



## Office of Health Care Access Certificate of Need Application

### Final Decision

**Applicants:** Bridgeport Hospital  
Danbury Hospital  
Greenwich Hospital  
Norwalk Hospital  
Saint Vincent's Medical Center  
Stamford Hospital

**Docket Number:** 02-584

**Project Title:** The lease of a second mobile unit for the Fairfield County Mobile PET Collaborative and upgrade of both mobile units from PET to PET-CT modality

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

**Filing Date:** May 29, 2003

**Hearing Date:** Waived

**Decision Date:** August 11, 2003

**Default Date:** August 27, 2003

**Staff Assigned:** Karen Roberts

**Project Description:** Bridgeport Hospital, Danbury Hospital, Greenwich Hospital, Norwalk Hospital, Saint Vincent's Medical Center, and Stamford Hospital ("Hospitals" or "Applicants"), together known as the Fairfield County Mobile PET Collaborative ("FCMPC"), propose to lease a second mobile unit for the Fairfield County Mobile PET Collaborative and to upgrade both mobile units from Positron Emission Tomography ("PET") to a combined Positron Emission Tomography - Computed Tomography ("PET-CT") or fusion modality, at a total capital expenditure of \$4,900,000, which represents the fair market value of two mobile PET-CT units.

**Nature of Proceedings:** On May 29, 2003, the Office of Health Care Access (“OHCA”) received a complete Certificate of Need (“CON”) application from Bridgeport Hospital, Danbury Hospital, Greenwich Hospital, Norwalk Hospital, Saint Vincent’s Medical Center, and Stamford Hospital (each “Hospitals” or “Applicants”), together known as the Fairfield County Mobile PET Collaborative (“FCMPC”), seeking authorization for the lease a second mobile unit for the Fairfield County Mobile PET Collaborative and the upgrade of both mobile units from Positron Emission Tomography (“PET”) to a combined Positron Emission Tomography - Computed Tomography (“PET-CT”) or fusion modality, at a total capital expenditure of \$4,900,000, which represents the fair market value of two mobile PET-CT units. Each Applicant is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes (“C.G.S.”).

The Applicants requested a waiver of public hearing for the CON application pursuant to Section 19a-643-45 of OHCA’s Regulations and claimed that the proposal was non-substantive as defined in Section 19a-643-95(3) of OHCA’s Regulations. Notice to the public was published in *The Advocate*, *Connecticut Post*, *The Hour*, and *The News Times*. OHCA received no comments concerning the Applicants’ request for waiver of public hearing during the public comment period. Therefore, on June 26, 2003, OHCA granted the Applicants’ request for waiver of the public hearing.

OHCA’s authority to review and approve, modify or deny this application is established by Sections 19a-638 and 19a-639, C.G.S. The provisions of these sections, 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, Current Utilization Statistics, Contribution to Accessibility and Quality of Health Care Delivery in the Region, and Impact of the Proposal on the Interests of Consumers of Health Care Services and Payers for Such Services**

1. Bridgeport Hospital (“Hospital”) is a not-for-profit acute care hospital located at 267 Grant Street in Bridgeport, Connecticut. (*April 17, 2003 CON application, page 303*)
2. Danbury Hospital (“Hospital”) is a not-for-profit acute care hospital located at a 24 Hospital Avenue in Danbury, Connecticut. (*April 17, 2003 CON application, page 304*)
3. Greenwich Hospital (“Hospital”) is a not-for-profit acute care hospital located on Perryridge Road in Greenwich, Connecticut. (*April 17, 2003 CON application, page 305*)
4. Norwalk Hospital (“Hospital”) is a not-for-profit acute care hospital located on Maple Street in Norwalk, Connecticut. (*April 17, 2003 CON application, page 306*)
5. Saint Vincent’s Medical Center (“Hospital”) is a not-for-profit acute care hospital located at 2800 Main Street in Bridgeport, Connecticut. (*April 17, 2003 CON application, page 307*)

