project; and \$147,802 for medical equipment. *(February 19, 2009, Initial CON Application, page 40)*
27. The proposal will be financed through Hospital operating funds. *(February 19, 2009, Initial CON Application, page 41)*
28. The Hospital projects operating gains of \$103,000, \$31,000, \$125,000, \$234,000 and \$368,000 for the fixed-based service for fiscal years 2010 through 2014, respectively. *(February 19, 2009, Initial CON Application, page 562)*
29. The Hospital contends that the proposal's fixed-based purchase option is a more cost effective alternative to the current mobile-based, lease arrangement. *(February 19, 2009, Initial CON Application, page 45)*

30. The Hospital considered the PET/CT lease expense of \$1,690,000 over the last four year period verses the proposed capital purchase and installation cost of \$1,444,285 over the seven year useful life of the equipment. *(February 19, 2009, Initial CON Application, page 45)*
31. Additionally, the Hospital considered the cost advantage of purchasing a PET equipment module (\$1,444,285) over the expenditure of purchasing a new PET/CT scanner, whose cost would be considerably more than the PET equipment module alone. *(February 19, 2009, Initial CON Application, page 45 and Attachment D, page 202; and June 5, 2009, Completeness Responses Letter, page 582)*
32. OHCA finds that the Hospital provided sufficient evidence to evaluate the comparative capital and operating costs associated with the mobile-based, lease service arrangement verses the fixed-base, purchase service arrangement and that the proposal is a cost effective approach in providing PET/CT services to individuals in the Hospital's service area.
33. The Hospital provided the following three-year projected payer mix for the proposed service:

Table 6: Three-Year Projected Payer Mix

Description	Year 1	Year 2	Year 3
Medicare*	46.4%	46.4%	46.4%
Medicaid*	10.4%	10.4%	10.4%
CHAMPUS and TriCare	--	--	--
Total Government	56.8%	56.8%	56.8%
Commercial Insurers*	36.4%	36.4%	36.4%
Self Pay	5.1%	5.1%	5.1%
Employee	1.7%	1.7%	1.7%
Total Non-Government	43.2%	43.2%	43.2%
Total Payer Mix	100%	100%	100%

* Includes managed care activity.

(February 19, 2009, Initial CON Application, page 43)

34. The Hospital provided a copy of the rate schedule for PET/CT services with an average rate of \$4,293 per scan. *(February 19, 2009, Initial CON Application, page 568)*
35. There is no State Health Plan in existence at this time. *(February 19, 2009, Initial CON Application, page 10)*
36. The Hospital claims that it has improved productivity and contained costs through the undertaking of energy conservation measures, group purchasing practices and applications of new technology and reengineering projects. *(February 19, 2009, Initial CON Application, page 37)*

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.

Norwalk Hospital ("Hospital") is a general acute care hospital located at 34 Maple Street in Norwalk, Connecticut. The Hospital proposes to establish a fixed-based positron emission tomography/computed tomography ("PET/CT") service. The Hospital currently operates an on-campus, mobile-based PET/CT service through a four-hospital consortium known as the Fairfield County Mobile PET Collaborative. The proposed fixed-based PET/CT service will be offered at the office of Norwalk Radiology and Mammography Center ("NRMC"), which is located at 148 East Avenue in Norwalk. The proposed fixed-based service will be accomplished through the addition of a new PET equipment module to NRMC's existing 16-slice CT scanner.

The Hospital asserts that the need for the fixed-based PET/CT service is based on its historical growth and current year's growth in the number of Hospital patients utilizing PET/CT services. In the most recently completed fiscal years ("FYs"), mobile-based PET/CT service volume has grown 11.7 % between FYs 2006 and 2007 and 13.3% between FYs 2007 and 2008. Additionally, in the first seven months of FY 2009, the Hospital has witnessed a 30% increase in its mobile-based PET/CT service volume over the same period in FY 2008. Consequently, OHCA was able to verify the Hospital's assertion of service volume growth. OHCA finds that the Hospital's PET/CT service volumes justify the need for a fixed-based service arrangement. Further, OHCA concludes that the Hospital's fixed-based service proposal would allow for greater PET/CT service accessibility than the current on-campus mobile van arrangement and would provide improved availability for patients requiring such scans.

With respect to the financial feasibility and cost effectiveness of the proposal, the total capital expenditure for the CON project is \$1,444,285. The project will be financed through the Hospital operating funds. The Hospital projects incremental gains from operations of \$103,000, \$31,000, \$125,000, \$234,000 and \$368,000 for the fixed-based service for fiscal years 2010 through 2014, respectively. From a financial perspective, the Hospital believes its proposal to establish a fixed-based, PET/CT service is a cost effective and prudent decision. The Hospital considered the PET/CT lease expense over the proposed capital purchase and the cost advantage of purchasing a PET equipment module over the expenditure of acquiring a new PET/CT scanner. OHCA finds that the Hospital can either incur a capital expenditure of \$1,444,285 for the PET equipment module now or ultimately continue to spend its resources for the leasing of PET/CT equipment, which limits the availability of the service. However, following the latter scenario will not address PET/CT availability concerns, the inability to treat all Hospital patients and accessibility factors inherent in the current mobile set-up. 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 in a prudent manner.

Order

Based on the foregoing Findings and Rationale, the Certificate of Need ("CON") application of Norwalk Hospital ("Hospital") for the establishment of a fixed-based positron emission tomography/computed tomography ("PET/CT") service in Norwalk, at a total capital expenditure of \$1,444,285, is hereby **approved** and is subject to the following conditions:

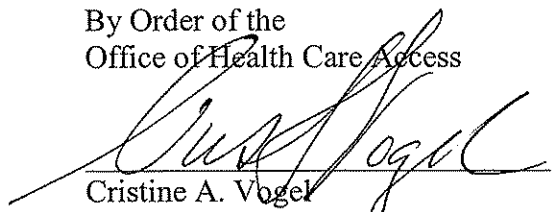
1. This CON authorization shall expire on October 1, 2010. Should the Hospital's project not be completed by that date, the Hospital must seek further approval from OHCA to complete the project beyond that date.
2. The Hospital shall not exceed the approved capital expenditure of \$1,444,285. In the event that the Hospital learns of potential cost increases or expects that final project costs will exceed those approved, the Hospital shall notify OHCA immediately.
3. The Hospital shall terminate the contract for the mobile-based PET/CT scanner after the new fixed-based, 16-slice PET/CT scanner has commenced operation. Furthermore, the Hospital shall provide evidence to OHCA of the termination of the contract for the mobile-based PET/CT scanner by no later than two months after the new fixed-based, 16-slice PET/CT scanner has commenced operation.
4. With respect to the acquisition of the new PET equipment module, the Hospital shall submit to OHCA in writing the following information by no later than one month after the new PET/CT scanner has become operational:
 - The name of the new PET module equipment manufacturer;
 - The model name and description of the new PET module equipment; and
 - The fixed-based 16-slice PET/CT scanner's initial date of operation.
5. Should the Hospital propose any change in the array of health care services offered or a change in its complement of existing major medical or imaging equipment, the Hospital 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.

Should the Hospital fail to comply with any of the aforementioned conditions, OHCA reserves the right to take additional action as authorized by law. All of the foregoing constitutes the final order of the Office of Health Care Access in this matter.

Date

9-3-09

By Order of the
Office of Health Care Access


Cristine A. Vogel
Commissioner