6. Stamford Hospital (“Hospital”) is a not-for-profit acute care hospital located on Shelburne Road in Stamford, Connecticut. *(April 17, 2003 CON application, page 308)*
7. A Certificate of Need was initially granted to the six Hospitals under Docket Number 00-509 on June 11, 2001 for the establishment of PET scanning services at the six Hospitals through the leasing of one mobile PET scanner. *(April 17, 2003 CON application, page 26)*
8. The Fairfield County Mobile PET Collaborative (“FCMPC”) is an informal collaboration formed to provide Positron Emission Testing (“PET”) services at the six Hospitals, all of which are in Fairfield County. FCMPC is not a legal entity and each Hospital acts independently within the Collaborative. *(April 17, 2003 CON application, pages 26 and 48)*
9. The FCMPC has established an Oversight Committee, with representatives from each FCMPC Hospital. Oversight Committee duties include developing and overseeing mechanisms to address ongoing operational questions or issues such as rotation schedule, patient scheduling, cancellations, equipment vendor performance issues, volume changes, payment and reimbursement, data collection, OHCA reporting and other reporting requirements. *(April 17, 2003 CON application, page 331)*
10. The FCMPC Hospitals contract with PET Scans of America Corporation, a mobile PET scan equipment vendor, to provide the authorized mobile PET scanner and actual services began at the FCMPC Hospitals in September and October of 2002, with start dates varying by Hospital. *(April 17, 2003 CON application, page 26)*
11. Based on then projected demands, a one-day per week schedule was established for each Hospital and it was initially intended that a single PET scanner would travel to each of the six hospitals Monday through Saturday. However, due to space limitations at Stamford Hospital and Greenwich Hospital, neither of these Hospitals could accommodate the mobile PET scanner on Mondays and both of these two Hospitals were only able to offer the service on Saturdays. In order to accommodate two hospitals requiring the scanner on Saturdays, a second mobile unit is utilized through the contractual arrangement with PET Scans of America Corporation. *(April 17, 2003 CON application, page 26)*
12. In a Certificate of Need Determination issued by OHCA under Report Number 02-A4, OHCA determined that the leasing of the second PET scanner required Certificate of Need authorization pursuant to Section 19a-639 of the Connecticut General Statutes as the fair market value of the second unit exceeds \$1,000,000. *(April 17, 2003 CON application, page 26)*
13. In addition to the need for a second PET scanner in order to accommodate both Stamford Hospital and Greenwich Hospital on Saturdays, Danbury Hospital may require an additional day or days of usage as Danbury Hospital is rapidly approaching the maximum number of patients (9) that can be treated on a single day with the current scanner. Actual use of both machines is based on patient demand. Danbury Hospital has scheduling backlogs of approximately two weeks. *(April 17, 2003 CON application page 28 and page 31)*

14. The second unit currently being utilized is also leased from PET Scans of America Corporation and is not currently utilized elsewhere in Connecticut. It is primarily utilized in New York and Pennsylvania and is used by the FCMPC on Saturdays at Stamford Hospital. Both of the two currently used mobile PET units are identical and have the exact same specifications. *(April 17, 2003 CON application, page 3)*
15. The hours of operation are currently 7:00 AM to 5:00 PM at each of the six hospitals. Danbury Hospital provides the PET scanning services on Tuesdays, Bridgeport Hospital on Wednesdays, Norwalk Hospital on Thursdays, and Saint Vincent's Medical Center on Fridays. As previously indicated both Stamford and Greenwich Hospitals provide the services on Saturdays. *(April 17, 2003, CON application, page 32)*
16. The Hospitals also propose to upgrade the equipment utilized in their programs from the current mobile PET scanning modality to a combined mobile PET-CT or fusion scanning modality. The combined PET-CT technology is expected to be available on a mobile basis in the Spring or Summer of 2003. *(April 17, 2003 CON Application, pages 25-26)*
17. Fixed PET-CT scanners or fusion scanners have begun to appear in the marketplace in recent years and provide significant benefits beyond the use of separate CT and PET images. Many patients who require a PET scan also require a CT scan. *(April 17, 2003 CON application, page 28)*
18. Both Hartford Hospital and Hospital of Saint Raphael have received Certificate of Need authorization from OHCA for the acquisition of fixed-base PET-CT scanners. There are currently no mobile PET-CT providers in the state. *(April 17, 2003, CON application page 32)*
19. The need to correlate PET with CT has led to the development of fusion scanners. The patient receives a CT and PET scan in the same session and resulting data is fused into a single digital image, which provides both anatomic and functional information. Image speed and patient throughput are significantly increased with fusion scanners. The average procedure time for combined PET-CT scans is approximately 22 minutes as opposed to twice that to acquire just the PET image. *(April 17, 2003, CON application page 28)*
20. The Hospitals' request to lease a second PET scanner and to upgrade from PET to PET-CT imaging modality is not expected to have any impact on the two authorized PET-CT providers in the state or on any other mobile PET units operating throughout the state. *(April 17, 2003, CON application page 33)*
21. Table #1 below identifies each Hospital's primary service area towns. The Fairfield County Mobile PET Collaborative's service area encompasses all of Fairfield County except the town of Sherman and includes five towns in western New Haven County. The table below includes only Connecticut towns and only primary services area towns.

**Table 1: Primary Service Areas for Six Hospitals (P=Primary)**

Town	Bridgeport Hospital	Danbury Hospital	Greenwich Hospital	Norwalk Hospital	St. Vincent's Medical Center	Stamford Hospital
Ansonia	P					
Bethel	P	P				
Bridgeport	P				P	
Brookfield		P				
Danbury		P				
Darien			P			P
Derby	P					
Easton	P				P	
Fairfield	P				P	
Greenwich			P			
Milford	P					
Monroe	P				P	
New Canaan			P	P		
New Fairfield		P				
Newtown (includes Sandy Hook)	P	P				
Norwalk			P	P		
Orange	P					
Redding	P	P				
Ridgefield		P				
Seymour	P					
Shelton	P				P	
Stamford			P			P
Stratford	P				P	
Trumbull	P				P	
Weston	P			P		
Westport	P			P		
Wilton	P			P		

*(April 17, 2003, CON application, pages 143-148 and 154-155)*

22. The Hospitals project that the six FCMPC hospitals combined will provide a total of 1,562 PET scans for Fiscal Year (“FY”) 2003, based on FY 2003 first five months actual performance (October 1, 2002 through February 28, 2003), Table 2 below:

**Table 2: FY 2003 First Five Months Actual and Annualized**

Hospital	FY 2003 Five Months Actual	Projected FY 2003 Annualized	Average number patients per day
Bridgeport Hospital	105	252	5
Danbury Hospital	139	334	7
Greenwich Hospital	124	298	6
Norwalk Hospital	87	209	4
St. Vincent’s Medical Center	113	271	5
Stamford Hospital	83	199	4
<b>Total</b>	<b>651</b>	<b>1562</b>	<b>31</b>

*(April 17, 2003, CON application page 31)*

23. The overwhelming majority of PET scans are for the staging and evaluation of treatment for certain types of cancer. Scan volume for the mobile PET scanner at the six hospitals combined has been, to date, primarily oncology-related as demonstrated in Table 3 below for the period October of 2002 through January 2003:

**Table 3: Scan Volume by General Cancer Description**

Cancer Type	Number of Scans	Percentage of Total
Lung	242	46%
Lymphoma	100	19%
Colorectal	55	11%
Breast	42	8%
Tumor Imaging	20	4%
Head and Neck	20	4%
Esophageal	15	3%
Melanoma	13	2%
Total Oncology	507	97%

*(April 17, 2003 CON application, pages 27 and 31)*

24. Neurological studies totaled 16 or 3% of the 523 total PET studies during this same timeframe depicted in Table 3 above. *(April 17, 2003 CON application, page 31)*
25. PET-CT is particularly useful for head and neck malignancies. PET is somewhat limited in localizing lesions in the dense anatomical structures of the head and identifying lesions with CT alone is also limiting. The combined PET-CT modalities produce a superior image for tumor localization. *(April 17, 2003, CON application page 28)*
26. Patients who will benefit most from combined PET-CT images are those for whom surgery or radiation therapy is planned. The combined image helps to guide the surgeon to the location of the malignancy and helps focus radiation therapy on the cancer and avoid damage to healthy surrounding tissue. *(April 17, 2003, CON application page 28)*

27. Based on historical Tumor Registry age-adjusted incidence rates for PET approved cancers, there has been growth in the following cancer types: Melanoma, Lung Cancer in women, Breast Cancer, Non-Hodgkin's Lymphoma, Esophagus Cancer, Hodgkin's and Colon Cancer. *(April 17, 2003, CON application page 36)*
28. PET-CT images are most beneficial to patients with colorectal cancer, abdominal/pelvic malignancies, and lymphoma, for staging and restaging. Recent studies have shown that restaging is more accurate and diagnosis more confident in rectal cancer patients who had a PET-CT versus PET scan, especially for patients with recurrent disease. *(April 17, 2003, CON application, page 29)*
29. Actual utilization for the six FCMPC hospitals combined for period October 1, 2002 through December 31, 2002 was primarily for the following specific studies:

**Table 4: Studies performed by each FCMPC Hospitals combined**

#	Reason for PET Study	Utilization statistic	Percentage of total
1	Lung, Pulmonary Nodule	77	20%
2	Lung, Initial Staging	42	11%
3	Lymphoma, Restaging	41	11%
4	Lung, Restaging	36	9%
5	Lymphoma, Initial Staging	28	7%
6	Breast CA, Staging/Restaging	26	7%
7	Lung, Diagnostic	21	5%
8	Colorectal, Initial Staging	20	5%
9	Tumor Imaging	18	5%
10	Colorectal, Restaging	12	3%
	Total for these 10 studies	321	83%
	Total for all other studies	61	17%
	Total all studies	382	100%

*(April 17, 2003 CON application, page 386)*

30. Table #5 identifies the effective service area population for each of FCMPC Hospital:

**Table 5: FY 2006 Effective Service Areas (ESA)**

Hospital	FY 2006 ESA Population
Bridgeport Hospital	163,416
Danbury Hospital	187,544
Greenwich Hospital	77,095*
Norwalk Hospital	141,686
St. Vincent's Medical Center	152,534
Stamford Hospital	147,548
Total	869,823

*\*Figure does not include 55,000, which represents the estimated New York population served by Greenwich Hospital). (Information extracted from April 17, 2003, CON application, page 36)*

31. Volume projections for FY2004 through FY2006 oncology cases are based on the expected number of new cancer cases and associated PET scans for each Hospital's effective service area population. New cancer cases have been projected for 2006 in order

to estimate growth in oncology PET scans from FY 2003 through FY 2006. Specific assumptions are as follows:

- ❖ The effective service area was calculated by applying inpatient market share figures to 2006 population projections for each service area town (*adjusted by OHCA to remove 55,000 representing New York population from Greenwich Hospital's ESA figures*).
- ❖ New cancer cases were estimated by applying a projected crude incidence rate for each cancer type to the effective service area. A crude rate for 2006 was projected based on the trend of age-adjusted incidence rates between 1984 and 2000.
- ❖ A 30% recurrent scan rate was applied to all cancer types.  
 (*April 17, 2003 CON application, page 35*)

32. In order to project a crude cancer incidence rate (expressed per 1,000 population) for FY 2006, the Hospitals assumed the average rate between 1980 and 1984 was the rate in 1984; determined the percent change between 1984 and 2000 for males and females; averaged the percent change between males and females; and calculated the percent change for a single year by dividing the average percent change between 1984 and 2000 by 16 years. The Hospitals utilized a conservative 50% of the calculated annual percent change in applying it to the 2000 crude rate to trend to 2006. The projected 2006 rates per 1000 are presented in Table 6 below:

**Table 6: FY 2006 Crude Cancer Incidence Rates by Cancer Type**

Type	FY 2006 Projected Crude Incidence Rates per 1,000
Lung	0.753
Breast	0.898
Hodgkins Lymphoma	0.040
Non-Hodgkins Lymphoma	0.222
Colon	0.485
Esophagus	0.058
Larynx	0.045
Oral, Pharynx	0.101
Melanoma	0.261

(*April 17, 2003 CON application, page 36-37*)

33. Based on the projected crude incidence rate for 2006 (from Table 6 above), the number of total cancers are expected for each hospital's ESA are depicted in Table 7 below:

(*Information extracted from April 17, 2003 CON application, page 37*)

**Table 7: FY 2006 Crude Cancer Incidence Rates by Cancer Type**

Hospital	Total Estimated Oncology Cases FY 2006
Bridgeport Hospital	468
Danbury Hospital	537
Greenwich Hospital	221*
Norwalk Hospital	406
St. Vincent's Medical Center	437
Stamford Hospital	422
Total	2,491

\**Calculation was adjusted to remove 55,000 from Greenwich Hospital ESA for New York population*



34. The following table identifies the assumed percentage of each type of cancer that will be appropriate for a PET study.

**Table 8: Percentage of Cancer Cases Appropriate for PET Study**

Cancer Type	Percentage Appropriate for PET Study
Lung	90%
Breast	45%
Lymphoma	90%
Colon	80%
Esophagus	55%
Head and Neck	55%
Melanoma	50%

*(April 17, 2003 CON application, page 37)*

35. Applying the percentages identified in Table 8 above to the estimated number of cancer cases by cancer types for each hospital and also applying an estimated 30% recurrent scan rate, the projected number of oncology related PET-CT studies for FY2006 for each Hospital is as follows:

**Table 9: Number of Cancer Cases Appropriate for PET Study**

Hospital	Total Projected FY 2006 Oncology Cases
Bridgeport Hospital	414
Danbury Hospital	475
Greenwich Hospital	195
Norwalk Hospital	359
St. Vincent's Medical Center	386
Stamford Hospital	374
Total	2,203

*Above figures do not adjust projections for out of service area studies for Danbury or Norwalk Hospitals or for the 55,000, which represents Greenwich Hospital's New York state population.  
(Information extracted from April 17, 2003 CON application, page 38)*

36. The above utilization projections only include Medicare approved conditions to date and are therefore conservative as it is likely that Medicare could approve additional disease states in the next 2-3 years. It is expected that Medicare will continue to expand coverage to new uses for PET scanning, such as Alzheimer's, prostate cancer, thyroid cancer, various sarcomas, pelvic malignancies, cervical and ovarian carcinomas, pancreatic tumors, and potentially, detection of unknown primary tumors. *(April 17, 2003 CON application, pages 34- 35 and 38)*

37. Currently Medicare reimburses for PET scans for metabolic brain imaging for pre-surgical evaluation of refractory seizures. PET is reimbursed by some private insurance for dementia imaging and for the evaluation of central nervous system malignancies. PET scanning has also been used to evaluate patients with memory disorders of unknown etiology, brain tumors, Alzheimer's disease and some psychiatric patients with obsessive-compulsive disorders, which are not currently approved by Medicare for reimbursement. *(April 17, 2003 CON application, page 39)*
38. The Hospitals have done, to date, only a small number of neurological PET scans. Growth in neurological volume is dependent on further approvals for Medicare coverage by the Center for Medicare and Medicaid Services. *(April 17, 2003 CON application, page 39)*
39. FY 2006 PET studies performed for neurological conditions is projected as follows:

**Table 10: FY 2006 Neurological Volume by Hospital**

Hospital	Total Projected FY 2006 Neurology Cases
Bridgeport Hospital	22
Danbury Hospital	5
Greenwich Hospital	4
Norwalk Hospital	2
St. Vincent's Medical Center	9
Stamford Hospital	11
Total	54*

*\*Scan Volume is rounded to the nearest whole number  
(April 17, 2003 CON application, page 39)*

40. The combined PET-CT modality also provides significant benefit to cardiac patients. PET scanning is used for two types of cardiac scanning, myocardial viability and myocardial perfusion imaging ("MPI"). Myocardial viability studies are generally performed using a radiopharmaceutical called fluorine-18 fluorodeoxyglucose or F-18 FDG. Viability testing provides information to cardiologists to help them decide between revascularization and a less invasive therapy. These studies could be performed on the current mobile PET scanner but there has been little demand to date. *(April 17, 2003, CON application page 29)*
41. Myocardial perfusion imaging is conducted with a radiopharmaceutical called Rubidium-82 and demonstrates the distribution of blood flow to the heart. This information is used to diagnose and localize coronary artery disease and can also assess the effectiveness of revascularization attempts. *(April 17, 2003, CON application page 29)*
42. Rubidium does not require a cyclotron and is produced by a generator, which is located at the scanner site. Rubidium has a very short half-life (70 seconds) and therefore the scanner must have high sensitivity and minimum dead time in order to properly image. *(April 17, 2003 CON application, page 29)*

43. The Rubidium generator is mobile and travels to each site. The generator is enclosed in a steel cart. The generator is delivered and picked up on a daily basis. *(May 29, 2003 completeness responses, page 6)*
44. The schedule of cardiac MPI patients will be based on demand. Each hospital will likely group these tests on a particular day or portion of a day in order to provide the most cost effective and efficient service. Rubidium will be ordered the evening before based on the schedule for the next day. *(May 29, 2003 completeness responses, page 7)*
45. Currently the main technology used for nuclear cardiac scanning is the SPECT camera or Single Photon Emission Computed Tomography camera. PET scanning appears to be emerging as a “gold standard” for the diagnosis and management of coronary artery disease, although it is projected that SPECT will continue to play a dominant role, at least for the next several years. *(April 17, 2003, CON application page 29)*
46. Advantages of PET scanning over SPECT scanning for MPI include:
- ❖ Attenuation correction (better spatial resolution);
  - ❖ Depth-independent doubling of image resolution; and
  - ❖ Improved image contrast.
- (April 17, 2003, CON application, page 30)*
47. PET scanning is particularly beneficial in the diagnosis and assessment of coronary artery disease for three patient subgroups:
- ❖ Women (as breast tissue can interfere with SPECT images);
  - ❖ Obese patients; and
  - ❖ Patients who cannot exercise and must be pharmacologically stressed.
- (April 17, 2003, CON application page 30)*
48. Combined PET-CT imaging will allow cardiac studies to be completed in half the time as the current PET scanner, which is essential to perform the cardiac perfusion studies due to the short half-life of Rubidium. *(April 17, 2003, CON application page 30)*
49. Projected cardiac volume is based on the following assumptions:
- ❖ Mobile PET-CT will be available in FY 2004.
  - ❖ Cardiac scanning, both with FDG and Rubidium will begin in FY 2004.
  - ❖ FDG myocardial viability scanning will represent 5% of the total including oncology and neurology scanning volume.
  - ❖ Rubidium perfusion scanning will include a growing percentage of patients currently receiving a SPECT scan who are unable to exercise and must be pharmacologically stressed. Actual SPECT volume for patients pharmacologically stressed was collected for the first five months of FY 2003 and annualized. This volume was assumed to increase 5% per year between FY 2003 and FY 2006.

- ❖ Beginning in FY 2004, it is projected that 30% of myocardial viability scanning will be done utilizing PET-CT versus SPECT, growing to 40% in FY 2005 and 50% in FY 2006.

*(April 17, 2003 CON application, pages 40 – 41)*

50. The Hospitals project the following PET-CT studies using FDG for cardiac procedures:

**Table 11: Projected Cardiac Procedures using FDG for FY 2004 – FY 2006**

Hospital	FY 2004 Cardiac FDG	FY 2005 Cardiac FDG	FY 2006 Cardiac FDG
Bridgeport Hospital	16	20	23
Danbury Hospital	21	24	28
Greenwich Hospital	16	17	18
Norwalk Hospital	14	17	19
St. Vincent's Medical Center	16	19	21
Stamford Hospital	14	17	20
Total	97	114	129

*(April 17, 2003 CON application, page 42)*

51. All six Hospitals are hospital-based SPECT providers. Non-hospital-based SPECT providers in the regions include the following:

- ❖ Cardiac Specialists; Fairfield
- ❖ Cardiology Associates; Norwalk
- ❖ Cardiology Associates of Bridgeport; Bridgeport
- ❖ Cardiology Associates of Fairfield County; Stamford
- ❖ Cardiology Associates of Southern Connecticut; Bridgeport
- ❖ Cardiology Physicians; Bridgeport
- ❖ Drs. Fisher and Pollack; Danbury

*(May 29, 2003 completeness responses, page 2)*

52. Based on FY 2003 first five months actual SPECT volume for pharmacologically stressed patients at each Hospital, the Hospitals project that, in total, the Hospitals will perform 1,602 PET-CT cardiac perfusion scanning studies in FY 2006, as depicted in Table #12:

**Table 12: Hospital-Based SPECT Volume & Projected MPI Volume**

Hospital	FY 2003 Stressed SPECT First Five Months Actual	FY 2003 Stressed SPECT Volume Annualized	Projected FY 2004 MPI (w/ 30% shift from SPECT to PET-CT)	Projected FY 2005 MPI (w/ 40% shift from SPECT to PET-CT)	Projected FY 2006 MPI (w/ 50% shift from SPECT to PET-CT)
Bridgeport Hospital	119	286	90	126	165
Danbury Hospital	221	530	167	234	307
Greenwich Hospital	198	475	150	210	275
Norwalk Hospital	279	670	211	295	388
St. Vincent's Medical Center	88	211	67	93	122
Stamford Hospital	248	595	187	262	345
<b>Total</b>	<b>1,153</b>	<b>2,767</b>	<b>872</b>	<b>1,220</b>	<b>1,602</b>

Above assumes 5% growth per year in the number of patients pharmacologically stressed.  
 (April 17, 2003 CON application, page 41)

53. The Hospitals only include the shift of some historical hospital-based SPECT studies for pharmacologically stressed patients and the CON utilization projections do not assume any changes will take place in the use of SPECT in the physician's private practice settings. (May 29, 2003 completeness responses, page 2)

54. The following table totals the FY 2006 projected PET-CT scans for each Hospital for oncological, neurological and cardiac-related studies:

**Table 13: Total Projected Volume for all scan types combined for FY 2006**

Hospital	FY 2006
Bridgeport Hospital	624
Danbury Hospital	815
Greenwich Hospital	492
Norwalk Hospital	768
St. Vincent's Medical Center	538
Stamford Hospital	750
<b>Total</b>	<b>3,987*</b>

\*Again noting that the oncology-related projections are only for Hospital service area Connecticut residents only and does not include a 55,000 New York population adjustment for Greenwich Hospital or any out-of-area adjustments for Danbury or Norwalk Hospital)  
 (Information extracted from April 17, 2003, CON application, page 41)

55. The Society of Nuclear Medicine has issued a Procedure Guideline for Tumor Imaging Using F-18 FDG and a Procedure Guideline for Myocardial Perfusion Imaging 2.0. The Tumor Imaging guideline has been incorporated into the current quality assurance plans at each Applicant Hospital and the plans will be modified to incorporate use of Rubidium for myocardial perfusion imaging. (April 17, 2003, CON application, page 44)

56. A Quality Assurance plan prepared by PET Scans of America is utilized by each of the FCMPC Hospitals. *(April 17, 2003, CON application, page 46)*

57. PET Scans of America Corporation provides and will continue to provide the following:

- ❖ Delivery and set-up, operation and clean-up of the mobile scanners;
- ❖ Two certified nuclear medicine technologists;
- ❖ Training of two physicians from each hospital site;
- ❖ Marketing support and remote work station;
- ❖ Quality assurance program and guaranteed upgrades.  
*(April 17, 2003 CON application, page 58)*

**Financial Feasibility of the Proposal and  
its Impact on the Hospitals' Rates and Financial Condition,  
Impact of the Proposal on the Interests of Consumers of Health Care  
Services and Payers for Such Services**

58. The total capital cost for the CON proposal is \$4,900,000, which represents the use of two PET-CT scanners for the six Fairfield County Mobile PET Collaborative hospitals. *(May 29, 2003 completeness responses, page 1)*

59. PET Scans of America Corporation will provide two General Electric or CTI (SIEMENS) PET-CT scanners that have an approximate per unit fair market value of \$2,450,000 for either system, which includes the Trailer, Hot-Lab and PET-CT unit. The term of the current equipment vendor contract with each hospital would be extended upon delivery and first patient use of the PET-CT unit by forty-two months. *(April 17, 2003 CON application, page 337)*

60. The FCMPC Hospitals will select the mobile PET-CT equipment. *(April 17, 2003, CON application page 30 and May 29, 2003 completeness responses, page 6)*

61. The equipment lease is based on a per scan amount. The amount varies based on the number of scans performed each day. The current per scan charge is \$1,200.00. *(April 17, 2003, CON application, pages 51 and 52)*

62. Each of the FCMPC Hospitals bill for the technical services for the current PET studies and will bill for the technical services for the proposed PET-CT studies. The physician who interprets the studies will bill separately for their professional fee. *(April 17, 2003, CON application page 47)*

63. It is assumed that PET-CT will be available by the FCMPC Hospitals beginning in FY 2004 and cardiac perfusion imaging and Cardiac FDG will begin during FY 2004. *(April 17, 2003, CON application page 35)*

64. Current and projected payer mix for each FCMPC hospital is depicted in Table 14 below:

**TABLE 14: Payer Type and Mix by Percentage for each FCMPC Hospital**

Type of Payer	Payer Mix for FCMPC Hospital for Current and Projected Years 1 – 3 (e)					
	Bridgeport Hospital	Danbury Hospital	Greenwich Hospital	Norwalk Hospital	St. Vincent's Medical Center	Stamford Hospital
Medicare (a)	51.4%	36%	29%	44%	49.7%	38%
Medicaid (a) and (b)	14.9%	4%	1%	7%	10.74%	9%
Government	66.3%	40%	30%	51%	60.44%	47%
Commercial Insurers (a)	31.9%	58%	61%	46% (c)	33.74%	48%
Self-Pay	1.8% (c)	2%	7%	3% (d)	3.92%	5%
Workers Compensation.	-	-	2%	-	1.9%	-
Uncompensated Care	-	-	-	-	-	-
Non-Government	33.7%	60%	70%	49%	39.56%	53%
<b>Total</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

(a) Includes Managed Care Activity

(b) Includes Other Medical Assistance

(c) Includes Workers Compensation

(d) Includes Uncompensated Care

(e) Current payer mix is not estimated to change for years 1-3 for any of the Hospitals  
*(April 17, 2003, CON Application, pages 53-56)*

65. The following Table #15 identifies the incremental projected impact of the proposal on each Hospital for FY 2006, which is year three of project implementation.

**TABLE 15: Financial Impact for each Hospital for projected FY 2006**

	Bridgeport Hospital	Danbury Hospital	Greenwich Hospital	Norwalk Hospital	Saint Vincent's Medical Center	Stamford Hospital
Incremental Net Patient Revenue	\$408,377	\$583,000	\$499,120	\$799,462	\$231,602	\$616,000
Incremental Total Operating Expense	\$160,050	\$567,000	\$479,310	\$706,750	210,925	\$619,000
Incremental Gain/(loss) from Operations	\$248,327	\$16,000	\$19,810	\$92,712	\$20,677	\$(3,000)

*(April 17, 2003 CON application, page 340 and May 29, 2003 completeness responses, pages 52-69)*

## **Consideration of Other Section 19a-637, C.G.S. Principles and Guidelines**

The following findings are made pursuant to other principles and guidelines set forth in Section 19a-637, C.G.S.:

66. There is no State Health Plan in existence at this time. *(April 17, 2003 CON Application, page 25)*
67. The Hospitals have adduced evidence that this proposal is consistent with their long-range plans. *(April 17, 2003 CON Application, page 25)*
68. The Hospitals have improved productivity and contained costs through energy conservation, reengineering, group purchasing, and the application of technology. *(April 17, 2003 CON Application, page 46)*
69. The proposal will not result in changes to the Hospitals' current teaching and research responsibilities. *(April 17, 2003 CON Application, page 46)*
70. There are no distinguishing characteristics of the patient/physician mix of the Hospitals. *(April 17, 2003 CON Application, page 46)*
71. The Hospitals have sufficient technical, financial and managerial competence to provide efficient and adequate service to the public. *(April 17, 2003, CON Application, pages 44-47)*



## Rationale

Bridgeport Hospital, Danbury Hospital, Greenwich Hospital, Norwalk Hospital, Saint Vincent's Medical Center, and Stamford Hospital, together known on an informal basis as the Fairfield County Mobile PET Collaborative, propose to lease a second mobile unit for the Fairfield County Mobile PET Collaborative Hospitals and to upgrade both mobile units from Positron Emission Tomography ("PET") to a combined Positron Emission Tomography - Computed Tomography ("PET-CT") or fusion modality, at a total capital expenditure of \$4,900,000, which represents the fair market value of two mobile PET-CT units.

Fixed PET-CT scanners or fusion scanners have begun to appear in the marketplace in recent years and provide significant benefits beyond the use of separate CT and PET images. Many patients who require a PET scan also require a CT scan. There are currently no mobile PET-CT providers in the state and mobile PET-CT technology is expected to be widely released in the marketplace soon. With PET-CT technology, the patient receives a CT and PET scan in the same session and resulting data is fused into a single digital image, which provides both anatomic and functional information. Image speed and patient throughput are significantly increased with fusion scanners.

The introduction of the PET technology at the six Fairfield County Mobile PET Collaborative Hospitals was made available through a mobile PET unit that provided service to each Hospital one day a week. Initially, a one-day per week schedule was established for each Hospital and it was intended that a single PET scanner would travel to each of the six hospitals Monday through Saturday. However, due to space limitations at Stamford Hospital and Greenwich Hospital, neither of these Hospitals could accommodate the mobile PET scanner on Mondays and both of these two Hospitals were only able to offer the service on Saturdays. In order to accommodate two hospitals requiring the scanner on Saturdays, a second mobile unit is utilized through the contractual arrangement with the equipment vendor. In addition to the need for a second PET scanner in order to accommodate both Stamford Hospital and Greenwich Hospital on Saturdays, Danbury Hospital may require an additional day or days of usage as it is rapidly approaching the maximum number of patients that can be treated on a single day with the current scanner and Danbury Hospital has scheduling backlogs of approximately two weeks.

The Hospitals are also proposing to upgrade its PET technology to PET-CT technology for both units leased from an equipment vendor. The overwhelming majority of PET scans are for the staging and evaluation of treatment for certain types of cancer. Currently, 97% of scan volume for the mobile PET scanners at the six Hospitals combined has been oncology-related, with 46% for Lung Cancers, 19% for Lymphoma and 11% for Colorectal Cancers. Neurological studies have averaged only 3% of total PET studies and currently very few or no cardiac related scans are being performed. PET-CT technology is particularly useful for head and neck malignancies. PET alone is somewhat limited in localizing lesions in the dense anatomical structures of the head and identifying lesions with CT alone is also limiting. The combined PET-CT modalities produce a superior image for tumor localization. Patients who will benefit most from combined PET-CT images are those for whom surgery or radiation therapy is planned. The combined image helps to guide the surgeon to the location of the malignancy and helps focus radiation therapy on the cancer and avoid damage to healthy

surrounding tissue. PET-CT images are most beneficial to patients with colorectal cancer, abdominal/pelvic malignancies, and lymphoma, for staging and restaging. Recent studies have shown that restaging is more accurate and diagnosis more confident in rectal cancer patients who had a PET-CT versus PET scan, especially for patients with recurrent disease.

The combined PET-CT modality also will provide significant benefit to cardiac patients. PET scanning is used for two types of cardiac scanning, myocardial viability and myocardial perfusion imaging. Currently the main technology used for nuclear cardiac scanning is the SPECT camera or Single Photon Emission Computed Tomography camera. PET scanning appears to be emerging as a "gold standard" for the diagnosis and management of coronary artery disease, although it is projected that SPECT will continue to play a dominant role, at least for the next several years. Advantages of PET scanning over SPECT scanning for myocardial perfusion imaging include attenuation correction (better spatial resolution), depth-independent doubling of image resolution and improved image contrast. PET scanning is particularly beneficial in the diagnosis and assessment of coronary artery disease for women, obese patients and patients who cannot exercise and must be pharmacologically stressed. Combined PET-CT imaging will allow cardiac studies to be completed in half the time as the current PET scanner.

The FY 2006 PET-CT volume projections for the six Hospitals combined is 3,987, which reflects the need to serve the primary service area Connecticut towns in FY 2006 for the six Applicant Hospitals. These projections include scanning for oncology, neurology, and cardiac purposes. Danbury Hospital is expected to achieve the highest utilization. The Hospitals each project incremental increases in net patient revenues relating to this project and all but Stamford is projecting to realize a gain from operations related to this project by year three.

OHCA finds that there is a clear public need for the addition of a second mobile PET scanner for use by the six Fairfield County Mobile PET Collaborative Hospitals and for the upgrade of imaging modality from PET to PET-CT for the two mobile units leased from its equipment vendor. Both aspects of the CON proposal will improve the quality and accessibility of each Hospital's PET scanning services. In addition, the scan projections and the financial projections relating to the operational aspects of this project appear reasonable and achievable.

Based upon the foregoing Findings and Rationale, the Certificate of Need application of Bridgeport Hospital, Danbury Hospital, Greenwich Hospital, Norwalk Hospital, Saint Vincent's Medical Center, and Stamford Hospital, together known as the Fairfield County Mobile PET Collaborative, to lease a second mobile unit for the Fairfield County Mobile PET Collaborative and to upgrade both mobile units from PET to a combined PET-CT modality, at a total capital expenditure of \$4,900,000, which represents the fair market value of two mobile PET-CT units, is hereby GRANTED.

## Order

The request of Bridgeport Hospital, Danbury Hospital, Greenwich Hospital, Norwalk Hospital, Saint Vincent's Medical Center, and Stamford Hospital ("Applicants" or "Hospitals"), together known as the Fairfield County Mobile PET Collaborative, to lease a second mobile unit for the Fairfield County Mobile PET Collaborative and to upgrade both mobile units from PET to a combined PET-CT modality, at a total capital expenditure of \$4,900,000, which represents the fair market value of two mobile PET-CT units, is approved subject to the following conditions:

1. The authorization shall expire August 11, 2004. Should the Applicants' project not be completed by that date, the Applicants must seek further approval from OHCA to complete the project beyond that date.
2. The CON is approved for each of the Applicants' main campus locations only as follows:
  - ❖ Bridgeport Hospital located at 267 Grant Street in Bridgeport.
  - ❖ Danbury Hospital located at a 24 Hospital Avenue in Danbury.
  - ❖ Greenwich Hospital located on Perryridge Road in Greenwich.
  - ❖ Norwalk Hospital located on Maple Street in Norwalk.
  - ❖ Saint Vincent's Medical Center located at 2800 Main Street in Bridgeport.
  - ❖ Stamford Hospital located on Shelburne Road in Stamford.
3. The following shall be filed with OHCA by August 11, 2004:
  - a) Identification of the specific equipment chosen for the PET-CT services;
  - b) A copy of agreement(s) or contract(s) with PET Scans of America Corporation (or any successor equipment vendor) regarding the use of the authorized PET-CT equipment;
  - c) A copy of any agreement or contract for the delivery of Rubidium for Cardiac MPI studies; and
  - d) An updated PET Scans of America Quality Assurance Plan addressing mobile PET-CT.
4. The Applicants shall not exceed the approved capital cost of \$4,900,000, which represents the fair market value of two mobile PET-CT units. In the event that the Applicants learn of potential cost increases or expect that the final project costs will exceed those approved, the Applicants shall file with OHCA a request for approval of the revised project budget.
5. The days and hours of operation for the authorized PET-CT scanners are at the discretion of the Fairfield County Mobile PET Consortium and its member Hospitals based on operating needs and demands.

6. Bridgeport Hospital, Danbury Hospital, Greenwich Hospital, Norwalk Hospital, Saint Vincent's Medical Center, and Stamford Hospital shall file a combined "Fairfield County Mobile PET Collaborative" utilization statistics report for the authorized PET-CT scanning services on a quarterly calendar year basis for two full years of operations. Each quarterly filing shall be submitted to OHCA by no later than one month following the end of each reporting period (e.g., January, April, July, and October). The initial report shall list the date on which the PET-CT scanning service commenced operation for each Hospital. The quarterly reports shall include the following:

- Total number of scans scheduled for the PET-CT scanning service for each hospital;
- Total number of scans performed by the PET-CT scanning service for each hospital;
- Average patient waiting time from the scheduling of the scan to the performance of the scan for each hospital;
- Number of scans by patient zip code for each hospital;
- Hours and days of operation for each week and in total for each hospital; and
- Number of scans by Medicare diagnostic code for each hospital.

All of 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

Date signed:  
August 11, 2003

Signed by:  
Mary M. Heffernan  
Commissioner

MMH:kr